In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 1: Overview

April 26, 2021

February 1, 2001 Email

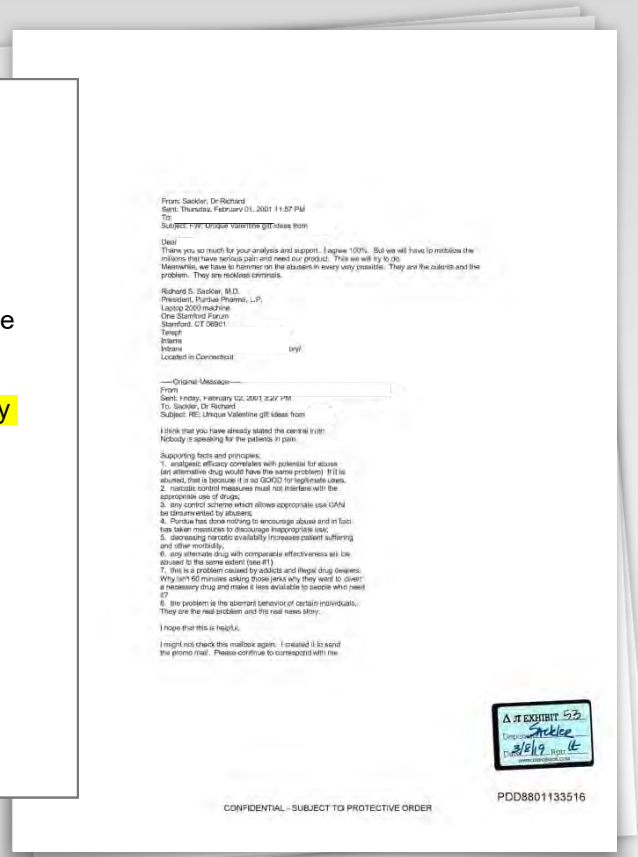
Sent: Thursday, February 01, 2001 11 :57 PM
To:
Subject: FW: Unique Valentine gift ideas from

Dear

Thank you so much for your analysis and support. I agree 100%. But we will have to mobilize the millions that have serious pain and need our product. This we will try to do.

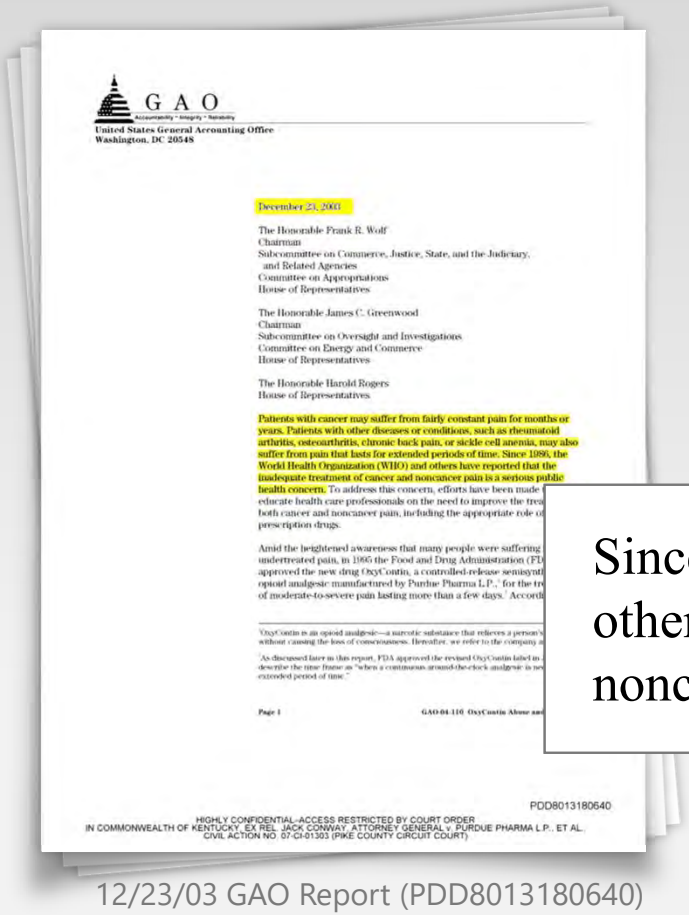
Meanwhile, we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.

Richard S. Sackler, M.D.
President, Purdue Pharma, L.P.
Laptop 2000 machine
One Stamford Forum
Stamford, CT 06901
Telephone
Internet
Intranet http://library.pharma.com/directory/
Located in Connecticut



2/1/01 Email from R. Sackler (PDD8801133516)

Chronic Pain Was The Public Health Concern



GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

December 23, 2003

The Honorable Frank R. Wolf
Chairman
Subcommittee on Commerce, Justice, State, and the Judiciary,
and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable James C. Greenwood
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Harold Rogers
House of Representatives

Patients with cancer may suffer from fairly constant pain for months or years. Patients with other diseases or conditions, such as rheumatoid arthritis, osteoarthritis, chronic back pain, or sickle cell anemia, may also suffer from pain that lasts for extended periods of time. Since 1986, the World Health Organization (WHO) and others have reported that the inadequate treatment of cancer and noncancer pain is a serious public health concern. To address this concern, efforts have been made

PDD8013180640

HIGHLY CONFIDENTIAL--ACCESS RESTRICTED BY COURT ORDER
IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL.
CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

12/23/03 GAO Report (PDD8013180640)

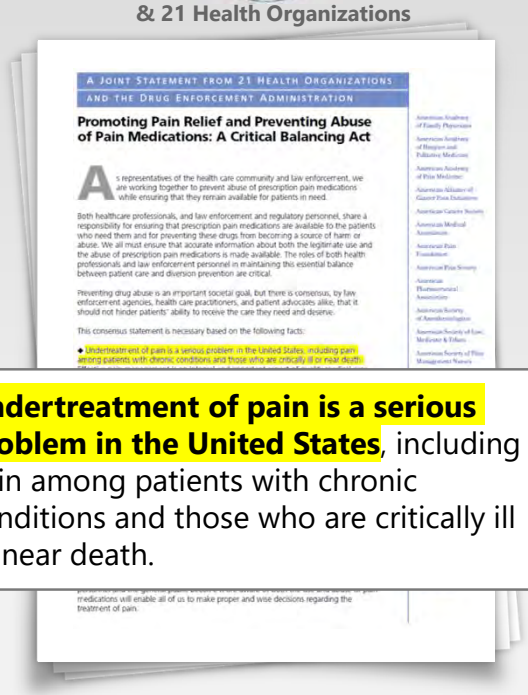
GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

December 23, 2003

Since 1986, the World Health Organization (WHO) and others have reported that inadequate treatment of cancer and noncancer pain is a serious public health concern.

Chronic Pain Was The Public Health Concern

& 21 Health Organizations

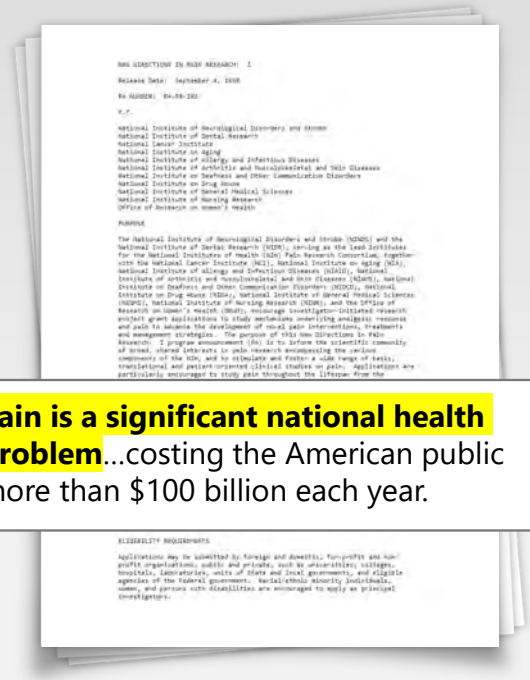

A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION

Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death.

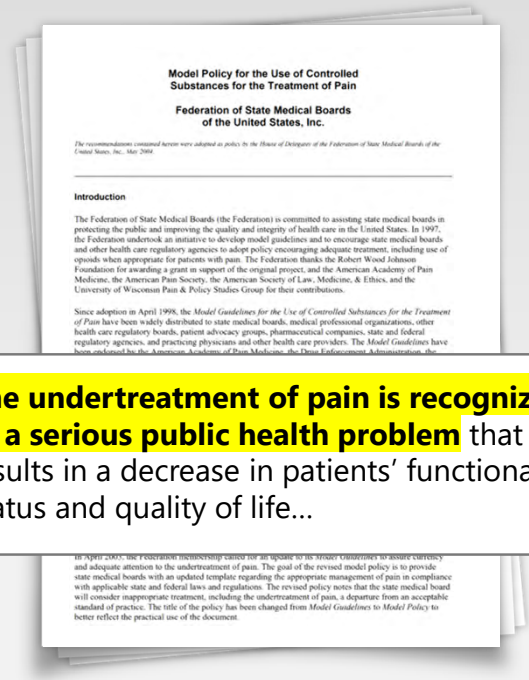
A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, *Promoting Pain Relief and Preventing Abuse of Pain Medication: A Critical Balancing Act* (2001)

National Institutes of Health



Pain is a significant national health problem...costing the American public more than $100 billion each year.

National Institute of Health, *New Directions in Pain Research* (1998)


Model Policy for the Use of Controlled Substances for the Treatment of Pain

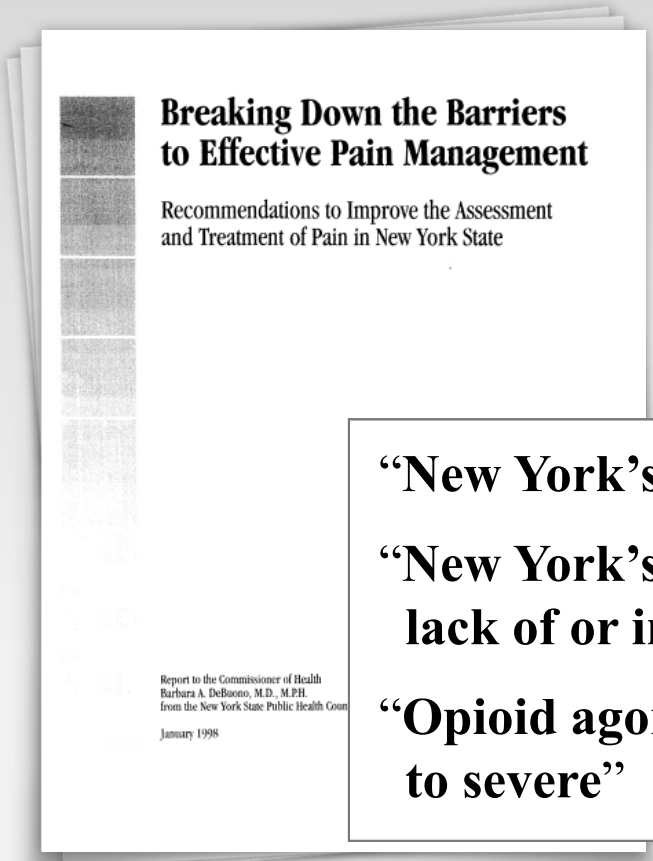
Federation of State Medical Boards of the United States, Inc.

Introduction

The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life...

Federation of State Medical Boards of the United States, Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (May 2004)

Chronic Pain Was The Public Health Concern



STATE OF NEW YORK
DEPARTMENT OF HEALTH
CORNING TOWER BUILDING
ALBANY, N.Y. 12237

PUBLIC HEALTH COUNCIL

February 13, 1998

"New York's residents have a right to adequate pain management"

"New York's residents currently experience needless pain due to lack of or inadequate treatment"

"Opioid agonists ... should be employed early when pain is moderate to severe"

2/13/98 New York Public Health Council Report at p. 2 and Additional Principle for Acute Pain Management No. 3

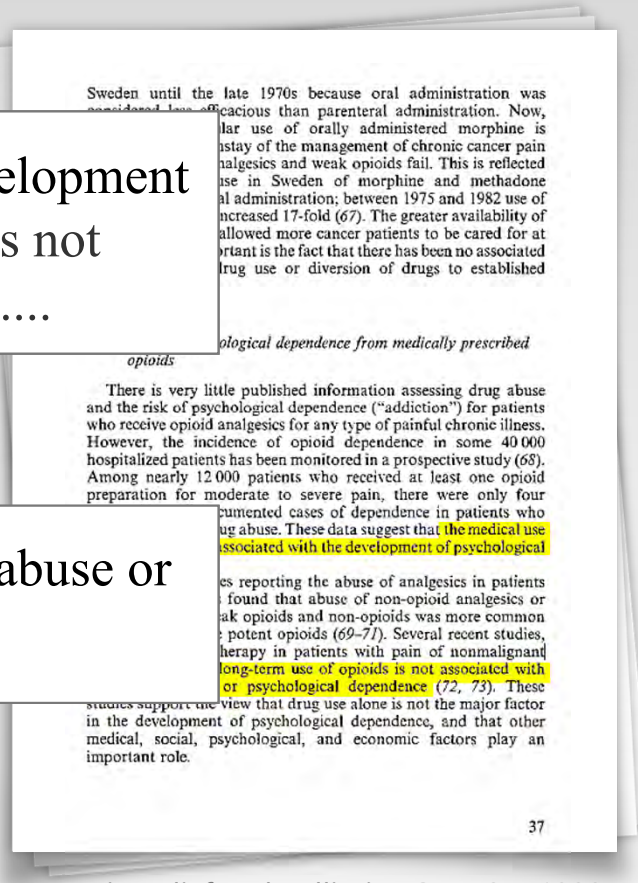
Prevailing Scientific Consensus: Medical Use of Opioids Is Rarely Associated with Addiction

In 1986, the World Health Organization stated that:

> [T]he medical use of opioids is rarely associated with the development of psychological dependence…. [C]ontinuing use of opioids is not associated with substance abuse or psychological dependence....

In 1990, it added:

> [L]ong-term use of opioids is not associated with either drug abuse or psychological dependence.



Sweden until the late 1970s because oral administration was
cacious than parenteral administration. Now,
lar use of orally administered morphine is
stay of the management of chronic cancer pain
algesics and weak opioids fail. This is reflected
se in Sweden of morphine and methadone
l administration; between 1975 and 1982 use of
ncreased 17-fold (67). The greater availability of
llowed more cancer patients to be cared for at
rtant is the fact that there has been no associated
rug use or diversion of drugs to established

ological dependence from medically prescribed opioids

There is very little published information assessing drug abuse and the risk of psychological dependence ("addiction") for patients who receive opioid analgesics for any type of painful chronic illness. However, the incidence of opioid dependence in some 40 000 hospitalized patients has been monitored in a prospective study (68). Among nearly 12 000 patients who received at least one opioid preparation for moderate to severe pain, there were only four
umented cases of dependence in patients who
g abuse. These data suggest that the medical use
ssociated with the development of psychological

es reporting the abuse of analgesics in patients
found that abuse of non-opioid analgesics or
ak opioids and non-opioids was more common
potent opioids (69–71). Several recent studies,
herapy in patients with pain of nonmalignant
long-term use of opioids is not associated with
or psychological dependence (72, 73). These
view that drug use alone is not the major factor in the development of psychological dependence, and that other medical, social, psychological, and economic factors play an important role.

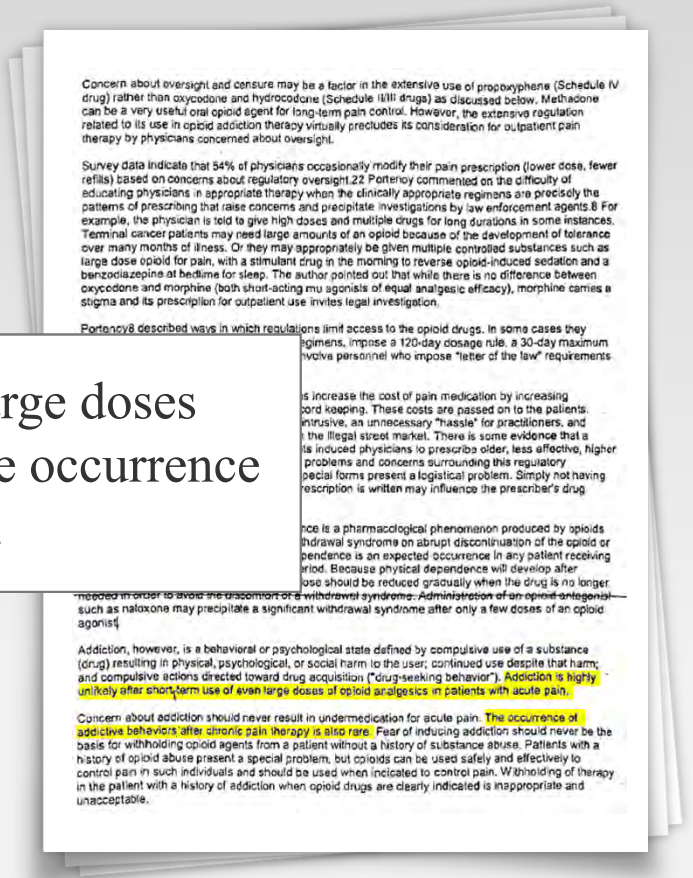
37

World Health Organization, Cancer Pain Relief, 30 (1986); World Health Organization, *Cancer Pain Relief and Palliative Care*, 37 (1990)

Prevailing Scientific Consensus: Medical Use of Opioids Is Rarely Associated with Addiction

In 1995, the American Medical Association reported that:

> [A]ddiction is highly unlikely after short-term use of even large doses of opioid analgesics in patients with acute pain … [and] [t]he occurrence of addictive behaviors after chronic pain therapy is also rare.



Concern about oversight and censure may be a factor in the extensive use of propoxyphene (Schedule IV drug) rather than oxycodone and hydrocodone (Schedule II/III drugs) as discussed below. Methadone can be a very useful oral opioid agent for long-term pain control. However, the extensive regulation related to its use in opioid addiction therapy virtually precludes its consideration for outpatient pain therapy by physicians concerned about oversight.

Survey data indicate that 54% of physicians occasionally modify their pain prescription (lower dose, fewer refills) based on concerns about regulatory oversight.22 Portenoy commented on the difficulty of educating physicians in appropriate therapy when the clinically appropriate regimens are precisely the patterns of prescribing that raise concerns and precipitate investigations by law enforcement agents.8 For example, the physician is told to give high doses and multiple drugs for long durations in some instances. Terminal cancer patients may need large amounts of an opioid because of the development of tolerance over many months of illness. Or they may appropriately be given multiple controlled substances such as large dose opioid for pain, with a stimulant drug in the morning to reverse opioid-induced sedation and a benzodiazepine at bedtime for sleep. The author pointed out that while there is no difference between oxycodone and morphine (both short-acting mu agonists of equal analgesic efficacy), morphine carries a stigma and its prescription for outpatient use invites legal investigation.

Portenoy8 described ways in which regulations limit access to the opioid drugs. In some cases they
egimens, impose a 120-day dosage rule, a 30-day maximum
nvolve personnel who impose "letter of the law" requirements

s increase the cost of pain medication by increasing
ord keeping. These costs are passed on to the patients.
ntrusive, an unnecessary "hassle" for practitioners, and
the illegal street market. There is some evidence that a
ts induced physicians to prescribe older, less effective, higher
problems and concerns surrounding this regulatory
pecial forms present a logistical problem. Simply not having
rescription is written may influence the prescriber's drug

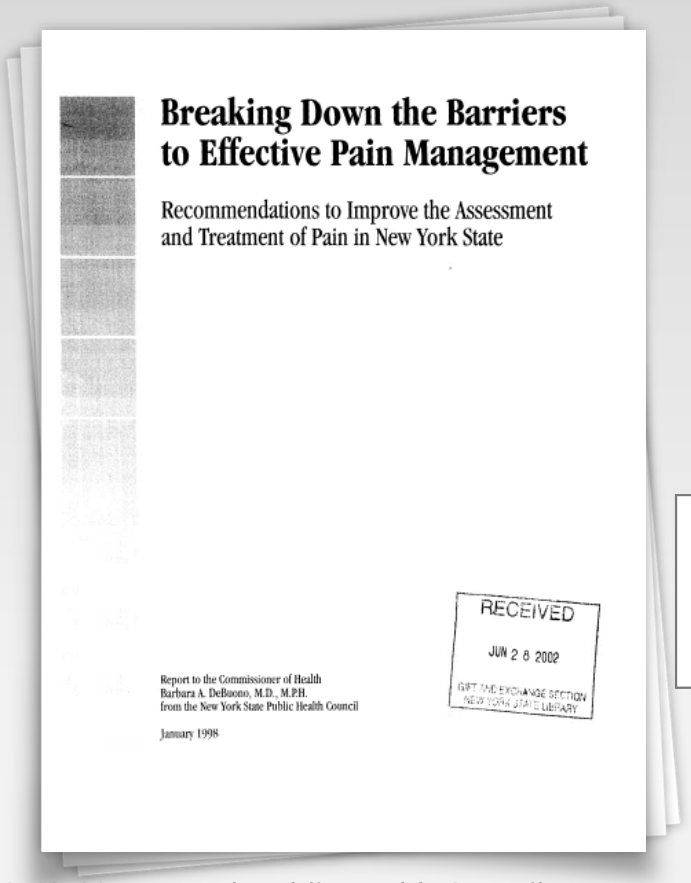
nce is a pharmacological phenomenon produced by opioids
thdrawal syndrome on abrupt discontinuation of the opioid or
pendence is an expected occurrence in any patient receiving
riod. Because physical dependence will develop after
ose should be reduced gradually when the drug is no longer
~~needed in order to avoid the discomfort of a withdrawal syndrome. Administration of an opioid antagonist~~
such as naloxone may precipitate a significant withdrawal syndrome after only a few doses of an opioid agonist.

Addiction, however, is a behavioral or psychological state defined by compulsive use of a substance (drug) resulting in physical, psychological, or social harm to the user; continued use despite that harm; and compulsive actions directed toward drug acquisition ("drug-seeking behavior"). Addiction is highly unlikely after short-term use of even large doses of opioid analgesics in patients with acute pain.

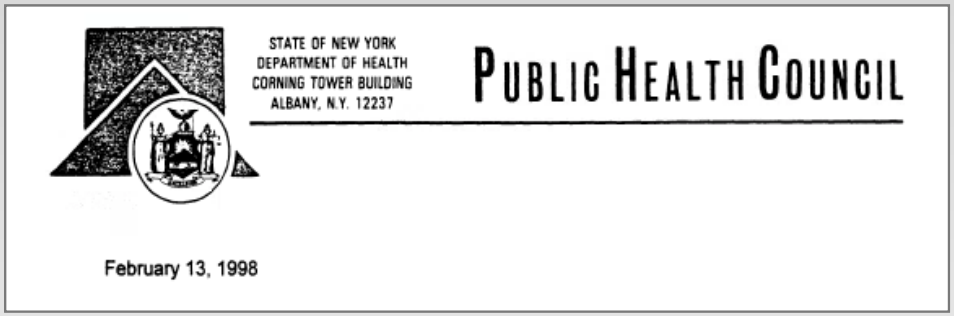
Concern about addiction should never result in undermedication for acute pain. The occurrence of addictive behaviors after chronic pain therapy is also rare. Fear of inducing addiction should never be the basis for withholding opioid agents from a patient without a history of substance abuse. Patients with a history of opioid abuse present a special problem, but opioids can be used safely and effectively to control pain in such individuals and should be used when indicated to control pain. Withholding of therapy in the patient with a history of addiction when opioid drugs are clearly indicated is inappropriate and unacceptable.

AMA Council on Scientific Affairs, *AMA Positions on Pain Therapy* (June 1995)

Prevailing Scientific Consensus: Medical Use of Opioids Is Rarely Associated with Addiction



2/13/98 New York Public Health Council Report



In 1998, the New York Public Health Council stated:

> **"Unfortunately, the public does not understand that opioid addiction when treating bona fide pain is rare"**

States Protected Doctors From Prosecution for Overprescribing Painkillers

The New York Times

August 9, 1999

A Shift in the Treatment of Chronic Pain

With Laws as Shield, Doctors Are More Willing to Prescribe Drugs

By HOLCOMB B. NOBLE

After 40 years of debate among doctors, medical review boards and law-enforcement officials, state legislatures have begun passing laws to shield doctors from being prosecuted for prescribing powerful medications against intractable pain.

At the same time, leaders of major medical institutions said, a fundamental change has been occurring among doctors, who are now more willing to prescribe narcotics and other such medication to treat pain

or overprescribe drugs as a form of mercy killing or assisted suicide. At the same time, patients or their families have complained bitterly that they or their loved ones have often been left without relief to suffer needlessly for long periods.

In the early 80's, for example, Dr. Harvey Rose, a pain specialist in Sacramento, Calif., was accused by the California Medical Board of overprescribing pain medication. He succeeded in fighting the charge, but only after spending four years and $140,000. He then helped lead the

cording to the National Conference of State Legislatures, are California, Colorado, Florida, Minnesota, Missouri, Nebraska, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, West Virginia and Wisconsin. A decade ago, no states had such protection.

Most of the changes have come in the last three years, and a dozen more states, along with the United States Senate, are considering similar legislation.

Besides the new legal protections,

Jose Luis Villegas for The New York Times

as accused of overprescribing pain medications in the 1980's. rotect doctors who prescribe drugs to treat chronic pain.

cer patients in nursing 65 or older, showing that cent of those in pain were medication. And in 1995, published a survey in ly members of one group scious patients who died reported that 50 percent re in moderate to severe last eight days of their h some patients refuse ar lower than the number who want pain relief if hoice.

he changes in law and rd guidelines, pain treatins controversial. In Sacr. Rose said he had to rously to get the right medicine for his wife to pain as she was dying of 994 — and then again last nself when he was recuom a quadruple bypass.

ruary, another Californank Fisher, was charged counts of murder in the hree patients treated at Redding. Dr. Fisher was le to post the bail set at to await trial. He said he rge number of patients, m poor people who had been snubbed by other doctors. "I

feel like I'm being punished for be having in good conscience and fo doing the right thing," he said.

But a spokesman for the California Attorney General's Office insisted that enough evidence had been pre sented at a preliminary hearing by other doctors who said "an inordi nate amount of painkillers" had bee prescribed to justify a trial. The prosecutor's concern was that, rath er than treating real pain, the doctor was simply supplying drugs to those who abused them and who had no medical need.

A group of Dr. Fisher's patients came to his defense, including the husband of one of the alleged victims, who said she had had grave health problems and did not die from her medications. The head of the local county health center called Dr. Fisher's arrest "a disaster, like a natural disaster, like an earthquake," and said the county was suddenly left with hundreds of people who were unable to get the medication they needed.

On July 16, the murder charges were dropped and Dr. Fisher was released after four months in jail, on the ground that there was insufficient evidence of an intent to kill. But the doctor is not free and clear: the three murder indictments were reduced to manslaughter.

supply narcotics to addicts for profit,

by medical disorders. The states, ac-

els high enough to relieve very se-

ported a Brown University study of

been snubbed by other doctors. "I

"Nineteen states now have laws that protect doctors from prosecution by state and local law-enforcement agencies for overprescribing painkillers so long as the medications are needed to treat pain caused by medical disorders. The states … are California, Colorado, Florida, Minnesota, Missouri, Nebraska, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, West Virginia and Wisconsin."

Holcomb Noble, *A Shift in the Treatment of Chronic Pain*, NY Times (Aug. 9, 1999)

States Disciplined Doctors for Undertreating Pain

The New York Times

Oregon Board Disciplines Doctor for Not Treating Patients' Pain

Sept. 4, 1999

See the article in its original context from September 4, 1999, Section A, Page 14 | Buy Reprints

New York Times subscribers* enjoy full access to TimesMachine—view over 150 years of New York Times journalism, as it originally appeared.

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In what appears to be the first such action in the nation, the Oregon Board of Medical Examiners this week disciplined a doctor for insufficiently treating pain in his patients.

The decision underscores the medical community's changing attitudes about how doctors should help patients deal with se and chronic pain.

Like many state medical boards, the Oregon board had focuse disciplining doctors who had overprescribed drugs. But in thi week's case, the board found that Dr. Paul Bilder of Roseburg had not prescribed enough drugs to alleviate pain in six patie between 1993 and 1998.

The board ordered Dr. Bilder to complete a physician's educat program and a program on physician-patient communications. It also ordered that he undergo psychiatric treatment.

The New York Times

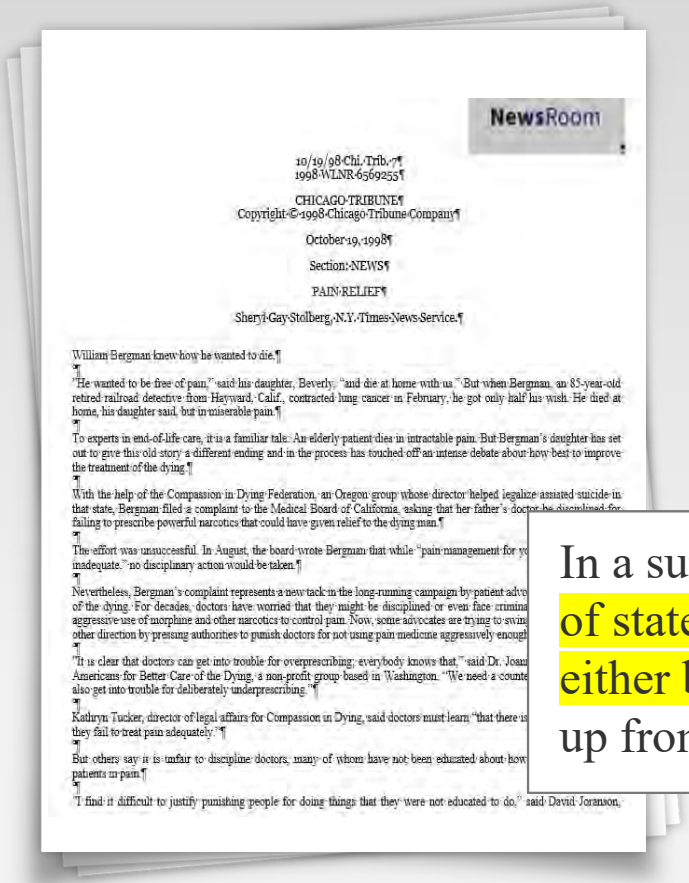
Oregon Board Disciplines Doctor for Not Treating Patients' Pain

September 4, 1999

…in this week's case, the board found that Dr. Paul Bilder of Roseburg, Ore., had not prescribed enough drugs to alleviate pain in six patients between 1993 and 1998.

https://www.nytimes.com/1999/09/04/us/oregon-board-disciplines-doctor-for-not-treating-patients-pain.html

States Disciplined Doctors for Undertreating Pain



NewsRoom

10/19/98 Chi. Trib. 7
1998 WLNR 6569255

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October 19, 1998

Section: NEWS

PAIN RELIEF

Sheryl Gay Stolberg, N.Y. Times News Service.

William Bergman knew how he wanted to die.

"He wanted to be free of pain," said his daughter, Beverly, "and die at home with us." But when Bergman, an 85-year-old retired railroad detective from Hayward, Calif., contracted lung cancer in February, he got only half his wish. He died at home, his daughter said, but in miserable pain.

To experts in end-of-life care, it is a familiar tale. An elderly patient dies in intractable pain. But Bergman's daughter has set out to give this old story a different ending and in the process has touched off an intense debate about how best to improve the treatment of the dying.

With the help of the Compassion in Dying Federation, an Oregon group whose director helped legalize assisted suicide in that state, Bergman filed a complaint to the Medical Board of California, asking that her father's doctor be disciplined for failing to prescribe powerful narcotics that could have given relief to the dying man.

The effort was unsuccessful. In August, the board wrote Bergman that while "pain management for y
inadequate," no disciplinary action would be taken.

Nevertheless, Bergman's complaint represents a new tack in the long-running campaign by patient advo
of the dying. For decades, doctors have worried that they might be disciplined or even face crimina
aggressive use of morphine and other narcotics to control pain. Now, some advocates are trying to swin
other direction by pressing authorities to punish doctors for not using pain medicine aggressively enough

"It is clear that doctors can get into trouble for overprescribing; everybody knows that," said Dr. Joan
Americans for Better Care of the Dying, a non-profit group based in Washington. "We need a counte
also get into trouble for deliberately underprescribing."

Kathryn Tucker, director of legal affairs for Compassion in Dying, said doctors must learn "that there is
they fail to treat pain adequately."

But others say it is unfair to discipline doctors, many of whom have not been educated about how
patients in pain.

"I find it difficult to justify punishing people for doing things that they were not educated to do," said David Joranson,

Chicago Tribune

PAIN RELIEF

October 19, 1998

In a survey conducted last year, Joranson's group found that 8.1 percent of state medical board members questioned knew of doctors who had either been investigated or disciplined for undertreating pain. That was up from 5 percent in 1991.

Sheryl Stolberg, *Pain Relief*, Chicago Tribune (Oct. 19, 1998)

States Passed Laws to Encourage Prescribing Opioids And Other Controlled Substances

NEW YORK STATE DEPARTMENT OF HEALTH

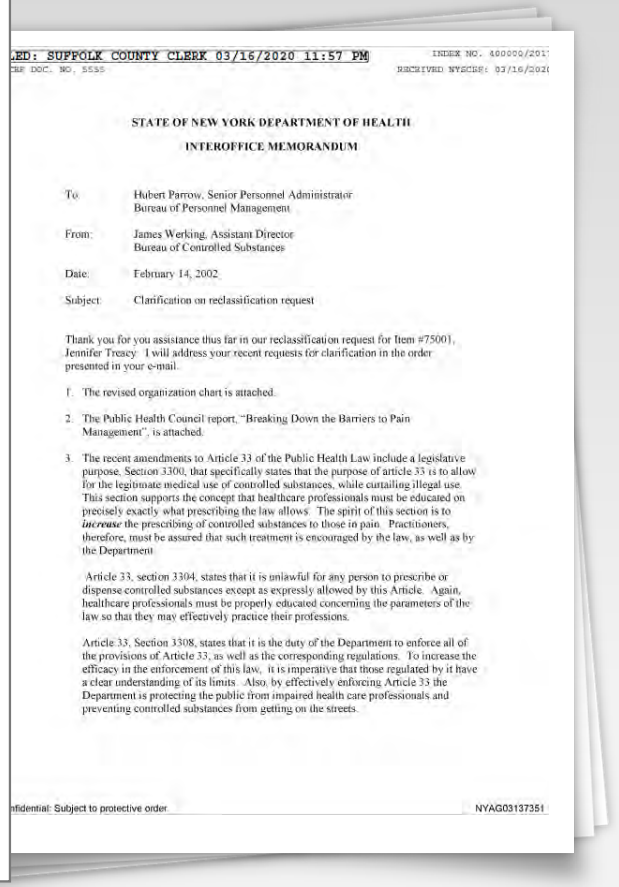
INTEROFFICE MEMORANDUM

***

From: James Werking, Assistant Director
Bureau of Controlled Substances
Date: February 14, 2002

***

3. The recent amendments to Article 33 of the Public Health Law include a legislative purpose, Section 3300.... The spirit of this section is to ***increase*** the prescribing of controlled substances to those in pain. Practitioners, therefore, must be assured that such treatment is encouraged by the law, as well as by the Department.



In re Opioid Litigation, No. 400000/2017 (Suffolk N.Y.), Doc. 5555

February 1, 2001 Email

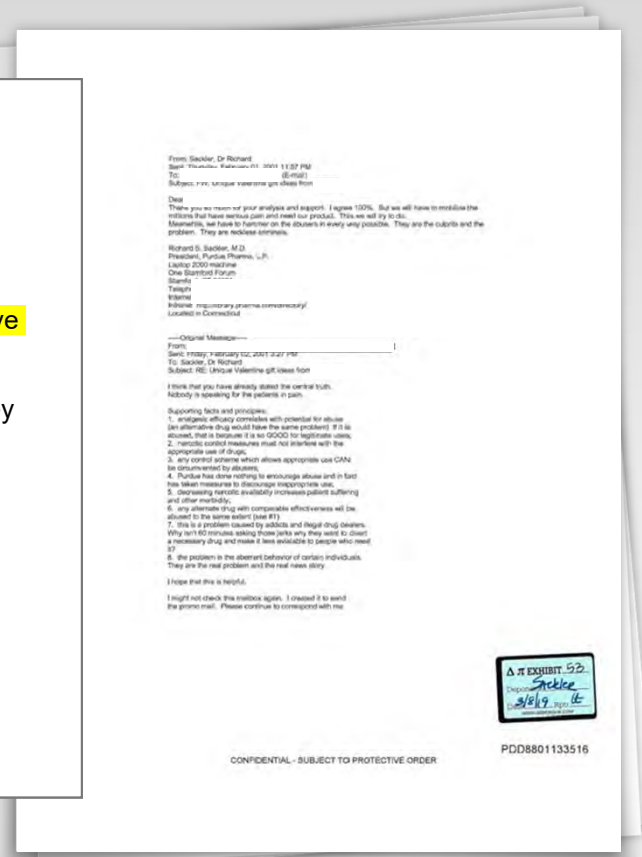
Sent: Thursday, February 01, 2001 11 :57 PM
To:
Subject: FW: Unique Valentine gift ideas from

Dear

Thank you so much for your analysis and support. I agree 100%. But we will have to mobilize the millions that have serious pain and need our product. This we will try to do.

Meanwhile, we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.

Richard S. Sackler, M.D.
President, Purdue Pharma, L.P.
Laptop 2000 machine
One Stamford Forum
Stamford, CT 06901
Telephone
Internet
Intranet http://library.pharma.com/directory/
Located in Connecticut



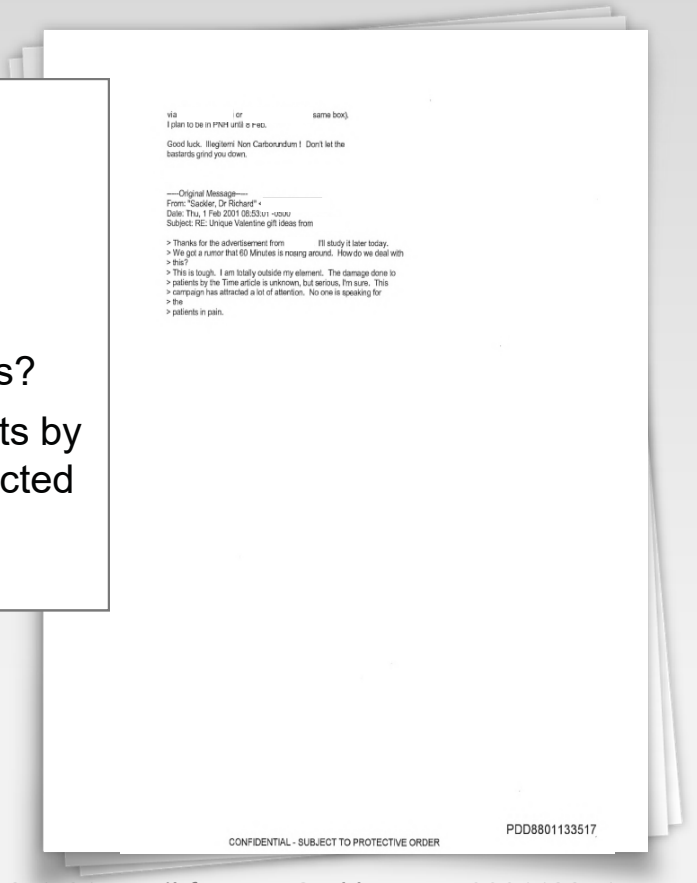
2/1/01 Email from R. Sackler (PDD8801133516)

February 1, 2001 Email

From: "Sackler, Dr Richard"
Date: Thu, 1 Feb 2001 08:53:01 -0500
Subject: RE: Unique Valentine gift ideas from

Thanks for the advertisement from . I'll study it later today.
We got a rumor that 60 Minutes is nosing around. How do we deal with this?

This is tough. I am totally outside my element. The damage done to patients by the Time article is unknown, but serious, I'm sure. This campaign has attracted a lot of attention. No one is speaking for the patients in pain.


CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PDD8801133517

2/1/01 Email from R. Sackler (PDD8801133517)

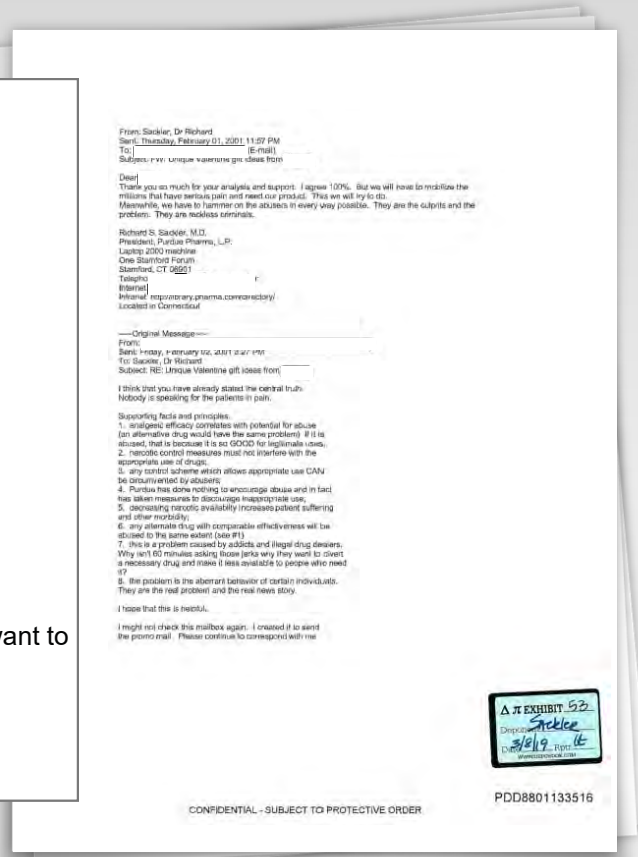
February 1, 2001 Email

From:
Sent: Friday, February 02, 2001 3:27 PM
To: Sackler, Dr Richard
Subject: RE: Unique Valentine gift ideas from

I think that you have already stated the central truth.
Nobody is speaking for the patients in pain.

Supporting facts and principles:
1. analgesic efficacy correlates with potential for abuse (an alternative drug would have the same problem) If it is abused, that is because it is so GOOD for legitimate uses;
2. narcotic control measures must not interfere with the appropriate use of drugs;
3. any control scheme which allows appropriate use CAN be circumvented by abusers;
4. Purdue has done nothing to encourage abuse and in fact has taken measures to discourage inappropriate use;
5. decreasing narcotic availabilty increases patient suffering and other morbidity;
6. any alternate drug with comparable effectiveness will be abused to the same extent (see #1)
7. this is a problem caused by addicts and illegal drug dealers. Why isn't 60 minutes asking those jerks why they want to divert a necessary drug and make it less avialable to people who need it?
8. the problem is the aberrant behavior of certain individuals. They are the real problem and the real news story.

I hope that this is helpful. …

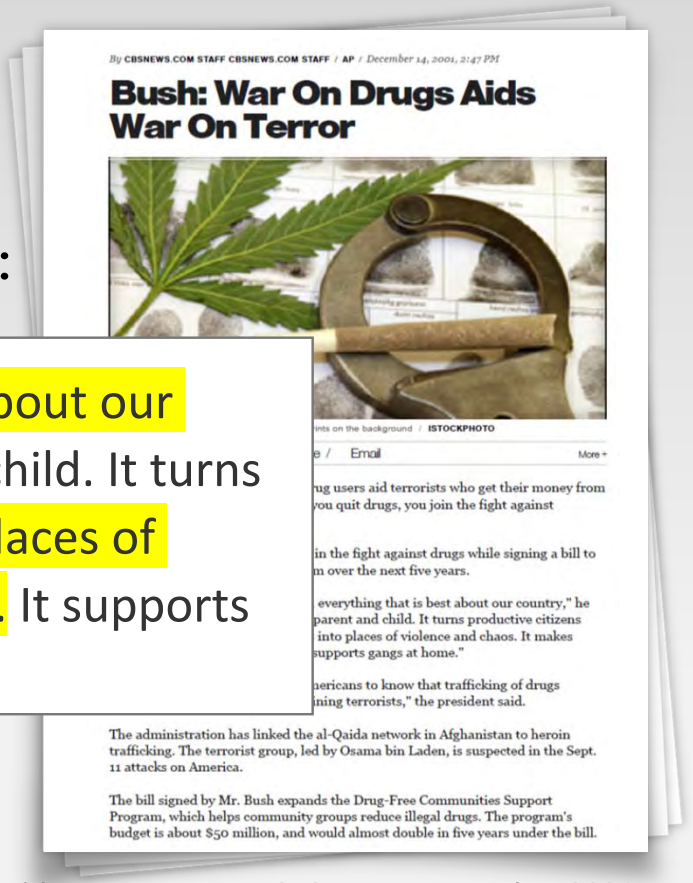


2/1/01 Email to R. Sackler (PDD8801133516)

President Bush: “Drug Abuse Threatens Everything, Everything That Is Best about Our Country.”

President George W. Bush speech on drug abuse (2001):

"Drug abuse threatens everything, everything that is best about our country," he said. "It breaks the bond between parent and child. It turns productive citizens into addicts. It transforms schools into places of violence and chaos. It makes playgrounds into crime scenes. It supports gangs at home."



By CBSNEWS.COM STAFF CBSNEWS.COM STAFF / AP / December 14, 2001, 2:47 PM

Bush: War On Drugs Aids War On Terror

...nts on the background / ISTOCKPHOTO

...e / Email More+

...ug users aid terrorists who get their money from ...ou quit drugs, you join the fight against

...in the fight against drugs while signing a bill to ...m over the next five years.

... everything that is best about our country," he ...parent and child. It turns productive citizens ... into places of violence and chaos. It makes ...supports gangs at home."

...ericans to know that trafficking of drugs ...ining terrorists," the president said.

The administration has linked the al-Qaida network in Afghanistan to heroin trafficking. The terrorist group, led by Osama bin Laden, is suspected in the Sept. 11 attacks on America.

The bill signed by Mr. Bush expands the Drug-Free Communities Support Program, which helps community groups reduce illegal drugs. The program's budget is about $50 million, and would almost double in five years under the bill.

Bush: War on Drugs Aids War on Terror, *CBS News* (December 2001)

2007 Guilty Plea And State and Federal Settlements

2007 Federal Guilty Plea And Settlement

MARKETPLACE

THE WALL STREET JOURNAL. Friday, May 11, 2007 B1

An Addiction U-Turn On OxyContin
HEALTH B3

SCIENCE JOURNAL

Scientists Draw Link Between Morality And Brain's Wiring

Course Change:
Airline's Board Removes Founder Neeleman as CEO; A Need for 'New Processes'

By Susan Carey And Paolo Prada

THE WALL STREET JOURNAL

OxyContin Maker Pleads Guilty

Purdue Frederick to Pay $634.5 Million Settlement For Hiding Addiction Risk

By Heather Won Tesoriero

In one of the largest drug-company criminal settlements, the maker of narcotic painkiller OxyContin will pay $634.5 million after guilty pleas by **Purdue Frederick** Co. and three of its executives.

The company pleaded guilty to misbranding the drug with the intent to defraud and mislead the public about its addictive qualities. The three executives pleaded guilty to misbranding the drug.

The guilty pleas cap a five-year criminal investigation by the U.S. attorney in the Western District of Virginia over closely held Purdue's sales and marketing of its top-selling painkiller. According to U.S. Attorney John Brownlee, the company promoted OxyContin as less addictive and

Heather Won Tesoriero, *OxyContin Maker Pleads Guilty, Purdue Frederick to Pay $634.5 Million Settlement for Hiding Addiction Risk,* Wall Street Journal (May 11, 2007)

The New York Times

In Guilty Plea, OxyContin Maker to Pay $600 Million

By Barry Meier May 10, 2007

From left, Howard R. Udell, the top lawyer for Purdue Pharma; Dr. Paul D. Goldenheim, the company's former medical director; and Michael Friedman, Purdue's president.

Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, NY Times (May 10, 2007)

Los Angeles Times

Firm admits deceit about painkiller

Purdue Pharma and three executives will pay $634.5 million over OxyContin claims.

By Martin Zimmerman

Firm admits deceit about painkiller

L.A. manager named NBC diversity chief

Martin Zimmerman, *Firm Admits Deceit About Painkillers*, Los Angeles Times (May 11, 2007)

2007 Federal Guilty Plea And Settlement

- Purdue admitted that from **December 12, 1995 through June 30, 2001,** it "marketed and promoted OxyContin" as "**less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications**."

> [It was] more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous use.

> OxyContin potentially creates less chance for addiction than immediate-release opioids.

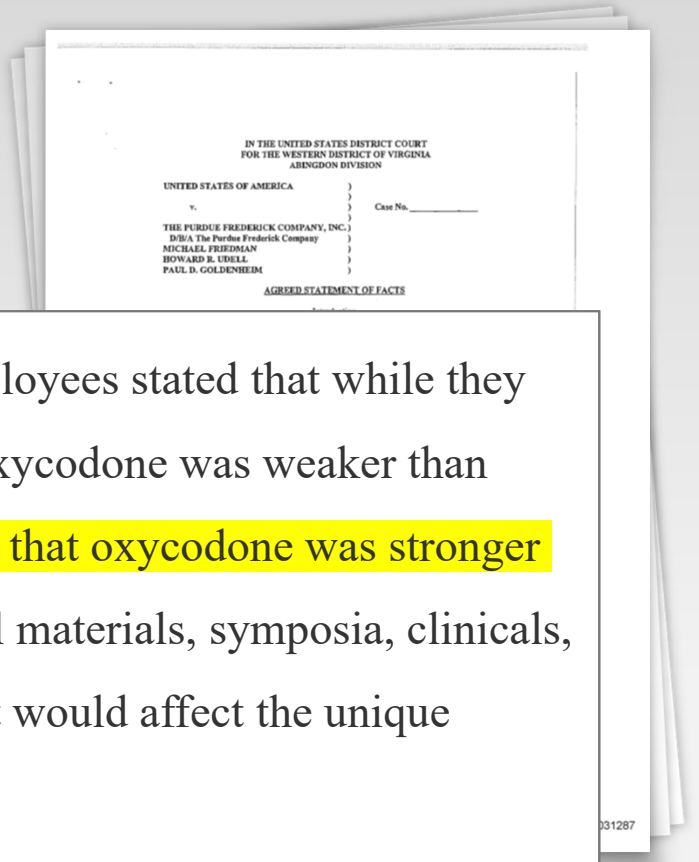
> OxyContin had fewer 'peak and trough' blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

> Patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.

> OxyContin did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to 'weed out' addicts and drug seekers.

2007 Agreed Statement of Facts ¶¶13, 20

2007 Federal Guilty Plea And Settlement


IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA
v. Case No.
THE PURDUE FREDERICK COMPANY, INC.
D/B/A The Purdue Frederick Company
MICHAEL FRIEDMAN
HOWARD R. UDELL
PAUL D. GOLDENHEIM

AGREED STATEMENT OF FACTS

031287

Purdue admitted:

29. In or about May 1997, certain PURDUE supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians mind (*sic*)."

2007 Agreed Statement of Facts ¶29

49 States And D.C. Settled Deceptive Marketing Claims in 2007

All Issued Releases to Individuals
All Retained Right to Investigate & Obtain Information

27 Consent Judgments

1. **Arizona**
2. **Arkansas**
3. **California**
4. **Connecticut**
5. **District of Columbia**
6. **Idaho**
7. **Illinois**
8. Kentucky
9. **Louisiana**
10. **Maine**
11. **Maryland**
12. **Massachusetts**
13. **Montana**
14. **Nebraska**
15. **Nevada**
16. **New Mexico**
17. **North Carolina**
18. **Ohio**
19. **Oregon**
20. **Pennsylvania**
21. **South Carolina**
22. **Tennessee**
23. **Texas**
24. **Vermont**
25. **Virginia**
26. **Washington**
27. **Wisconsin**

49 Medicaid Settlements

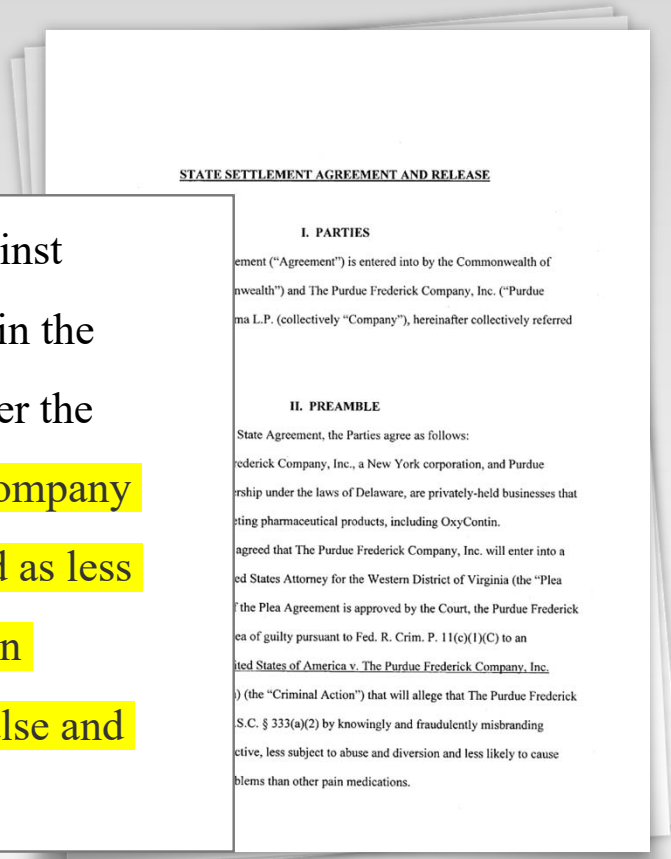
1. Alabama
2. Alaska
3. **Arizona**
4. **Arkansas**
5. **California**
6. Colorado
7. **Connecticut**
8. Delaware
9. **District of Columbia**
10. Florida
11. Georgia
12. Hawaii
13. **Idaho**
14. **Illinois**
15. Indiana
16. Iowa
17. Kansas
18. **Louisiana**
19. **Maine**
20. **Maryland**
21. **Massachusetts**
22. Michigan
23. Minnesota
24. Mississippi
25. Missouri
26. **Montana**
27. **Nebraska**
28. **Nevada**
29. New Hampshire
30. New Jersey
31. **New Mexico**
32. New York
33. **North Carolina**
34. North Dakota
35. **Ohio**
36. Oklahoma
37. **Oregon**
38. **Pennsylvania**
39. Rhode Island
40. **South Carolina**
41. South Dakota
42. **Tennessee**
43. **Texas**
44. Utah
45. **Vermont**
46. **Virginia**
47. **Washington**
48. **Wisconsin**
49. Wyoming

Bolded states entered into both settlements

49 Medicaid Settlements — with 48 States and Washington, D.C.

2007 Massachusetts Settlement ¶II.D:

D. The Commonwealth contends that it has certain civil claims against Company for, during the time period from 1995 through 2005, engaging in the following conduct with respect to the marketing of OxyContin (hereinafter the "Covered Conduct"): Specifically, the Commonwealth alleges that the Company marketed OxyContin as less subject to abuse, illicit use and diversion and as less addictive and less likely to cause tolerance and withdrawal than other pain medications and that Company knew that these marketing claims were false and misleading, causing damage to the Medicaid Program.



STATE SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

ement ("Agreement") is entered into by the Commonwealth of
nwealth") and The Purdue Frederick Company, Inc. ("Purdue
ma L.P. (collectively "Company"), hereinafter collectively referred

II. PREAMBLE

State Agreement, the Parties agree as follows:
rederick Company, Inc., a New York corporation, and Purdue
rship under the laws of Delaware, are privately-held businesses that
eting pharmaceutical products, including OxyContin.
agreed that The Purdue Frederick Company, Inc. will enter into a
ed States Attorney for the Western District of Virginia (the "Plea
the Plea Agreement is approved by the Court, the Purdue Frederick
ea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an
ited States of America v. The Purdue Frederick Company, Inc.
) (the "Criminal Action") that will allege that The Purdue Frederick
.S.C. § 333(a)(2) by knowingly and fraudulently misbranding
ctive, less subject to abuse and diversion and less likely to cause
blems than other pain medications.

2007 Massachusetts Settlement ¶II.D

27 Consent Judgments — with 26 States and Washington, D.C.

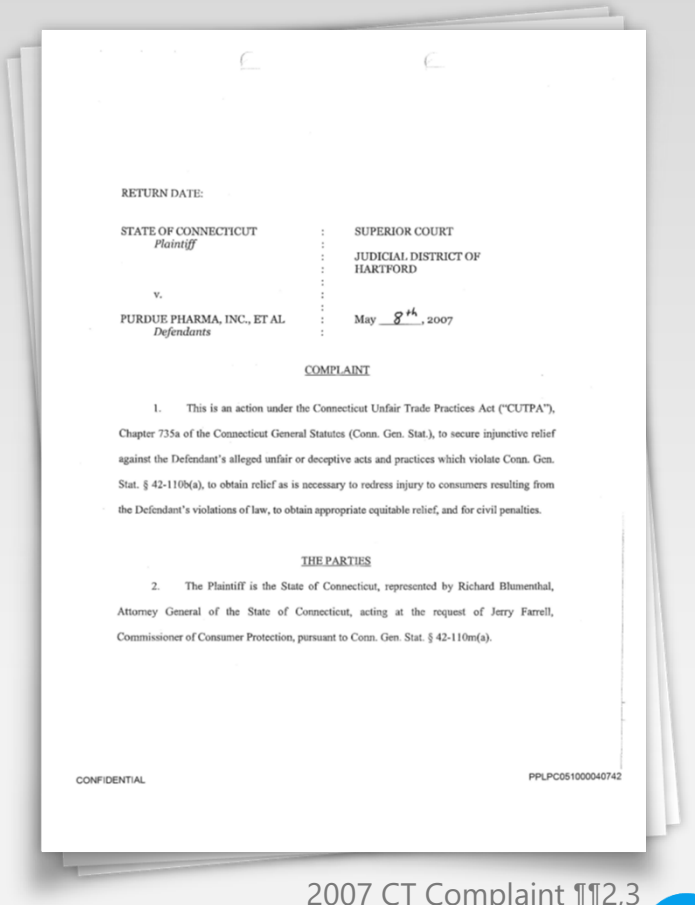
The States alleged that Purdue:

…minimize[d] the risks of abuse, addiction, and diversion in its marketing

…portray[ed] "addiction" to opioids as exceedingly rare.

…designed seminars, trainings and "educational" programs … [to] promote OxyContin as the opioid of choice, get healthcare professionals "comfortable" with prescribing high strength narcotic opioids, and ultimately increase OxyContin prescriptions.

…aggressively promoted OxyContin, without a concomitant focus on limiting OxyContin to serious and prolonged pain.



RETURN DATE:

STATE OF CONNECTICUT
Plaintiff

v.

PURDUE PHARMA, INC., ET AL
Defendants

SUPERIOR COURT

JUDICIAL DISTRICT OF HARTFORD

May 8th, 2007

COMPLAINT

1. This is an action under the Connecticut Unfair Trade Practices Act ("CUTPA"), Chapter 735a of the Connecticut General Statutes (Conn. Gen. Stat.), to secure injunctive relief against the Defendant's alleged unfair or deceptive acts and practices which violate Conn. Gen. Stat. § 42-110b(a), to obtain relief as is necessary to redress injury to consumers resulting from the Defendant's violations of law, to obtain appropriate equitable relief, and for civil penalties.

THE PARTIES

2. The Plaintiff is the State of Connecticut, represented by Richard Blumenthal, Attorney General of the State of Connecticut, acting at the request of Jerry Farrell, Commissioner of Consumer Protection, pursuant to Conn. Gen. Stat. § 42-110m(a).

CONFIDENTIAL

PPLPC051000040742

2007 CT Complaint ¶¶2,3

All 2007 Settlements Released Current And Former Directors, Officers And Owners

2007 Federal Settlement

2007 Consent Judgments

2007 Medicaid Settlements

...the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Purdue and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns from any civil or administrative monetary claim the United States has or may have...

2007 Federal Settlement ¶2

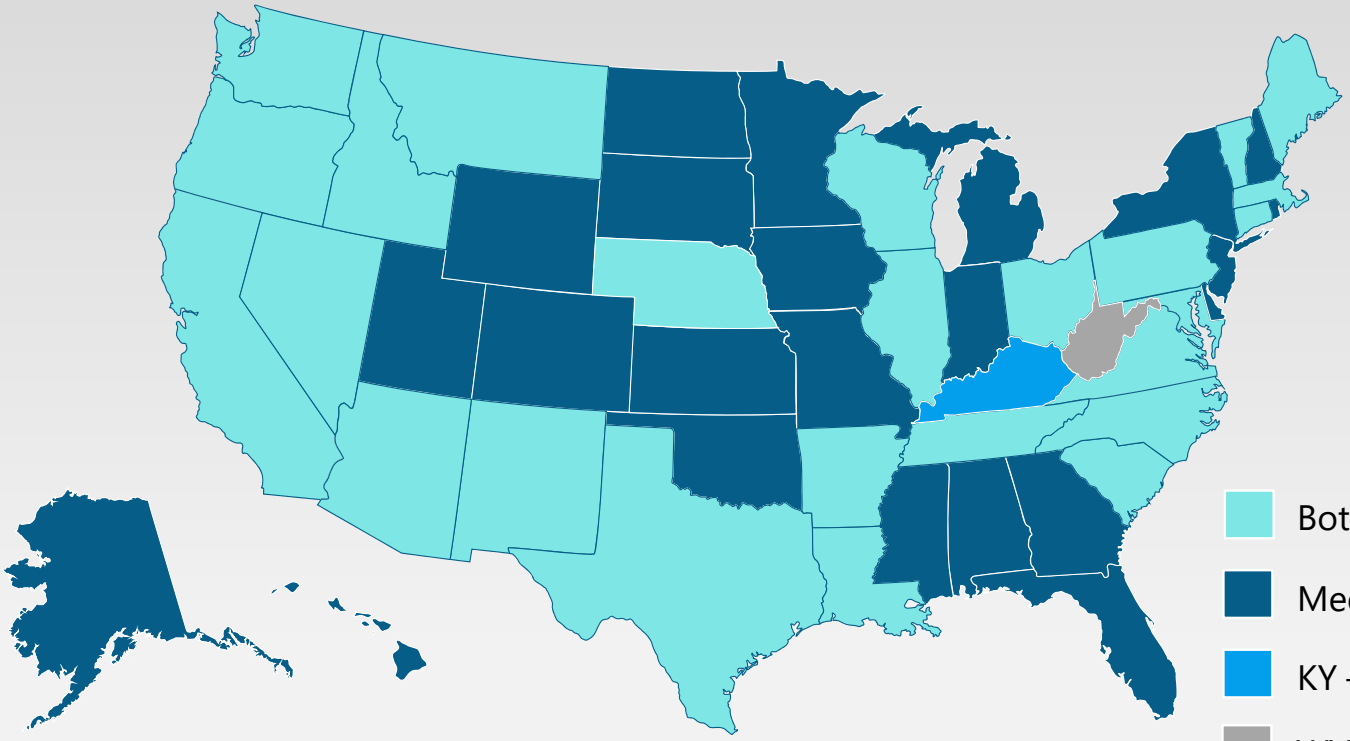
…the State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, co-promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment…

2007 Maryland Consent Judgment ¶35

…the State agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the State's Medicaid program against Company and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns for the Covered Conduct.

2007 New York Settlement ¶4

2007 Settling Jurisdictions — Claims before 2007 Have Been Released



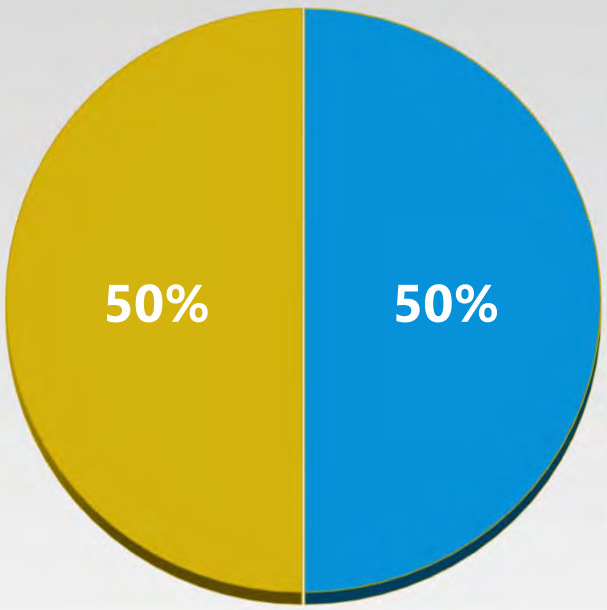
Both Medicaid and Consent Judgment

Medicaid Claims Settlements

KY – Consent Judgment and 2015 Settlement

WV – 2004 Settlement

After May 2007, Family Members Were Directors Only, Not Officers



- **Richard Sackler**
  - Purdue Pharma, Inc. ("PPI") Director from October 2, 1990 to July 24, 2018
  - President of PPI and Purdue Pharma, L.P. ("PPLP") from December 1, 1999 to March 4, 2003
  - Co-Chairman of PPI and PPLP from March 4, 2003 to May 11, 2007
  - Senior VP of Purdue Frederick Co. ("PFC") from January 1, 1986 to March 7, 2005
  - PFC Director from June 15, 1993 to March 7, 2005
- **Jonathan Sackler**
  - PPI Director from October 2, 1990 to December 8, 2018
  - Senior Vice President of PPI and PPLP from December 1, 1999 to May 2007
  - PFC Director from January 1, 1995 to March 7, 2005
- **Beverly Sackler**
  - PPI Director from January 15, 1993 to October 14, 2017
  - PFC Director from June 15, 1993 to March 7, 2005
- **David Sackler**
  - PPI Director from July 19, 2012 to August 14, 2018

Purdue's 2020 Guilty Plea and Civil Settlement

Purdue's 2020 Federal Guilty Plea

- Purdue pled guilty to a 3-count Information charging it with conspiracy to defraud the United States and violate the Food, Drug & Cosmetics Act
- In Schedule A to its plea agreement, Purdue admitted to:
  1. Fraud on the DEA and aiding and abetting prescribers in dispensing prescription drugs without a legitimate medical purpose (Count 1)
  2. Payments to two prescribers to induce them to write prescriptions in violation of the Anti-Kickback Statute (Count 2)
  3. Payments to Practice Fusion in violation of the Anti-Kickback Statute (Count 3)
- <u>Nothing in Schedule A to Purdue's plea agreement suggests that the former directors knew anything about Purdue's misconduct</u>

Purdue's Plea Does Not Create Liability for the Directors

- None of Purdue's misconduct is alleged against the former directors in DOJ's separate civil settlement with the former Sackler directors
  - The DEA and Practice Fusion are unmentioned in the DOJ's allegations against the family (Addendum A to the Sackler Settlement Agreement)
  - The Key Opinion Leader, Speaker Program and all other kickback allegations in Addendum A to Purdue's Civil Settlement (¶¶6-9, 176, 182, 187, 191, 212) are omitted from Addendum A to the Sackler Settlement Agreement
  - Nothing in DOJ's allegations in Sackler Addendum A even suggests Board awareness of the misconduct Purdue pled to

Purdue's Plea Does Not Create Liability for the Directors

- **Purdue's plea carries no collateral estoppel effect against former directors because they had no control over Purdue when it was entered**

  Stichting Ter Behartiging Van de Belangen Van Oudaandeelhouders In Het Kapitaal Van Saybolt Int'l B.V. v. Schreiber, 327 F.3d 173, 184, 186 (2d Cir. 2003)

- **The fact of the plea does not create *Caremark* liability for the former directors:**

  "[O]ur case law gives deference to boards and has dismissed *Caremark* cases even when illegal or harmful company activities escaped detection, when the plaintiffs have been unable to plead that the board failed to make the required good faith effort to put a reasonable compliance and reporting system in place."

  Marchand v. Barnhill, 212 A.3d 805, 821 (Del. 2019)

Claims: Overview

Two Principal Categories

Marketing Claims

Purdue and the Sacklers on its Board caused the opioid crisis by deceptively marketing FDA-approved prescription opioids, especially OxyContin

Diversion Claims

Purdue and the Sacklers on its Board caused the opioid crisis by negligently failing to prevent improper diversion of prescription opioids, especially OxyContin

Representative Allegations — New York and Massachusetts Complaints

- The New York and Massachusetts Complaints make extensive — and false — marketing and diversion allegations
- They are the template for almost all claims filed against the Sackler families

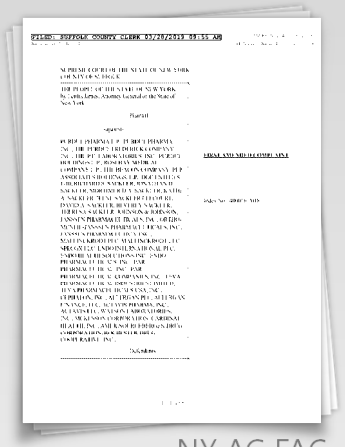
THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

Plaintiff,

-against-

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., THE P.F. LABORATORIES, INC., PURDUE HOLDINGS L.P., ROSEBAY MEDICAL COMPANY L.P., THE BEACON COMPANY, PLP ASSOCIATES HOLDINGS, L.P., DOE ENTITIES 1-10, RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, DAVID A. SACKLER, BEVERLY SACKLER, THERESA SACKLER, [et al.],

Defendants.

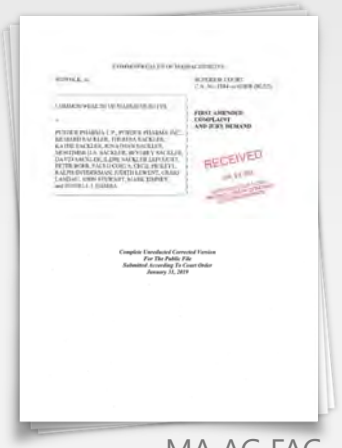


NY AG FAC

COMMONWEALTH OF MASSACHUSETTS

v.

PURDUE PHARMA L.P., PURDUE PHARMA INC., RICHARD SACKLER, THERESA SACKLER, KATHE SACKLER, JONATHAN SACKLER, MORTIMER D.A. SACKLER, BEVERLY SACKLER, DAVID SACKLER, ILENE SACKLER LEFCOURT, PETER BOER, PAULO COSTA, CECIL PICKETT, RALPH SNYDERMAN, JUDITH LEWENT, CRAIG LANDAU, JOHN STEWART, MARK TIMNEY, and RUSSELL J. GASDIA



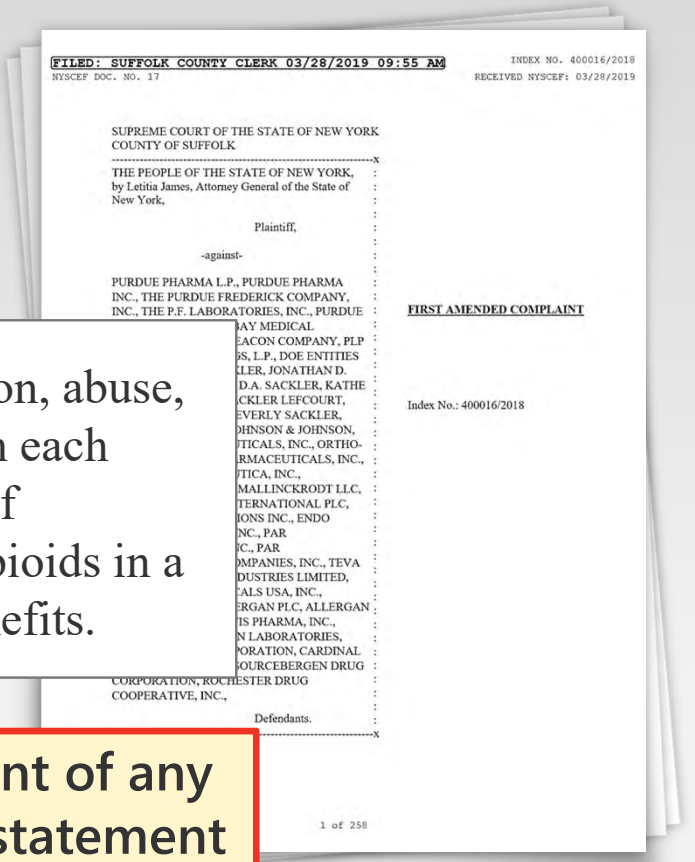
MA AG FAC

Marketing Claims

They allege:

- Purdue deceptively minimized the risks and overstated the benefits of its FDA-approved opioids
- Individuals were "actively involved" in that deception

387. Despite having full knowledge of opioids' risk of addiction, abuse, and diversion, the Sacklers, as the owners of Purdue involved with each and every material decision relating to the development and sale of Purdue's opioids, were actively involved in marketing Purdue's opioids in a way that deceptively minimized those risks and overstated the benefits.


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

Plaintiff,

-against-

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., THE P.F. LABORATORIES, INC., PURDUE

FIRST AMENDED COMPLAINT

Index No.: 400016/2018

CORPORATION, ROCHESTER DRUG COOPERATIVE, INC.,

Defendants.

1 of 258

No evidence the Board was asked to approve the content of any marketing material, or directed or encouraged any misstatement

NY AG FAC ¶387

Diversion Claims: Purdue's Diversion Efforts Were Insufficient

NY AG FAC ¶853:

> 853. Each Defendant is strictly liable for violating the [New York Controlled Substances Act] in each separate instance in which it: (i) failed to maintain effective controls to prevent the diversion of controlled substances; (ii) failed to report suspicious orders for controlled substances; (iii) failed to report actual or alleged incidents of known or possible diversion of controlled substances; (iv) failed to provide truthful statements in its licensing filings with New York authorities; (v) and/or failed to notify New York authorities when its actions and/or omissions caused it to violate the NYCSA.

NY AG FAC ¶853

NY AG FAC ¶874:

> 874. Each of the Defendants breached its duties through its . . . violations of the New York Controlled Substances Act, in the course of its manufacture, distribution, sale, and/or marketing of opioid drugs within the state.

NY AG FAC ¶874

No evidence Board members personally participated in Purdue's anti-diversion efforts

The Directors' Good Faith And Reasonableness

Board Was Continually Advised Purdue Was Operating in Compliance with Law

- From 2007-2018, management certified to the Board every quarter that Purdue was operating in compliance with law and documented it in quarterly reports
- From 2007-2012, there was federal oversight of Purdue's compliance
  - The Board received confirmation each year from the OIG of HHS that Purdue was operating in compliance with its Corporate Integrity Agreement ("CIA")
  - The CIA was designed to ensure compliance with federal healthcare law
- In 2012, when the monitorship ended, the Board was informed that Purdue hired Skadden to provide continuing review of the compliance program
- Management reported to the Board that Purdue's compliance program was audited twice by outside counsel and received positive reviews both times
  - King & Spalding in 2005 and Skadden in 2015

Board Required, Monitored and Incentivized Compliance with Law

- The Board implemented a strict compliance regime, adopting a state-of-the-art Compliance Charter in 2005
- The Board updated the Compliance Charter in 2007 to incorporate elements of the Corporate Integrity Agreement
- The Board monitored management's implementation of the Compliance Charter and received detailed presentations showing its effective implementation
- The Board incentivized compliance by incorporating it into bonus calculations — increasing bonuses if compliance duties were honored, reducing bonuses if not

There Was Federal Oversight of Purdue from 2007 through 2012

- Purdue operated under a CIA
- An Independent Review Organization ("IRO") monitored Purdue's compliance with the CIA
- Purdue and the IRO reported to the OIG of HHS

CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

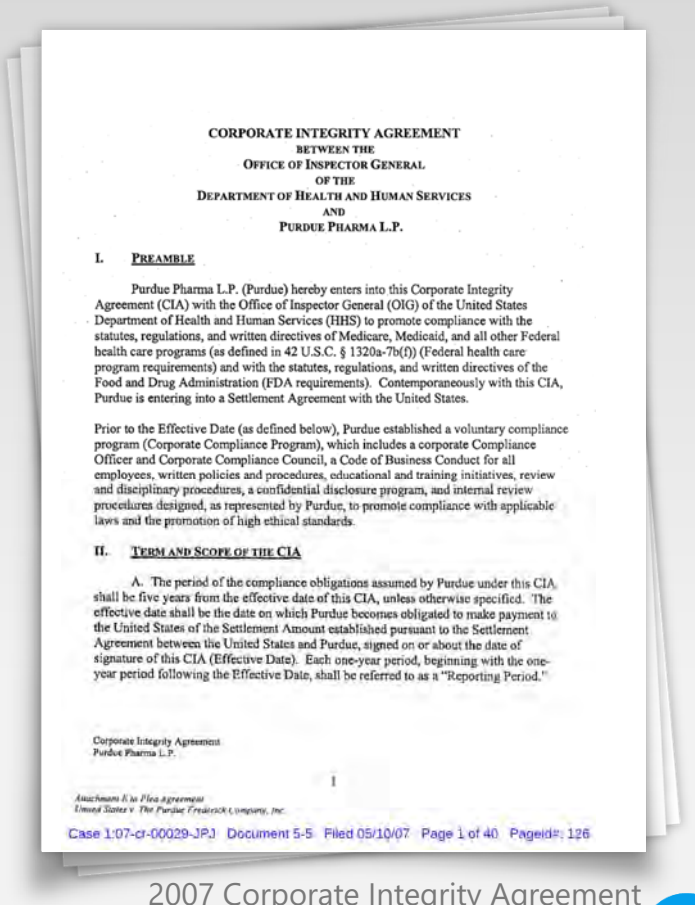
OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

PURDUE PHARMA L.P.



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PURDUE PHARMA L.P.

I. PREAMBLE

Purdue Pharma L.P. (Purdue) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Purdue is entering into a Settlement Agreement with the United States.

Prior to the Effective Date (as defined below), Purdue established a voluntary compliance program (Corporate Compliance Program), which includes a corporate Compliance Officer and Corporate Compliance Council, a Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by Purdue, to promote compliance with applicable laws and the promotion of high ethical standards.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Purdue under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which Purdue becomes obligated to make payment to the United States of the Settlement Amount established pursuant to the Settlement Agreement between the United States and Purdue, signed on or about the date of signature of this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

Corporate Integrity Agreement
Purdue Pharma L.P.

1

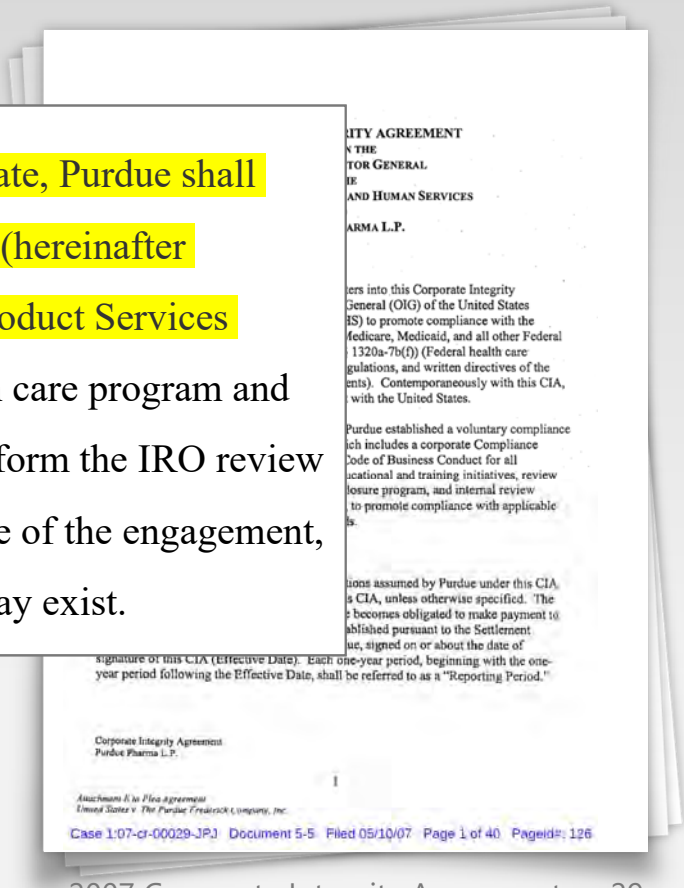
Attachment E to Plea Agreement
United States v. The Purdue Frederick Company, Inc.

Case 1:07-cr-00029-JPJ Document 5-5 Filed 05/10/07 Page 1 of 40 Pageid#: 126

2007 Corporate Integrity Agreement

The IRO Monitored Purdue's Compliance with the CIA

a. *Engagement of Independent Reviewers*. Within 120 days after the Effective Date, Purdue shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a Promotional and Product Services Engagement. Each IRO engaged by Purdue shall have expertise in Federal health care program and FDA requirements. Each IRO shall assess, along with Purdue, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.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AND HUMAN SERVICES
ARMA L.P.
ers into this Corporate Integrity
General (OIG) of the United States
HS) to promote compliance with the
Medicare, Medicaid, and all other Federal
1320a-7b(f)) (Federal health care
gulations, and written directives of the
ents). Contemporaneously with this CIA,
with the United States.
Purdue established a voluntary compliance
ich includes a corporate Compliance
Code of Business Conduct for all
ucational and training initiatives, review
losure program, and internal review
to promote compliance with applicable
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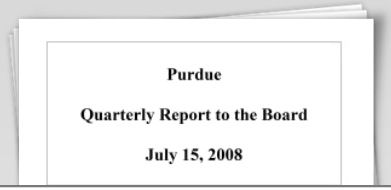
ions assumed by Purdue under this CIA,
s CIA, unless otherwise specified. The
becomes obligated to make payment to
ablished pursuant to the Settlement
ue, signed on or about the date of
signature of this CIA (Effective Date). Each one-year period, beginning with the one-
year period following the Effective Date, shall be referred to as a "Reporting Period."
Corporate Integrity Agreement
Purdue Pharma L.P.
1
Attachment B to Plea Agreement
United States v. The Purdue Frederick Company, Inc.
Case 1:07-cr-00029-JPJ Document 5-5 Filed 05/10/07 Page 1 of 40 Pageid#: 126

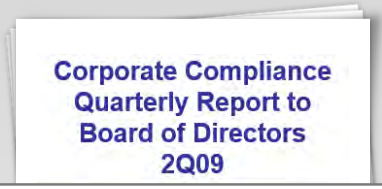
2007 Corporate Integrity Agreement, p. 29

Board Was Informed That the OIG Annually Confirmed Compliance with The CIA for the 5-Year Period from 2007 to 2012



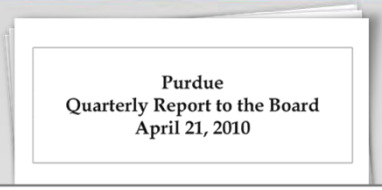
"By letter dated May 2nd we received **confirmation that the OIG was satisfied with Purdue's Implementation Report**, and confirmed that "**it appears that Purdue has successfully implemented the initial requirements of its Corporate Integrity Agreement**."

Quarterly Report to Board, July 15, 2008 , p. 28 (PPLP004367297)



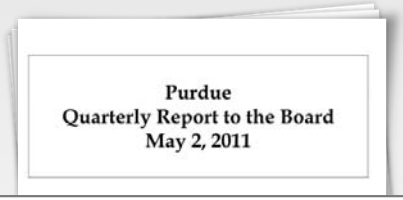
"By May 6th letter, **OIG confirmed Purdue's compliance with the requirements of our CIA** during the first year, based on their review of our Annual Report and other materials."

Quarterly Compliance Report Q2 2009, p. 6 (PPLPC012000236639)



"By letter dated April 1st, Purdue's **OIG Monitor confirmed** that ... **Purdue was in compliance with the terms of its Corporate Integrity Agreement** during the second reporting period"

Quarterly Report to Board, April 2010, p. 12 (PPLP004317547)



"We have received **the Office of Inspector General's (OIG) January 28th letter confirming satisfactory completion** of their review of Purdue's Third Annual Report: " **it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement**"

Quarterly Report to Board, May 2, 2011, p. 23 (PPLPC012000322448)

"Based on our review of this additional information and the information provided in Purdue's Fourth Annual Report, **it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement** during the fourth annual reporting period."

OIG Letter to Purdue, Mar. 8, 2012, p. 1 (PPLP004366816)

"From Letter dated January 24th, **Office of Inspector General, HHS**: ..."**[I]t appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA)** during the fifth annual reporting period.... [T]he Purdue CIA has now concluded."

Quarterly Compliance Report, Q1 2013, p. 2 (PPLP004409695)

Board Understood That Compliance Was Equally Strict after CIA Ended

Purdue's Compliance Program

Post-CIA there will be little change in Purdue's compliance program

- We will continue to address compliance risks company-wide
- We will continue to do nearly all CIA-required compliance activities
- We will drop a small percentage of total workload that was OIG-centric (e.g., reporting to OIG), but expand other valuable activities

Efforts already underway to communicate to employees about Purdue's compliance program post-CIA

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HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004408048

2Q 2012 Quarterly Compliance Report (PPLP004408046, -48)

Board Understood That Compliance Was Equally Strict after CIA Ended

Activities To be Continued (without change)

- Quarterly reports to Purdue's Board of Directors
- Hotline and other matters reviewed, investigated, documented in Axentis
- Investigation/disposition of compliance matters with Sales Discipline Committee, and reports to Corporate Compliance Council (CCC)
- No Reportable Events obligation after CIA, but significant matters will continue to be evaluated by Law and Compliance, and reviewed by CCC
- Promotion Monitoring Program (Field Contact Reports)
  - DM Ride-Alongs - CIA minimum of 5 days/rep/yr; Sales' standard is minimum of 8

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Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

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2Q 2012 Quarterly Compliance Report (PPLP004408046, -50)

Board Understood That Compliance Was Equally Strict after CIA Ended

Activities To be Continued (without change)

- Code of Ethics, Health Care Law Compliance Policies (HCLC), and Departmental SOPs to be reviewed, updated, distributed periodically
- Compliance Training requirements
  - Course material to be consolidated -- more relevant to actual risks
  - All employees and most contract employees to be trained
  - 3rd parties to receive only relevant, targeted training
  - Continue to train Field Force on significant FPI and Promotional Materials changes
- Screen employees and 3rd parties on hire and annually against government exclusion lists
- Record retention per 10 year Purdue SOP (vs. CIA 6 year retention)

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Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

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2Q 2012 Quarterly Compliance Report (PPLP004408046, -51)

Board Understood That Compliance Was Equally Strict after CIA Ended

Attorneys General Agreement

- 10 year AG Agreement, started in May 2007
- Purdue committed to continue OxyContin Abuse and Diversion Detection Program predicated on RSOP 1.7.1
- Annual reminder and training to employees continues
- Dear HCP Letter and Brochure providing written, non-branded education on abuse and diversion of opioids continues

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Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

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2Q 2012 Quarterly Compliance Report (PPLP004408046, -55)

Board Understood That Compliance Was Equally Strict after CIA Ended

Commercial Monitoring Program

Monitoring of both sales forces to be continued / strengthened

- Annual Ride-Alongs with sales personnel to better understand challenges faced by Sales Representatives
- District Meetings, other meetings
- Conventions/Product Theaters
- Speaker Programs
- Call Note Monitoring
- Field Contact Reports
- Documents and email communications reviews

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Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

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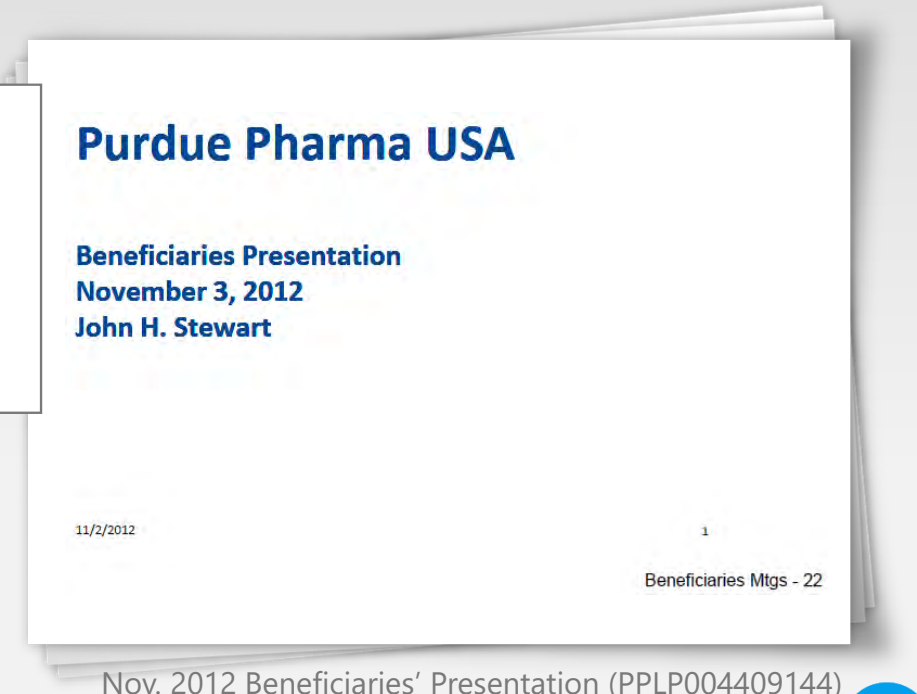
2Q 2012 Quarterly Compliance Report (PPLP004408046, -61)

Board Understood That Compliance Was Equally Strict after CIA Ended

Purdue monitored new Corporate Integrity Agreements to maintain a state-of-the-art compliance program

The following slides outline some of the new requirements of the latest CIAs. Purdue carefully reviews new CIAs and considers for adoption aspects that represent good practices.



Nov. 2012 Beneficiaries' Presentation (PPLP004409144)

From 2007 on, Board Received Quarterly Written and Oral Reports Confirming That Purdue Was Operating in Compliance with Law

2007	Q3	PPLPC019000172297	✓
2007	Q4	PPLPC019000195607	✓
2008	Q1	PPLP004401169	✓
2008	Q2	PPLP004401342	✓
2008	Q3	PPLP004402032	✓
2008	Q4	PPLP004402205	✓
2009	Q1	PPLP004402651	✓
2009	Q2	PPLPC012000236639	✓
2009	Q3	PPLP004402982	✓
2009	Q4	PPLP004403707	✓
2010	Q1	PPLP004404102	✓
2010	Q2	PPLP004404551	✓
2010	Q3	PPLP004405460	✓
2010	Q4	PPLP004405709	✓

2011	Q1	PPLP004406032	✓
2011	Q2	PPLP004406466	✓
2011	Q3	PPLP004406790	✓
2011	Q4	PPLP004407554	✓
2012	Q1	PPLP004407950	✓
2012	Q2	PPLP004408046	✓
2012	Q3	PPLP004408439	✓
2012	Q4	PPLP004409357	✓
2013	Q1	PPLP004409694	✓
2013	Q2	PPLP004409783	✓
2013	Q3	PPLP004410506	✓
2013	Q4	PPLP004410797	✓
2014	Q1	PPLP004411696	✓
2014	Q2	PPLP004411277	✓

2014	Q4	PPLP004411811	✓
2015	Q1	PPLP004412071	✓
2015	Q2	PPLP004412152	✓
2015	Q3	PPLP004412546	✓
2015	Q4	PPLP004412818	✓
2016	Q2	PPLP004413387	✓
2016	Q3	PPLP004413671	✓
2016	Q4	PPLP004413913	✓
2017	Q1	PPLP004414244	✓
2017	Q2	PPLPC021000899767	✓
2017	Q3	PPLPC022001020792	✓
2017	Q4	PPLPC021000920798	✓
2018	Q1	PPLP004414931	✓
2018	Q2	PPLP004415061	✓

Board Was Repeatedly Advised That Purdue Marketing Was in Full Compliance with Law

Investigation – DM Requirements

- Bottom Line
  - Investigation revealed that a few District Managers have fallen short of expectations
    - Reviews of call notes
    - Time spent in field doing ride-alongs with representatives
    - Routine administrative activities
    - Accurate and complete documentation (calendars, FCRs, etc.)
  - One CIA-related obligation (completion of FCRs) is deficient
  - Review of call notes and other monitoring has uncovered
    - No Improper Promotion
    - No Inappropriate discussion of abuse, diversion, tolerance, withdrawal
    - No violations of Law

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PPLP004402654

Corporate Compliance Quarterly Report to Board of Directors 1Q09

May 8, 2009
Bert Weinstein
Vice President, Corporate Compliance

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PPLP004402651

1Q 2009 Quarterly Compliance Report (PPLP004402651, -54)

Board Was Repeatedly Advised Purdue Marketing Was in Full Compliance with Law — Excerpts from Management Reports to the Board

2007: "the Company was in full compliance with all day zero CIA requirements"
- "We are confident of meeting all obligations"

2008: "First Annual Report to OIG submitted … certifies to all CIA requirements"
- "Purdue is also in full compliance with its AG Agreements"
- "State Law Reporting Update … No compliance issues identified"
- "No compliance issues identified"

2009: "Purdue's Second Annual Report to the OIG … certifies our compliance with all CIA requirements" ● "Purdue is also in full compliance with its AG Agreements"
- Of 837 inquiries concerning OxyContin, "None … were 'suspicious' under the CIA"

Sources: PPLPC012000157402, -60 (2007) [MA MTD Ex. 18]; PPLP004402032 [Leventhal Ex. 12] (2008); PPLP004402982 [Leventhal Ex. 18] (2009)

Board Was Repeatedly Advised Purdue Marketing Was in Full Compliance with Law — Excerpts from Management Reports to the Board

2010: "Year three of Purdue's five year CIA closes as of July 30, with all requirements met...." ● "100% completion of all requirements"

2011: "All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements" ● "No Reportable Events"

2012: "[T]he Company continued to maintain a state of effective compliance"

2013: "There are no significant violations or gaps to report" ● "The Company continues to have good systems and processes in place committed to the prevention and detection of violations, with continuous attention to improvement" ● "Overall Company compliance results - GOOD"

Sources: PWG000422476, -92 (2010) [MA MTD Ex. 54]; PPLP004406466 [Lev. Opp. Ex. 31] (2011); PPLP004407554 [Lev. Opp. Ex. 37] (2011); PPLP004408439 [Lev. Opp. Ex. 44] (2012); PPLP004410506 [Lev. Opp. Ex. 53] (2013); PPLP004410797 [Lev. Opp. Ex. 54] (2013)

Board Was Repeatedly Advised Purdue Marketing Was in Full Compliance with Law — Excerpts from Management Reports to the Board

2014: "There have been no significant compliance issues in … Full Year 2014"

2015: "There have been no significant compliance issues in the 1st quarter, 2015"
- "… in the 2nd quarter, 2015" • "… in the 3rd quarter, 2015"
- "… in the 4th quarter, 2015"

2016: "In 2016, there were no significant compliance issues"

2017: "No significant compliance issues to report"

Sources: PPLP004411812 [Leventhal Ex. 60]; PPLP004412072 [Leventhal Ex. 63]; PPLP004413917 [Leventhal Ex. 78]; PPLP004414932 [Leventhal Ex. 84]; PPLP004412153 [Leventhal Ex. 67]; PPLP004412547 [Leventhal Ex. 69]; PPLP004412819 [Leventhal Ex. 79]; PPLP004413672 [Leventhal Ex. 76]; PPLP004414245 [Leventhal Ex. 79];PPLPC0210008999767 [Leventhal Ex. 81 at p. 2]; PPLPC022001020793 [Leventhal Ex. 82]; PPLPC021000920798 [Leventhal Ex. 83 at p. 2]

The Board Was Proactive on Compliance — In 2005, It Adopted a Corporate Compliance Charter Requiring a Strict Compliance Regime

- The Charter required appointment of a VP of Corp. Compliance who would sit on the Exec. Comm. and report to the CEO, with authority to report to the Board
- The Charter required that the VP of Corporate Compliance implement a program satisfying the 7 elements of an "effective compliance program" as defined by the OIG of HHS and the Sentencing Guidelines:

• Policies to Prevent & Detect Violations of Law • Exclusion of Persons with Criminal Histories • Internal Reporting Mechanisms; Monitoring and Auditing to Detect Violations of Law • Procedures to Address Violations and Potential Misconduct	• Oversight of the Content and Operation of the Compliance Program • Communication of Compliance Standards; Education and Training Programs • Enforcement of Consistent Performance and Disciplinary Standards

- The Charter made all Purdue Executive Committee members responsible for ensuring compliance in all operating and staff departments at Purdue

The Board was informed in November 2005 that the Compliance Department had received a highly favorable King & Spalding audit of Purdue's Compliance Program

Source: 2005 Corporate Compliance Program Charter for PPLP and US IACs (PKY183307471)

In 2007, The Board Amended the Corporate Compliance Charter to Incorporate Requirements of the CIA

- The revised Charter required the VP of Corp. Compliance to report to the Board quarterly and authorized additional reports whenever the VP deemed it appropriate
- It required a Corporate Compliance Council chaired by the VP of Corp. Compliance with members from General Counsel's Office, H.R., Risk Management, Regulatory Affairs, Field Operations, Corporate Quality, Finance and Medical Research
- The Board responsibly monitored compliance through:
  - Formal quarterly compliance presentations were made to the Board
  - Informal inquiries and issues were discussed with the Board
  - The Board required objective measures of compliance success, which led to creation of Purdue's Business Scorecard [Source: PPLPC020000167045-47]
  - The Scorecard incentivized compliance based on goals set by Compliance Council
  - The results affected annual bonuses

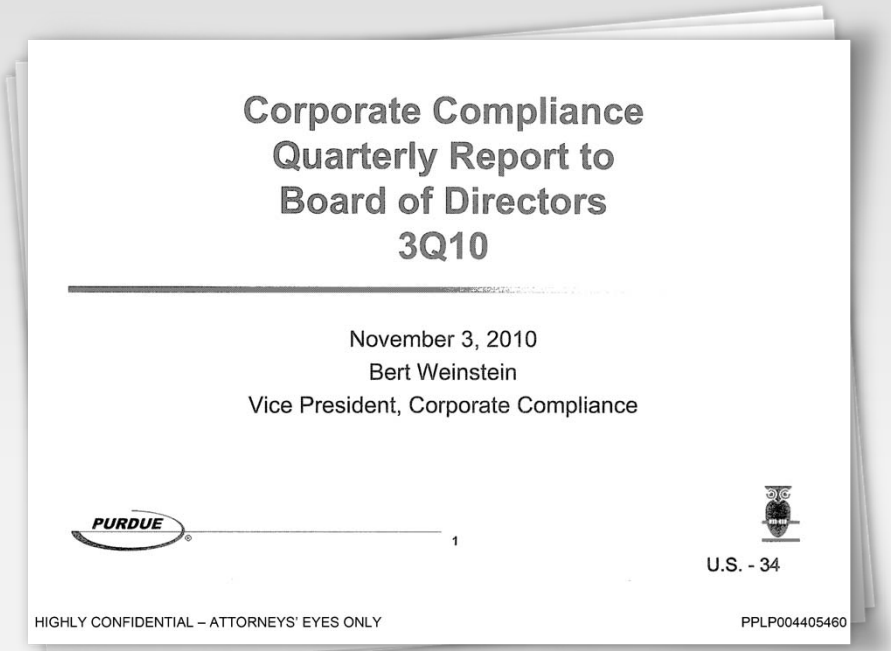
Source: PPLP004416591-98; PPLPC020000167047; PPLPC012000293628

The Corporate Compliance Charter Was Adopted Pursuant to OIG Guidance And Was Continually Reviewed And Updated

Purdue's Compliance Charter

- The Compliance Charter is the policy document adopted by the Board of Directors to govern the compliance function
- It incorporates the Seven Elements of an "effective compliance program" under the Federal Sentencing Guidelines
- Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, and is continually reviewed and updated in light of current standards and emerging developments.

PURDUE Confidential - FOIA EXEMPT 6


Corporate Compliance Quarterly Report to Board of Directors 3Q10

November 3, 2010
Bert Weinstein
Vice President, Corporate Compliance

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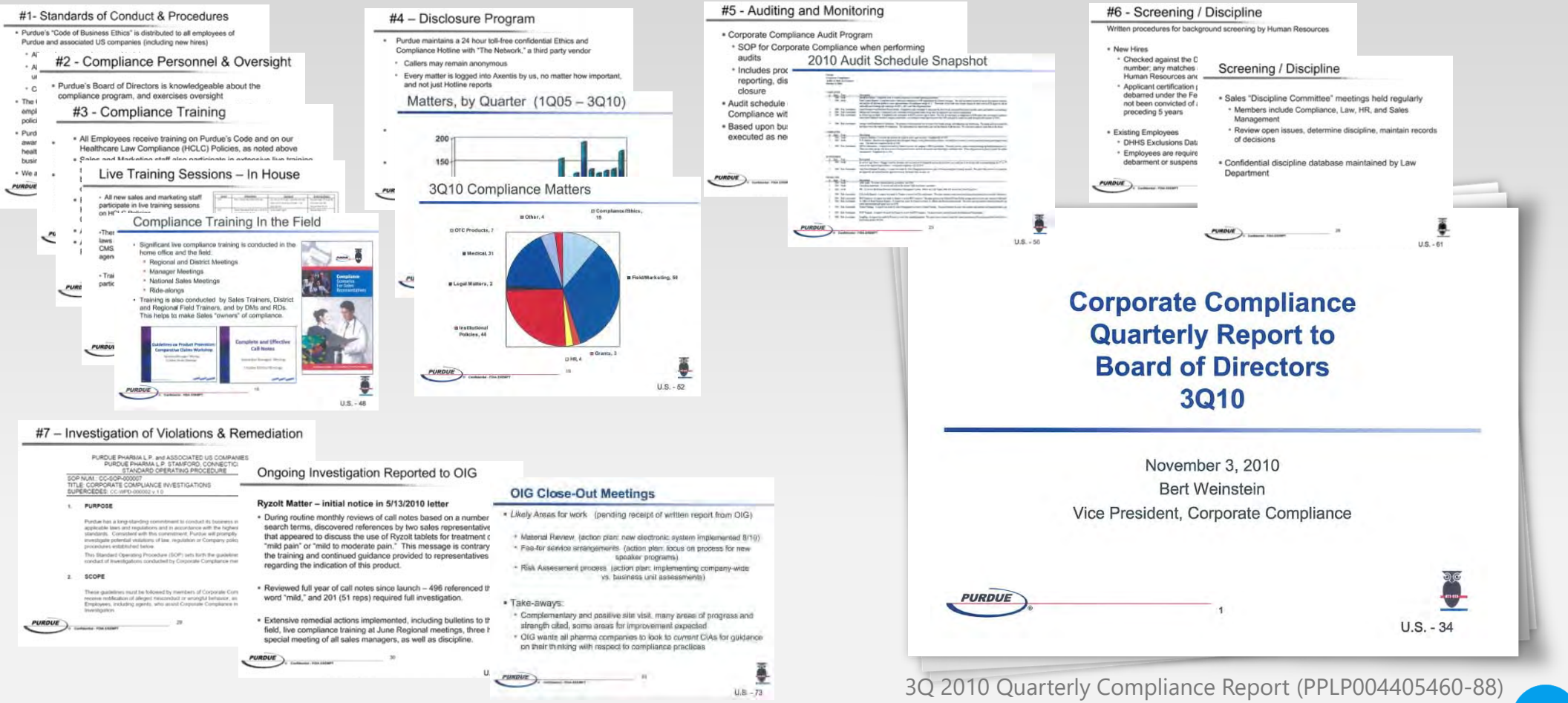
HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004405460

3Q 2010 Quarterly Compliance Report (PPLP004405465-5488)

Board Monitored Implementation of All Elements of the Corporate Compliance Charter



3Q 2010 Quarterly Compliance Report (PPLP004405460-88)

Board Monitored Implementation of the Corporate Compliance Charter

Investigation Matters

ALWAYS • ALL WAYS

During the August Board meeting, it was requested that we continue past practice of providing the Board with quarterly data on matters that have been investigated; see following slide.

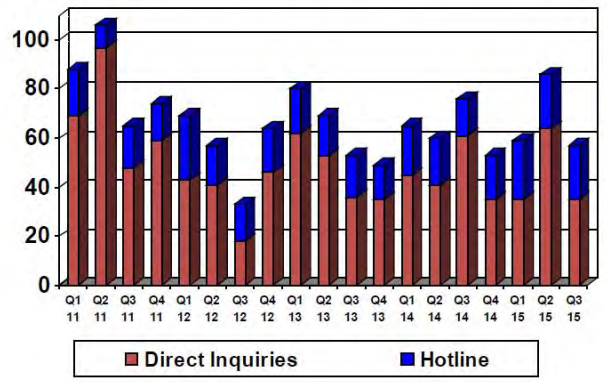
It is noted that none of the matters are significant, and generally concern inquiries by patients, appropriate product messaging by the field, Adverse Events, and preparation of call notes, for which remediation has included coaching, warning letters and bulletins to the field.

Quarterly Ethics and Compliance Report to Board of Directors for 3Q2015

December 1, 2015

Bert Weinstein

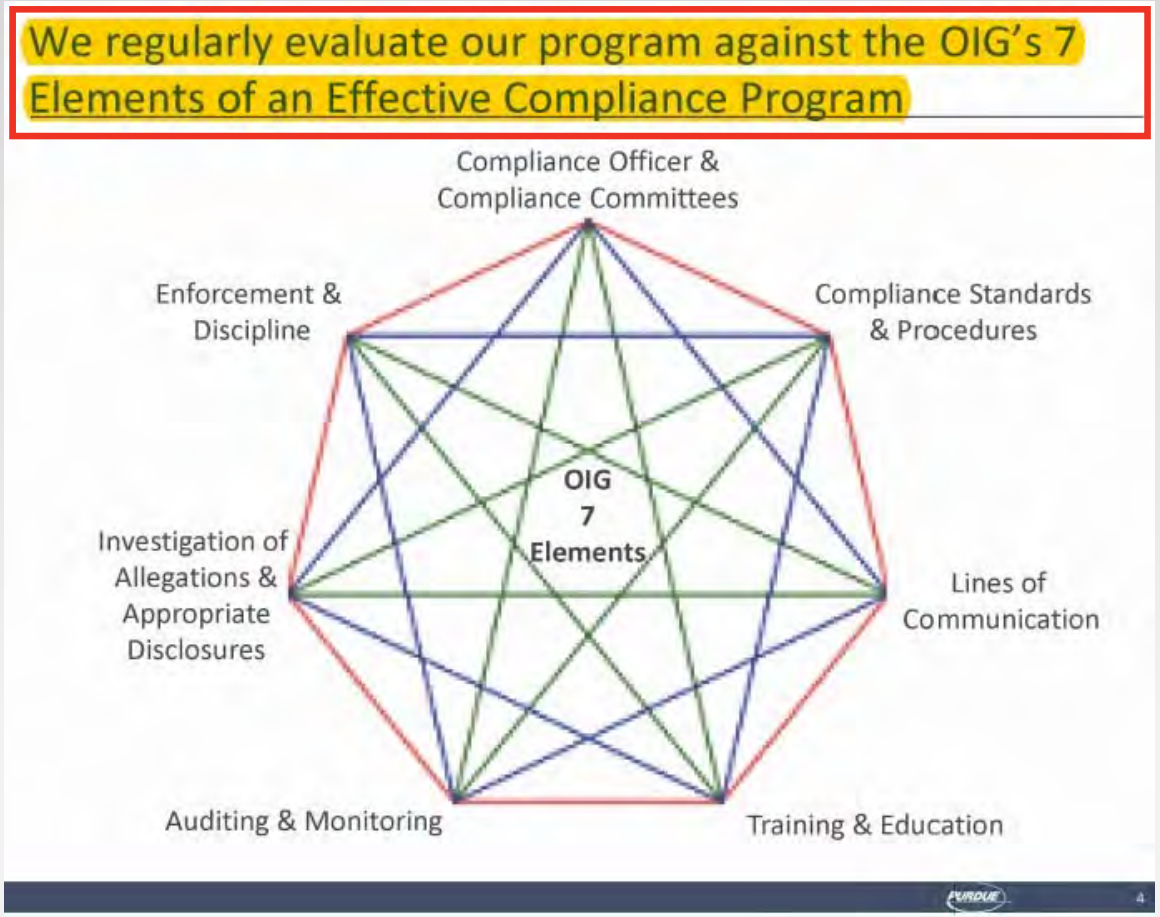
Matters by Quarter (1Q11 – 3Q15)

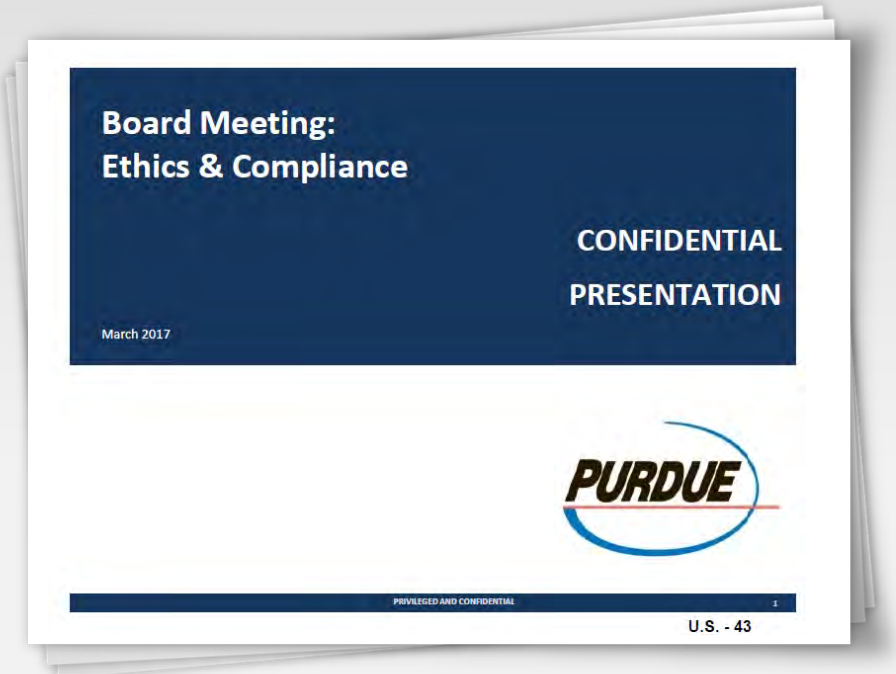


Data through Q3 2015

3Q 2015 Ethics & Compliance Rept. to Board (PPLP004412546, -50-51)

Board Monitored Implementation of All Elements of the Corporate Compliance Charter





March 2017 Ethics & Compliance Rept. to Board (PPLP00441393, -16)

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2009 Annual Bonus Business Success Scorecard

Performance Summary – Year-End

Category	Components	Factor Weight	Projected Performance Level	Payout Level
Sales	• Net Branded Sales Goal Attainment versus 2009 Budget of $2,657.7 million	40%	100%	40.0%
Operating Efficiency	• Efficiently operating the business to manage expenses within budget • The maximum payout on this component occurs at an operating expense reduction / savings of $30 million (excludes R&D and sales volume related expenses)	25%	150%	37.5%
Product Diversification	• Advancement of drug development projects through R&D, clinical research, and regulatory milestones •Assessment of the extent to which BD and IP operations contribute to diversification / commercial success	25%	R&D – 105.6% LBD – 105.0%	26.3%
Compliance	• Compliance results for Compliance Categories related to business operations and CIA requirements	10%	100%	10.0%
	Total Business Success Scorecard	100%		113.8%

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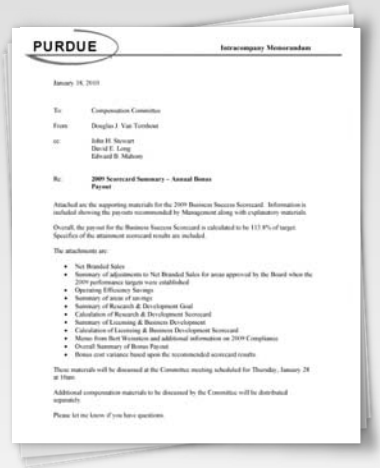
PURDUE Intracompany Memorandum

January 18, 2010

To: Compensation Committee

From: Douglas J. Van Tornhout

cc: John H. Stewart
David T. Long
Edward B. Mahony

Re: 2009 Scorecard Summary – Annual Bonus Payout

Attached are the supporting materials for the 2009 Business Success Scorecard. Information is included showing the payouts recommended by Management along with explanatory materials.

Overall, the payout for the Business Success Scorecard is calculated to be 113.8% of target. Specifics of the attainment scorecard results are included.

The attachments are:

- Net Branded Sales
- Summary of adjustments to Net Branded Sales for areas approved by the Board when the 2009 performance targets were established
- Operating Efficiency Savings
- Summary of areas of savings
- Summary of Research & Development Goal
- Calculation of Research & Development Scorecard
- Summary of Licensing & Business Development
- Calculation of Licensing & Business Development Scorecard
- Memo from Bert Weinstein and additional information on 2009 Compliance
- Overall Summary of Bonus Payout
- Bonus cost variance based upon the recommended scorecard results

These materials will be discussed at the Committee meeting scheduled for Thursday, January 28 at 10am.

Additional compensation materials to be discussed by the Committee will be distributed separately.

Please let me know if you have questions.

January 18, 2010 Memo to BOD Compensation Committee (PPLPC057000007180); *see also* SCK05575 (March 2, 2010 adoption by Board).

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2010 Business Success Scorecard
Overarching Objective - Compliance

- Compliance performance results will be used as an overall multiplier to the Scorecard Total
- Compliance Attainment will be assessed across five Risk Area Categories
- Performance in each Risk Area will be rated from 1 to 5 (highest attainment) - reflecting accomplishments, deficiencies and actions taken by management
- Ratings will range from 50% to 150% for each Risk Area
  - Ratings and resulting payout leverage will take multi-year successful attainment into account for determining ratings over 100%

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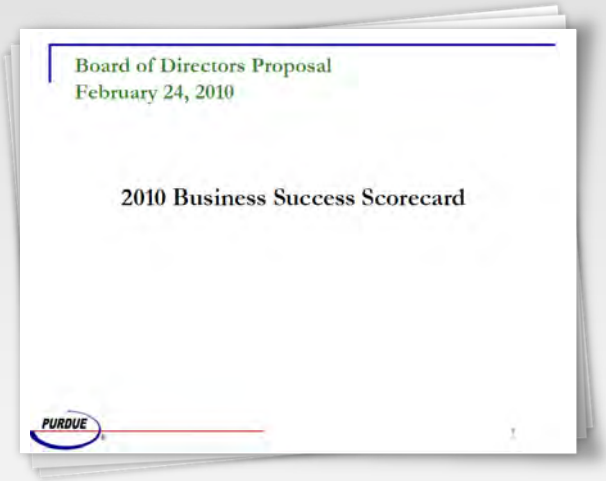

February 24, 2010 BOD Proposal (PURDUE-COR-00028015); Adopted (SCK06079)

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2010 Business Success Scorecard
Overarching Objective - Compliance

- Compliance Attainment will be determined based upon performance in the following Risk Areas
- In reporting on attainment related to these Risk Areas, Management will provide specific scorecard information for each Risk Area.

Risk Area	Components	Weight
CIA / Multistate AG	Satisfied CIA and AG requirements for all: Policies, Training, Communications, Screening, Committees, IRO Reviews, Hotline, Reporting to Board and OIG, Promotion and Medical Services Monitoring, Abuse and Diversion Detection Reports	20%
Sales and Marketing	Adherence to Sales SOPs and state and federal pricing requirements; Absence of FDA warning letters or agency action regarding practices; Timely reporting of Adverse Events, Reports of Concern, Product Complaints, and Abuse and Diversion Detection Reports; accurate state and federal expense reports	30%
Manufacturing and Quality	Successful GMP, GLP, DEA, OSHA, EPA, other applicable federal, state and local regulatory audits, inspections, permits, and good standing; Absence of FDA warning letters or agency action regarding practices	25%
Research & Development	Adherence to GLP and GCP standards; Absence of FDA warning letters or agency action regarding practices; Adherence to requirements for registration of clinical trials and reporting of results; Absence of issues with respect to regulatory status, Medical Services function, patient protection, integrity of scientific publications, and data integrity	15%
Administration / Other	E&Y and Internal Audit Function recommendations are implemented on a timely basis; Integrity of Material Review Process; Good standing with respect to HIPAA and Department of Labor	10%

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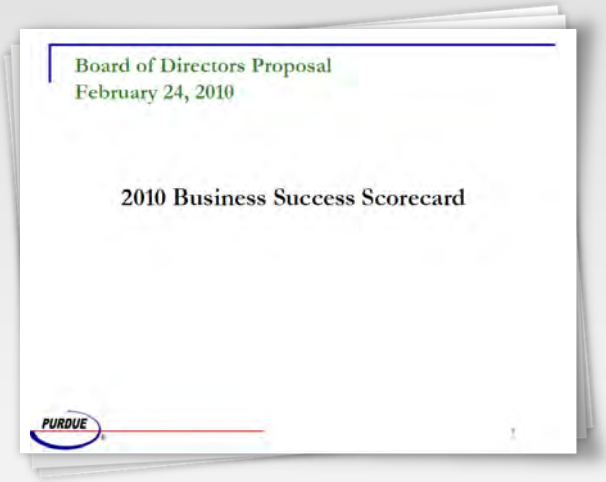

February 24, 2010 BOD Proposal (PURDUE-COR-00028015); Adopted (SCK06079)

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2011 Annual Bonus Business Success Scorecard
Performance – Actual Year-End

Category	Components	Factor Weight	Actual Performance Level	Payout Level	Payout
Sales	• Net Branded Sales Goal Attainment versus 2011 Budget of $3,259.0 million	30%	Net Sales of $2,295 million	50%	15.0%
	• Butrans prescription attainment versus objective of 529,000 prescriptions	20%	277,626 prescriptions	52.5%	10.5%
Operating Efficiency	• Efficiently operating the business • Target Payout at $15 million in qualified savings; • Maximum payout at savings of $45 million	20%	Qualifying savings calculated at $47.56 million	175%	35.0%
Research & Development	• Advancement of drug development projects through R&D, clinical research, and regulatory milestones	15%	See discussion	122.7%	18.4%
Licensing & Business Development	•Assessment of the extent to which BD and IP operations contribute to diversification / commercial success	15%	See discussion	91.3%	13.7%
	Total Business Measures	100%			92.6%
	Overarching Objective – Compliance Multiplier				102.25%
	Overall Performance Score				94.7%

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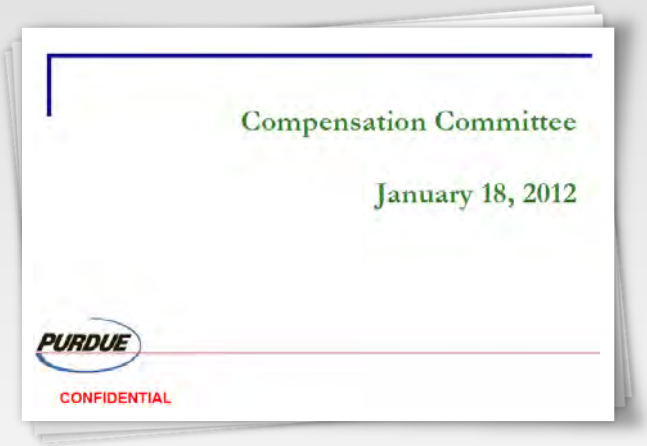

Jan. 18, 2012 BOD Compensation Committee Deck (PPLPUCC9002649696)

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2012 Attainment of Business Results

Overarching Objective - Compliance

- Risk Area Categories detailed below determine Compliance Attainment
- Management's proposed specific scorecard information for each Risk Area.

Risk Area	Components	Weight	Component Score	Overall Score
CIA / Multistate AG	Satisfied CIA and AG requirements; OIG Report linked to completion of the CIA	20%	3.25	0.65
Sales and Marketing	Adherence to Sales SOPs and state and federal pricing requirements; absence of FDA warning letters or agency action regarding promotional practices; accurate state and federal expense reports	40%	3.07	1.23
Manufacturing, Quality, R&D	Successful GMP, GLP, GCP, DEA, OSHA, EPA, other applicable federal, state and local regulatory audits, inspections and permits; adherence to requirements for registration of clinical trials and reporting of results; absence of issues with respect to regulatory status, Medical Services function, patient protection, integrity of scientific publications, and data integrity.	40%	3.11	1.24
				3.12

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Jan. 14, 2013 BOD Compensation Committee Deck

Board Incentivized Employees to Satisfy Compliance Requirements by Incorporating Compliance into Bonus Calculations

2012 Annual Bonus Determination

Business Success Scorecard Reflecting Proposed Adjustments

- Year-end performance and originally proposed scorecard
  - Results reflect proposed adjustments

	Category Weight	Year-end Results	Percent of Target Achieved	Projected Payout Score	Payout Level
Net Branded Sales	20%	$2,210.4 million	97.3%	92.9%	18.6%
Butrans Prescriptions	10%	470,923	82.2%	82.2%	8.2%
Intermezzo Prescriptions	10%	35,480	20.7%	0.0%	0.0%
Operating Profit	30%	$1,010.2 million	98.6%	98.6%	29.6%
Research & Development	20%	Rating = 3.5	112.5%	112.5%	22.5%
Licensing & Business Development	10%			66%	6.6%
Total	100%				85.5%
Compliance Multiplier					103.0%
Overall Scorecard					88.0%

- With 25% Individual portion at 100%, overall bonus payments would then average 91.0% of target

PURDUE

Jan. 14, 2013 BOD Compensation Committee Deck

The Compliance Structure Included Councils and Committees Charged with Ensuring Compliance with Law, Regulations and Company Policy

- Corporate Compliance Council
- Sales and Marketing Compliance Committee
- Vice Presidents' Compliance Council
- R&D Compliance
- Administrative Area Compliance Committee
- Grant Review Committees
- Reportable Events Committee
- Discipline Committee
- Quality Steering & Technical Operations Committees
- Executive Committee and Board of Directors

Source: PPLPC012000293628

Board Understood That Purdue Implemented Multiple Compliance Tools to Ensure Accurate Marketing

- **Marketing and Advertising Materials** – Required review and unanimous approval from Medical Services, Regulatory Affairs, and Legal.
- **Guidelines on Product Promotion** – Prohibited sales representatives from using promotional materials not approved.
- **Promotion Monitoring Program** – Required District Managers to observe and record interactions between sales reps and HCPs and to notify Compliance of any sales rep failure to comply with Purdue policies.
- **Sales Call Monitoring** – Legal or Compliance reviewed sales force call notes.
- **Audits** – Compliance conducted audits and monitored key risk activities.

Sources: PPLP004432089, PPLP004431206, PPLP004430145

Board Understood Sales Force Not Allowed to Deviate from Approved Materials

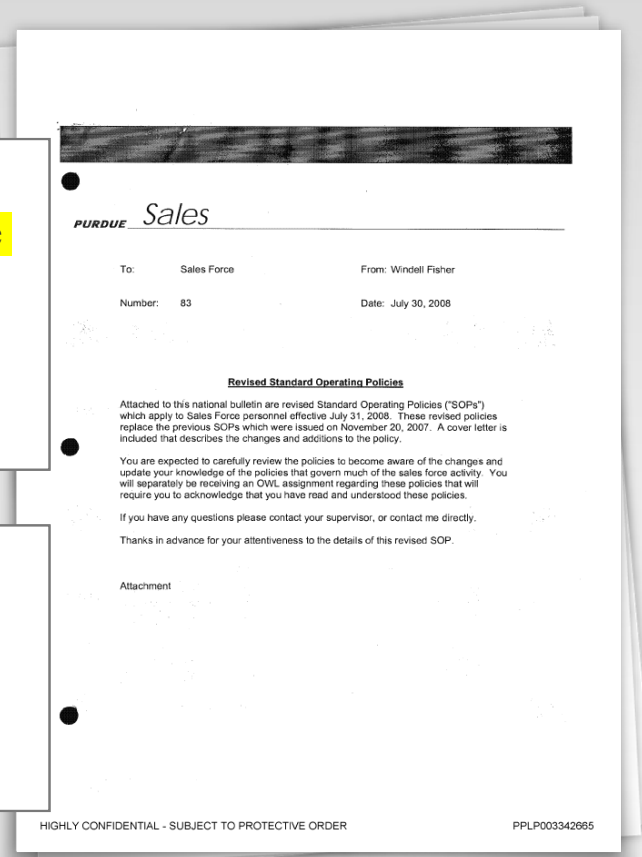
2008 Sales Force SOP Manual:

Policy Statement

All Materials that include product information must be approved by the home office in accordance with Purdue's *Material Review and Approval Process* SOP, a copy of which is available on the Policies and Standards page of the Purdue intranet. All product claims made verbally by Sales Force Personnel must be consistent with the product labeling and Company approved Materials.

Correspondence with HCPs

Sales Force Personnel generally are not permitted to draft and/or send correspondence to any Health Care Practitioner (HCP) that has not previously gone through the internal Material Review Process and received written approval for distribution except as provided below.



PURDUE Sales

To: Sales Force From: Windell Fisher

Number: 83 Date: July 30, 2008

Revised Standard Operating Policies

Attached to this national bulletin are revised Standard Operating Policies ("SOPs") which apply to Sales Force personnel effective July 31, 2008. These revised policies replace the previous SOPs which were issued on November 20, 2007. A cover letter is included that describes the changes and additions to the policy.

You are expected to carefully review the policies to become aware of the changes and update your knowledge of the policies that govern much of the sales force activity. You will separately be receiving an OWL assignment regarding these policies that will require you to acknowledge that you have read and understood these policies.

If you have any questions please contact your supervisor, or contact me directly.

Thanks in advance for your attentiveness to the details of this revised SOP.

Attachment

HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP003342665

7/30/08 Revised SOPs (PPLP003342665)

Board Was Informed That Employees Were Extensively Trained on Compliance

#3 - Compliance Training

- All Employees receive training on Purdue's Code and on our Healthcare Law Compliance (HCLC) Policies, as noted above
- Sales and Marketing staff also participate in extensive live training sessions on HCLC Policies, including both didactic and scenario-based training, on the laws and regulations of the FDA, CMS, and other regulatory agencies.
- Purdue formally adopted the PhRMA Code on Interactions with Healthcare Professionals, and trains employees on the PhRMA Code
- All Purdue employees are also trained on Purdue's CIA
- All Purdue employees complete training on Adverse Event and Product Complaint Reporting.

PURDUE Confidential - FOIA EXEMPT 11

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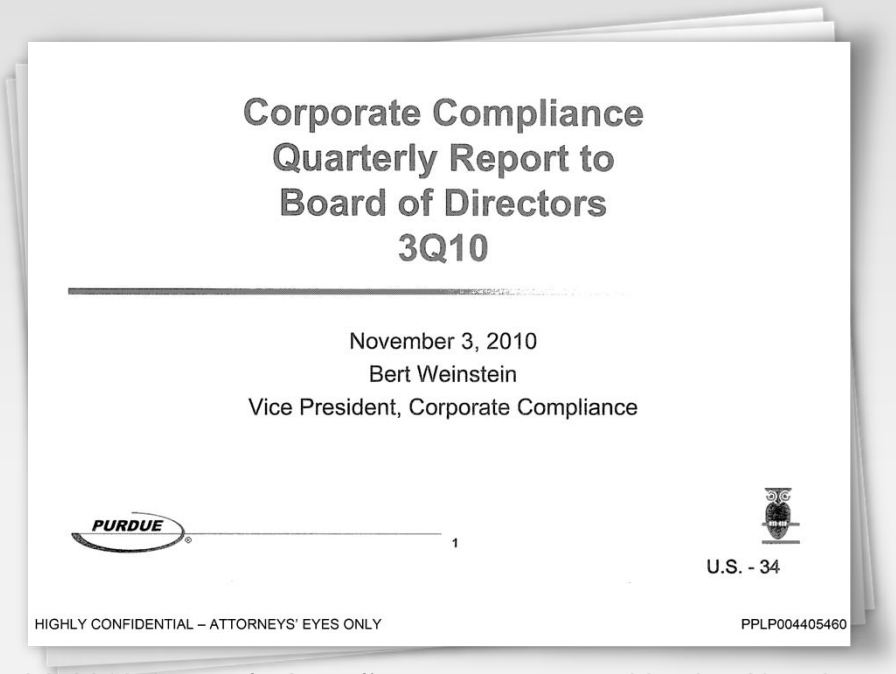
HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004405470



3Q 2010 Quarterly Compliance Report (PPLP004405460, -70)

Board Understood Purdue Audited Potential Areas of Risk

4Q13 Compliance Audits

Topper's Audit

- To assess the potential that the Annual Topper's Contest might incentivize the Sales Force to inappropriately promote products
- No negative findings – no correlation

Medical Information Requests

- To provide a level of assurance that inquires received by Medical Services were not solicited and/or confirm whether or not improper promotion may have occurred by Sales Representatives
- No negative findings – no correlation

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PPLP004410807

Quarterly Compliance Report to the Board of Directors for 4Q2013

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2014

PURDUE

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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

PPLP004410797

4Q 2013 Quarterly Compliance Report (PPLP004410797, -807)

Board Was Informed That All Compliance Issues Were Reported and Remediated

OIG Communications

Two outstanding matters closed by OIG with "no action"

1) Field Contact Report Matter

Recap: Investigation revealed that a few District Managers had fallen short of expectations for: reviews of call notes; time spent in field doing ride-alongs with representatives; routine administrative activities; accurate and complete documentation (calendars, FCRs, etc.)

OIG's November 24, 2009 email notes:

- "Purdue promptly notified OIG of its discovery" of the issue
- "promptly conducted a nationwide investigation"
- "took remedial action" in consultation with OIG
- "re-trained personnel"
- "commitments made…had been accomplished"
- *"At this time we have no further questions about this matter."*

PURDUE 4

OIG Communications

2) OxyContin Savings Card Investigation

Recap: In March, 2009 Purdue discovered and reported to OIG the existence of representative call notes with references to savings cards and federal healthcare programs. Use of the savings cards with such programs is unlawful, and explicitly prohibited by the terms of the cards themselves. Thoroughly investigated by outside counsel, with no evidence of any improper use, OIG remained concerned with risk.

OIG's November 24, 2009 email notes:

"Purdue has met its reporting obligation,' with no further action to be taken by OIG."

Purdue is nevertheless implementing two new safeguards – a new card activation process (like a credit card), and a new pharmacist verification process when prescriptions are filled

PURDUE 5

Corporate Compliance Quarterly Report to Board of Directors 4Q09

February 4, 2010
Bert Weinstein
Vice President, Corporate Compliance

4Q 2009 Quarterly Compliance Report (PPLP004403707, -10-11)

Board Was Informed That Most Compliance Issues Were Minor


Purdue
Quarterly Report to the Board
November 9, 2011

Annual Report was submitted to the Office of Inspector General on September 23rd. The Independent Review Organization's Report on its Transaction and Systems Reviews contained a limited number of **minor observations** and recommendations, to which the company responded as part of the Annual Report. This will be reported in more detail during the quarterly report to the Board.

Quarterly Report to the Board, November 2011, p. 25 (PPLP004366871)


Purdue
Quarterly Report to the Board
3rd Quarter, 2012
November 1, 2012

The Final Independent Review Organization (IRO) Report under Purdue's CIA was successfully concluded. . . . **All findings and observations are minor**, but highlight the continued importance of adherence to departmental SOPs, which we continue to address.

Quarterly Report to the Board, November 2012, p. 45 (PPLP004366816)


Purdue
Quarterly Report to the Board
2nd Quarter, 2013
July 23rd, 2013

[T]here have been **no *significant* compliance matters** to report

Quarterly Report to the Board, July 2013, p. 49 (PPLPC012000433388)

Board Was Informed That Serious Violations Resulted in Termination

Other Significant Matters

These additional matters involved violations of SOPs and policies, but are not "Reportable Events"

- District Manager determined representative (long term employee and multi-time Toppers winner) had falsified call records and expense reports. Representative terminated 12/08/08.
- On 12/12/08, sales representative who had previously been investigated for call note inconsistencies self-reported that she had improperly recorded call notes on at least two physicians. Further investigation disclosed representative not following call note reporting SOP. Representative terminated 01/12/09.
- Corporate Compliance received anonymous Hotline that a representative had been arrested for attempting to use a forged prescription for OxyContin. Representative terminated 01/15/09.

PURDUE

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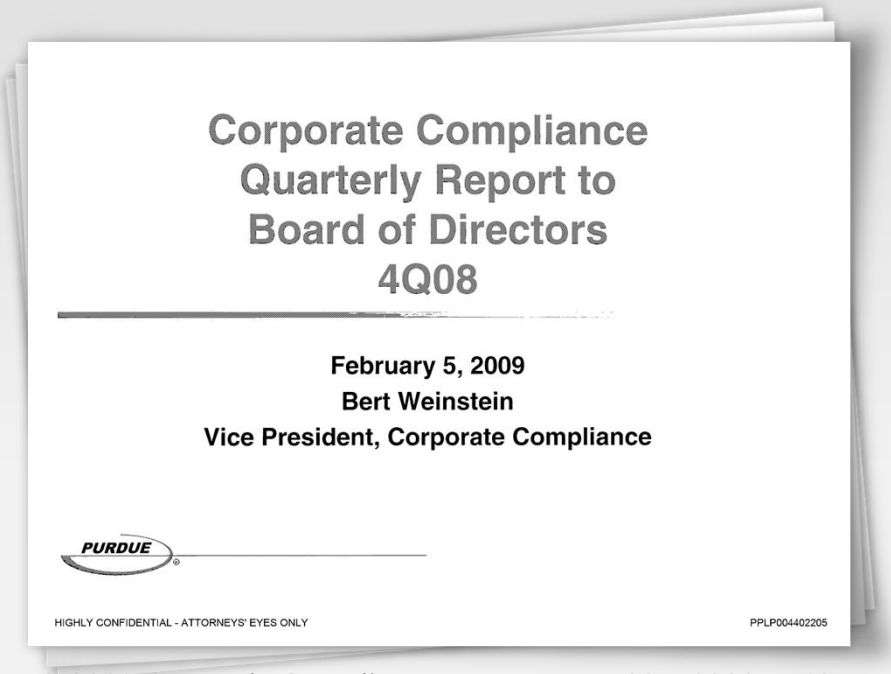
HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY PPLP004402212



4Q 2008 Quarterly Compliance Report (PPLP004402205, -12)

Board Was Informed That The Corporate Compliance Council Evaluated The Highest Priority Compliance Risks

3Q13 Compliance Risk Reduction

- Purdue evaluates the highest priority compliance risks through the senior-level Corporate Compliance Council's quarterly meetings
- 31 priority Compliance risks, among eight departments, have been identified and evaluated by the Council (high, medium, low), with quarterly updating of remediation activities
- As of 3Q, the following risk remains rated as "high," but with undertaking to reduce risk level by year-end
  - R&D Publications and Authorship – a focus of recent Corporate Integrity Agreements, with very specific compliance requirements; need of updated SOPs

PURDUE

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3Q 2013 Quarterly Compliance Report (PPLP004410506, -08)

Board Understood Purdue Constantly Monitored for Violations: Call Note Audits

3Q13 Field Sales Call Note Reviews

Call notes are reviewed for key words and by randomized selection, within 30 days of each month's-end

Total Calls From Field	Reviewed by Compliance	% of Calls Reviewed	Minor, or No Findings	Major Findings	% Reviewed w/ Major Findings
246,449	29,180	11.82%	253	10	0.03%

Call note reviews are a cornerstone of our overall sales oversight, with a total of 698 total matters evaluated at weekly Sales Discipline Committee meetings during the 3rd quarter

Remediation	# / % Total
DM Coaching	513 / 73%
No follow up needed	81/ 12%
Warning Letter	56 / 8%
Coaching Letter	41 / 5%
Probation Letter	7 / 1%

Top 5 Issues Found	# / % Total
Product Indication Errors	174 / 25%
#Products Discussed vs Reported	103 / 15%
Reformulation Messaging	94 / 13%
Poorly Written Call Note	82/ 12%
Potential Comparative Claim	45 / 6%

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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY PPLP004410510

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004410510

Quarterly Compliance Report to the Board of Directors 3Q2013

Bert Weinstein
Vice President, Corporate Compliance
October 28, 2013

PURDUE

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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY PPLP004410506

3Q 2013 Quarterly Compliance Report (PPLP004410506, -10)

Board Understood Purdue Constantly Monitored for Violations: Field Contact Report Audits

Compliance Audits Completed - 2014

Material Review (Medium Risk)

* To assess expired status of materials in the APRIMO system
* Report pending - No Critical Findings; 1 Major Finding (~5% of materials were expired but still in use); several positive practices were noted

Field Contact Report Audits (Medium Risk)

* One random audit and one for-cause audit (7 DMs)
* To assess whether District Managers were accurately documenting compliance issues on Field Contact Reports and appropriately evaluating Sales Representative compliance
* Report pending - No Critical Findings; 3 Major Findings (timeliness of expense reporting, poor call notes, accuracy of FCR documentation)

PURDUE

1Q 2014 Quarterly Compliance Report (PPLP004411166, -73)

Board Understood Purdue Constantly Monitored for Violations: Sales Compliance Review Committee

Sales Compliance Review Committee

* "SCRC" is a committee that addresses compliance-related issues arising within the Field Force.
* Compliance matters are surfaced in many ways, including, call note monitoring, Field Contact Reports, expense and other routine monitoring activities, reports via the Hotline; and from employees and others.
* There were 533 closed matters in 2014, involving 239 representatives; with 31 of these matters (6%) resulting in disciplinary action. Most resolutions involve various forms of coaching

Remediation	% Total
DM Coaching	76%
Coaching Letter	8%
No follow up	7%
Warning Letter	4%
RD Coaching	3%
Probation Letter	2%

Top 5 Issues Found	% Total
Product Indication	33%
Presentation / Products	22%
Adverse Events	14%
Unclear / Poorly Written	10%
Typo	8%

PURDUE

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Quarterly Compliance Report to Board of Directors 4Q2014

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2015

PURDUE

U.S. - 5

4Q 2014 Quarterly Compliance Report (PPLP004411811, -16)

The Board Was Informed That Outside Counsel Assessed And Endorsed The Compliance Program in 2015

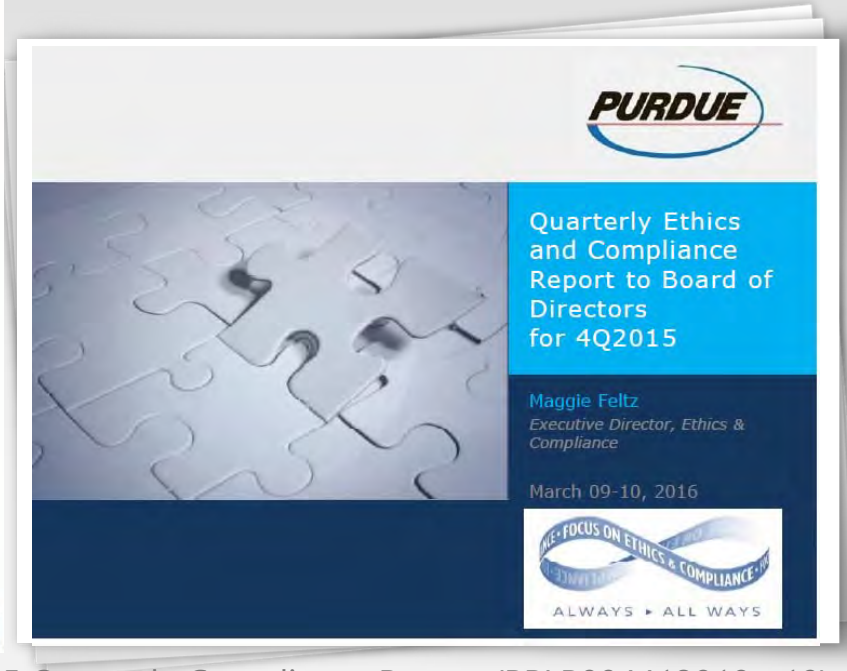
Bottom Line

Purdue continues to have strong systems and processes in place to prevent and detect violations of law, regulations, and Company policies, and to remediate issues before they become significant problems.

There have been no significant compliance issues in the 4th quarter, 2015.

This report focuses on:

- Positive review of Commercial Compliance program by outside counsel
- 2016 Ethics & Compliance Program Priorities
- Summary of Investigations
- Sunshine Act Update



4Q 2015 Quarterly Compliance Report (PPLP004412818, -19)

Board Informed the Speakers Program Was Carefully Monitored and Complied with Law

Board Understood Speakers Program Was Carefully Monitored

Speaker Program/Physician Retention Processes

- Corporate Compliance has worked closely with Sales and Marketing and others to implement compliant OxyContin and Butrans speaker programs, with appropriate procedures for making needs assessments, establishing objective selection criteria, fair market value compensation, compliance monitoring, and other practices, all in accordance with current OIG guidance's.
- We have attended all speaker training programs as well as a large sample of speaker programs to monitor compliance; a compliance monitoring program for speaker dinners is now in place. No compliance issues have presented to date.
- A vendor has been retained to prepare fair market valuation guidelines to be used Company-wide in retaining physicians.
- Procedures are in place with Law, Procurement, and Finance to ensure there are contracts in place for all physician arrangements prior to any payments.

PURDUE

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1Q 2011 Quarterly Compliance Report (PPLP004406032, -35)

Board Understood Speakers Program Was Carefully Monitored

2011 Planned Audits List

In consultation with other areas, Compliance makes determinations to audit and monitor compliance priority risks throughout Purdue. The activities are subject to change based on perceived risk over time.

Current audits and assessments include:

- Home Office expenses on HCPs
- Vermont State law sales compliance issues
- Call Note Audits
- District Manager Automobile Trunk Checks of Materials
- CIA Training / HRIS Database
- Aggregate Spend
- Fee for Service Arrangements
- FCPA / UK Bribery
- Speaker Programs

PURDUE

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Corporate Compliance Quarterly Report to Board of Directors 1Q2011

May 20, 2011
Bert Weinstein
Vice President, Corporate Compliance

PURDUE

1Q 2011 Quarterly Compliance Report (PPLP004406032, -46)

Board Understood Speakers Program Was Carefully Monitored

Sales and Marketing

"Risk Area"	Activity
Proper promotion	Policies, training, monitoring
CIA and Sales SOP Standards	Focused actions, monitoring
Material Review and use	New electronic system
Fee for service arrangements	Meeting OIG Safe Harbor fully
Speaker programs	Training, monitoring
Direct to consumer advertising	Material review, monitoring
E-marketing	Material review, monitoring
Sales force training	Audit, monitoring
Pricing	Law & Finance oversight, audits
Coupons / Value Cards	Call note review, auditing
Suspect prescribers	"ADD" program, Law oversight

PURDUE 7

Corporate Compliance Quarterly Report to Board of Directors 2Q2011

July 21, 2011

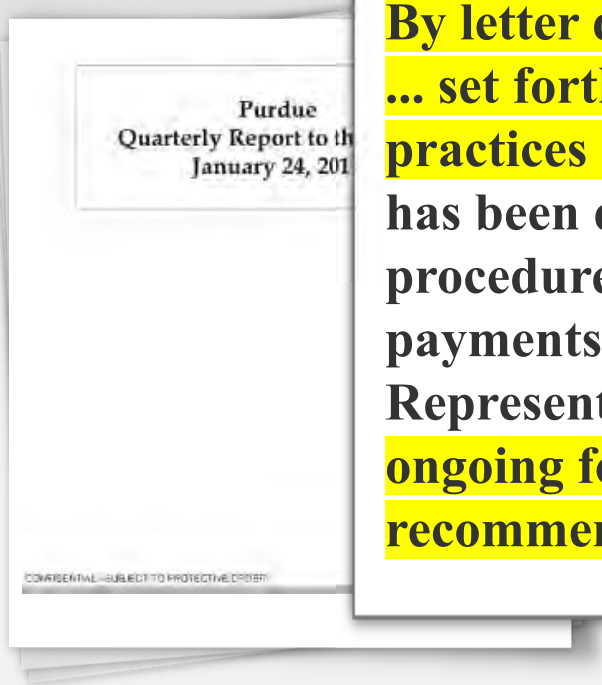
Bert Weinstein
Vice President, Corporate Compliance

PURDUE

2Q 2011 Quarterly Compliance Report (PPLP004406466, -72)

Board Understood Speakers Program Was Carefully Monitored

The Board was informed that Purdue was following the OIG Monitor's compliance recommendations for the Speakers Program



By letter dated December 3rd, Purdue's OIG Monitor Keshia Thompson ... set forth the Monitor's recommendations for good compliance practices for Purdue's new speaker programs.... Corporate Compliance has been deeply involved in assisting in preparation of appropriate procedures for "needs assessments," establishing fair market value payments for HCPs, training of Purdue District Managers and Representatives, and monitoring arrangements. These steps have been ongoing for over six months, and are consistent with OIG' s recommendations in their December 3rd letter.

Jan. 24, 2011, Quarterly Rept. to the Board at PPLP004366975

Board Understood Speakers Program Was Carefully Monitored

Speaker Program Update

- Speaker programs are a relatively high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities.
- FDA recently issued a warning letter on another company's program
- Purdue has a live monitoring process
  - All programs monitored and reported on by Purdue attendees
  - 8.5% of all speaker programs have had an independent monitor in attendance (exceeds recent CIA standards)
  - To date no substantive concerns have been identified, and minor issues appropriately addressed

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PPLP004407563

4Q 2011 Quarterly Compliance Report (PPLP004407554, -63)

Board Understood Speakers Program Was Carefully Monitored

Commercial Monitoring Program

Monitoring of both sales forces to be continued / strengthened

* Annual Ride-Alongs with sales personnel to better understand challenges faced by Sales Representatives
* District Meetings, other meetings
* Conventions/Product Theaters
* Speaker Programs
* Call Note Monitoring
* Field Contact Reports
* Documents and email communications reviews

PURDUE

Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

PURDUE 7.10.12

2Q 2012 Quarterly Compliance Report (PPLP004408046, -61)

Board Understood Speakers Program Was Carefully Monitored

Key Compliance Issues Seen in Q1

Speaker Programs – "Monitoring Forms"

- Issue – Speaker Monitoring Forms are critical to proper program compliance - not being submitted in a timely fashion
- Solution – Ongoing monthly monitoring by Corporate Compliance along with Sales Management training on requirements and impact- no longer an issue

Field Contact Reports

- Issue – Managers not completing documented work sessions every 90 days – SOP requirement
- Solution – As part of revised Sales SOP, new work session requirement changed from 8 days annually to 2 days per quarter- will be remedied with monthly monitoring and reporting

PURDUE

1Q 2013 Quarterly Compliance Report (PPLP004409694, -97)

Board Understood Speakers Program Was Carefully Monitored

4Q13 Speaker Program Monitoring

Speaker Programs are in government crosshairs

- Each Purdue program is reviewed by Field Sales monitoring form
- Independent monitors attend ~5% of programs, with selection based on speaker frequency or for cause
- Most common compliance issues by speakers: did not stay strictly on label and/or follow approved slide deck. Remediated through letters to attendees, corrective speaker training, and dismissal of speakers for repeated lapses. Level of risk is low given our remedial and oversight actions.

Year	Total Programs	Programs with Compliance Issues	% of Programs with Compliance Issues
2011	968	6	0.62%
2012	1290	12	0.93%
2013	732	3	0.41%

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U.S. - 113

Quarterly Compliance Report to the Board of Directors for 4Q2013

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2014

PURDUE

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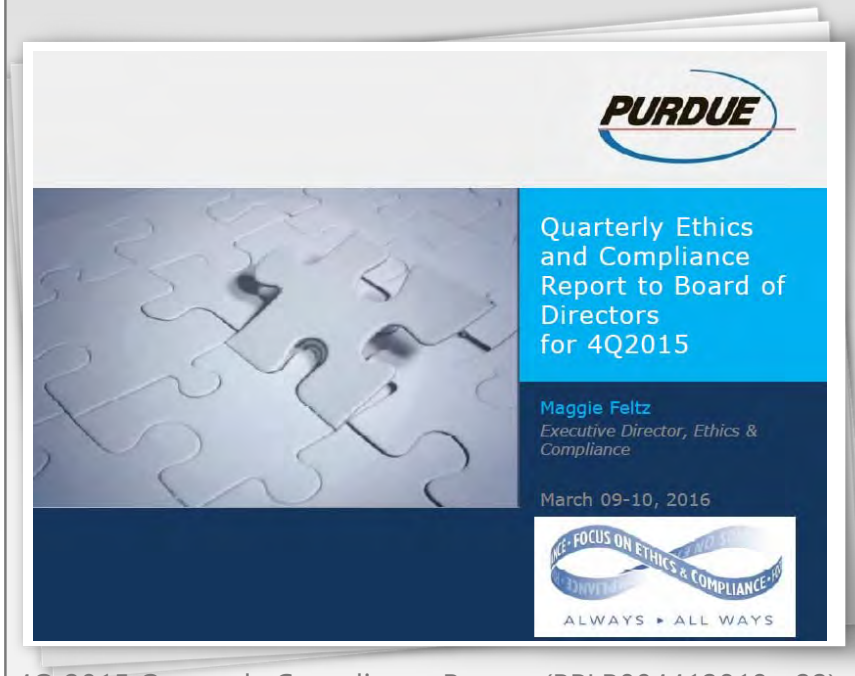
4Q 2013 Quarterly Compliance Report (PPLP004410797, -804)

Board Understood Speakers Program Was Carefully Monitored

2016 Compliance Priorities

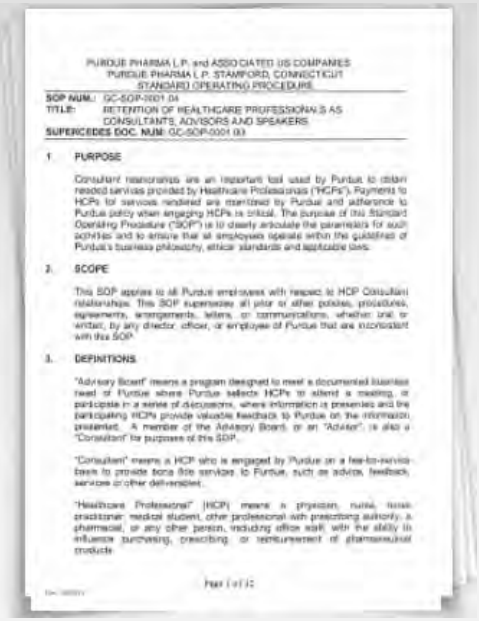
- An annual assessment of the most important areas of compliance risk is conducted each year, with a work stream that follows throughout the year focused on those risks.
- Risks are rated as high, medium and low (no high risks currently)
- Together with senior business heads, we are focusing on four areas deemed to present medium compliance risk, including:
  - Product Promotion training, focusing on:
    - Recently hired sales representatives
    - Further training for Commercial/Home Office Leadership
  - Managed Markets, focusing on new channels/customer segments
  - Field force Incentive Compensation
  - Speaker Programs



4Q 2015 Quarterly Compliance Report (PPLP004412818, -22)

Purdue Implemented SOPs — Supervised by The General Counsel's Office — Regulating The Use of HCPs As Speakers

Purdue will not pay any consulting fee, honorarium, grant, etc. to any HCP for the purpose of influencing the HCP to prescribe, order, purchase or recommend any product.



PURDUE PHARMA L.P. and ASSOCIATED US COMPANIES
PURDUE PHARMA L.P. STAMFORD, CONNECTICUT
STANDARD OPERATING PROCEDURE

SOP NUM.: GC-SOP-0001.04
TITLE: RETENTION OF HEALTHCARE PROFESSIONALS AS CONSULTANTS, ADVISORS AND SPEAKERS
SUPERCEDES DOC. NUM: GC-SOP-0001.03

1. PURPOSE

Consultant relationships are an important tool used by Purdue to obtain needed services provided by Healthcare Professionals ("HCPs"). Payments to HCPs for services rendered are maintained by Purdue and adherence to Purdue policy when engaging HCPs is critical. The purpose of this Standard Operating Procedure ("SOP") is to clearly articulate the parameters for such activities and to ensure that all employees operate within the guidelines of Purdue's business philosophy, ethical standards and applicable laws.

2. SCOPE

This SOP applies to all Purdue employees with respect to HCP Consultant relationships. This SOP supersedes all prior or other policies, procedures, agreements, arrangements, letters, or communications, whether oral or written, by any director, officer, or employee of Purdue that are inconsistent with this SOP.

3. DEFINITIONS

"Advisory Board" means a program designed to meet a documented business need of Purdue where Purdue selects HCPs to attend a meeting, or participate in a series of discussions, where information is presented and the participating HCPs provide valuable feedback to Purdue on the information presented. A member of the Advisory Board, or an "Advisor", is also a "Consultant" for purposes of this SOP.

"Consultant" means a HCP who is engaged by Purdue on a fee-for-service basis to provide bona fide services to Purdue, such as advice, feedback, services or other deliverables.

"Healthcare Professional" (HCP) means a physician, nurse, nurse practitioner, medical student, other professional with prescribing authority, a pharmacist, or any other person, including office staff, with the ability to influence purchasing, prescribing, or reimbursement of pharmaceutical products.

Page 1 of 12

Purdue will not support any program or pay any fee where the purpose is to promote products to the HCPs receiving the fee or is any way tied to or is a reward for prescriptions or recommendations for a product.

Compensation under the agreement must be consistent with fair market value and may not take into account the past, present, or future volume or value of referrals made or other business generated for any Purdue service or product, if any, by the HCP.

It is never appropriate to track "return on investment" or similar measures of a Consultant's use or prescribing of Purdue products after a Consulting engagement.

GC-SOP-0001.04 (PPLP003364388-4454)

Purdue Implemented Policies Strictly Limiting Any Remuneration of HCPs

It is never appropriate to provide a gift, meal, or entertainment in order to encourage a customer [including HCPs] **to prescribe, purchase, or order Purdue products.**

04/11Healthcare Law Compliance Policies (PCA000008931-974)

Gifts may never be provided to customers:

- **For the personal benefit of a customer** (such as floral arrangements, artwork, music CDs, or tickets to a sporting event)
- **As cash or a cash equivalent** (such as a loan, gift certificate, savings bond, or lottery ticket)....

[I]t is not appropriate for Purdue to offer entertainment or recreational activities to a Health Care Professional.

Grants may not be provided: ...

- **to influence or encourage the administration, dispensing, prescribing, purchasing, or recommending of Purdue products** ... [or]
- **to reward a "high volume" prescriber**

Board Advised That Audits Showed Prescribing Was Not Influenced by Consulting Payments to HCPs

4Q13 Compliance Audits

HCP Financial Relationships vs. HCP Prescribing

- To assess whether there is a relationship between HCP prescribing of Purdue product, and any financial compensation received from Purdue (e.g.,consulting services, speaker programs)
- No negative findings – no correlation

Material Review

- To assess the validity of the expired status of materials in the APRIMO system
- Audit still in progress – preliminary results indicate that ~5% of materials are expired, but still in use; this will be reported fully upon completion

PURDUE

U.S. - 117

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

PPLP004410808

Quarterly Compliance Report to the Board of Directors for 4Q2013

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2014

PURDUE

U.S. - 106

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

PPLP004410797

4Q 2013 Quarterly Compliance Report (PPLP004410797, -08)

Board Advised That Audits Showed Prescribing Was Not Influenced by Consulting Payments to HCPs

Compliance Audit

During Q2, an audit was conducted to explore whether HCP prescribing might have been influenced by consulting payments or other value received from Purdue

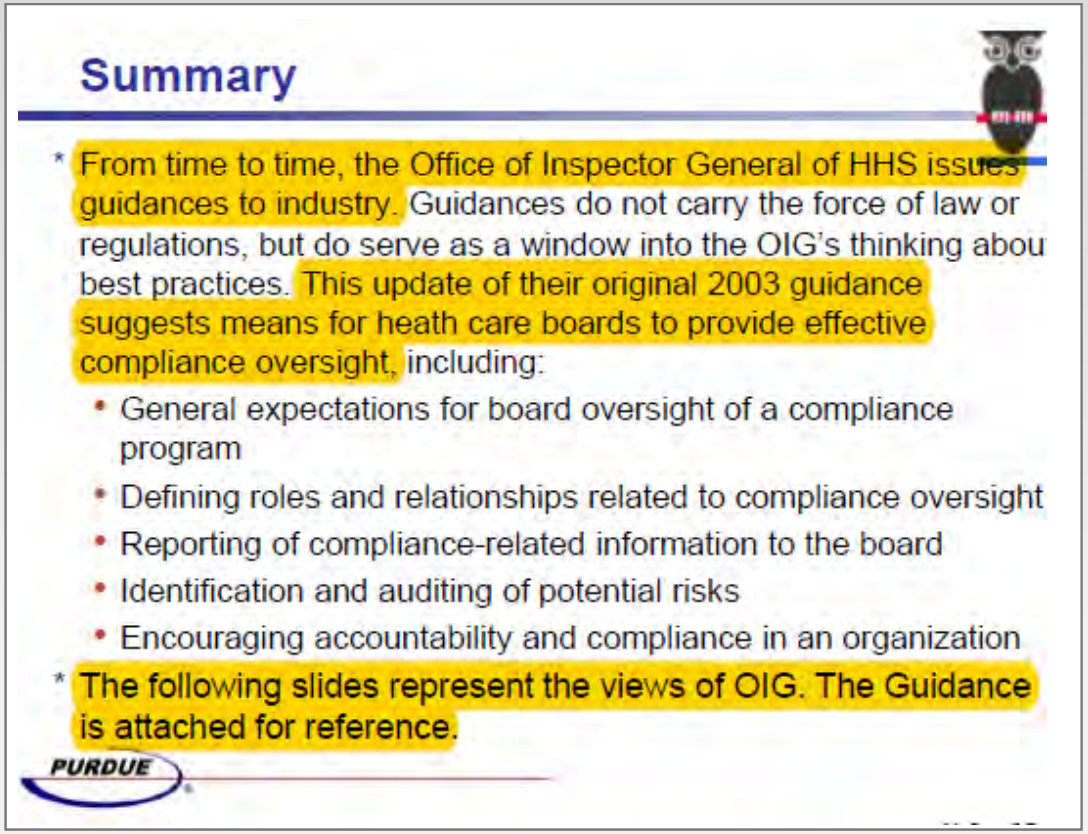
- Reviewed 100 highest *prescribers* of Butrans, 100 highest prescribers of OxyContin, and 100 highest Purdue-*compensated* HCPs in 2014
- Results – *There was no correlation found between Purdue's financial relationships with HCPs and their prescribing of Purdue products*
- For the 10 out of 200 "overlapping" HCPs that were both among the highest prescribers and the highest recipients of Purdue compensation, a deeper review indicated that their prescribing of Purdue products was consistent with their prescribing of other long-acting opioids, eliminating concerns that Purdue compensation improperly affected prescribing

PURDUE

2Q 2015 Quarterly Compliance Report (PPLP004412152, -55)

Board Followed Standards for Pharma Boards Issued by The OIG of HHS

In 2015, the Board Was Informed about Expectations for Board Oversight Issued by the OIG of HHS — And That It Was Satisfying Them



Summary

* From time to time, the Office of Inspector General of HHS issues guidances to industry. Guidances do not carry the force of law or regulations, but do serve as a window into the OIG's thinking abou best practices. This update of their original 2003 guidance suggests means for heath care boards to provide effective compliance oversight, including:
  - General expectations for board oversight of a compliance program
  - Defining roles and relationships related to compliance oversight
  - Reporting of compliance-related information to the board
  - Identification and auditing of potential risks
  - Encouraging accountability and compliance in an organization
* The following slides represent the views of OIG. The Guidance is attached for reference.

PURDUE

Quarterly Compliance Report to Board of Directors for 2Q2015

Bert Weinstein
Vice President, Corporate Compliance
August 20, 2015

PURDUE

2Q 2015 Quarterly Compliance Report (PPLP004412152, -56-63)

In 2015, the Board Was Informed about Expectations for Board Oversight Issued by the OIG of HHS — And That It Was Satisfying Them

Expectations for Board Oversight

Boards should be engaged in oversight of the compliance program

* Boards should ask the right questions of management to determine the effectiveness of the organization's compliance program
* Boards may benchmark company compliance programs against the Federal Sentencing Guidelines, OIG's Compliance Guidance for the Pharmaceutical Industry, and current OIG Corporate Integrity Agreements; ensuring management awareness of these resources is "a good first step"
* Boards may consider plans to stay abreast of the evolving compliance environment, such as updates from staff, to assure adequate resources
* Boards may want to consult with experienced regulatory, compliance or legal professionals

PURDUE

2Q 2015 Quarterly Compliance Report (PPLP004412152, -56-63)

In 2015, the Board Was Informed about Expectations for Board Oversight Issued by the OIG of HHS — And That It Was Satisfying Them

Reporting Information to the Board

The Board should set expectations and receive appropriate and timely information relating to compliance with applicable laws

* Boards should receive regular reports from a variety of key players, including audit, compliance, HR, Law, Quality, and IT functions
* Boards may request information concerning objective scorecards, investigations, audits, hotline activity, allegations of management misconduct, etc.
* Boards should create an expectation of open dialogue with compliance, legal, audit, and quality functions, and may consider "executive sessions" with senior management not present

PURDUE

Quarterly Compliance Report to Board of Directors for 2Q2015

Bert Weinstein
Vice President, Corporate Compliance
August 20, 2015

PURDUE

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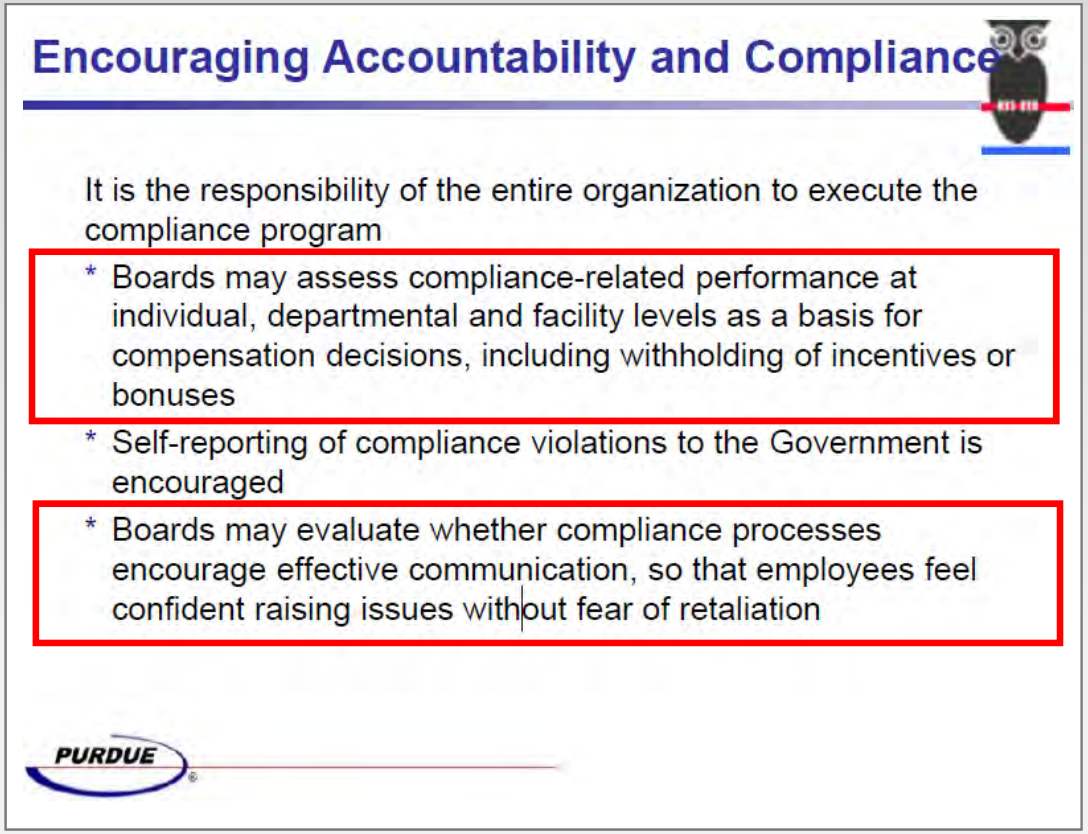

Encouraging Accountability and Compliance

It is the responsibility of the entire organization to execute the compliance program

* Boards may assess compliance-related performance at individual, departmental and facility levels as a basis for compensation decisions, including withholding of incentives or bonuses
* Self-reporting of compliance violations to the Government is encouraged
* Boards may evaluate whether compliance processes encourage effective communication, so that employees feel confident raising issues without fear of retaliation

PURDUE

Quarterly Compliance Report to Board of Directors for 2Q2015

Bert Weinstein
Vice President, Corporate Compliance
August 20, 2015

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2Q 2015 Quarterly Compliance Report (PPLP004412152, -56-63)

In 2015, the Board Was Informed about Expectations for Board Oversight Issued by the OIG of HHS — And That It Was Satisfying Them

Our Views

* Purdue's compliance program is regularly updated to account for regulatory guidance, including the Sentencing Guidelines, OIG's Compliance Guidance, and CIAs. Our quarterly reports speak to the evolving compliance environment, and seek to keep the Board well-informed of the status of compliance at Purdue, including any significant developments.
* We have a robust risk assessment process that is owned by the business units, updated quarterly, and reviewed by Purdue's senior executive-level compliance council to ensure collaboration, and includes robust auditing and monitoring of key compliance risks.
* The Purdue organization is well trained, sensitive to good compliance practices, and comfortable communicating with the Compliance department.
* We believe have no recommendations for altering practices as a result of this Guidance, will keep you informed of any developments, and will welcome any inquiries from you.

PURDUE

2Q 2015 Quarterly Compliance Report (PPLP004412152, -56-63)

The Board Reasonably Understood That Purdue Was Operating in Compliance with Law

- The Board implemented and monitored an extensive compliance program and financially incentivized compliance
- From 2007-2018, management certified to the Board every quarter that Purdue was operating in compliance with law and following OIG guidance for pharma boards
- From 2007-2012, Board received confirmation each year from the OIG of HHS that Purdue was operating in compliance with its CIA
- In 2012, when the OIG monitorship ended, the Board was informed that Purdue hired a major law firm to provide continuing review of the compliance program
- Management reported to the Board that Purdue's compliance program was audited twice by outside counsel and received positive reviews both times

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 1: Overview

April 26, 2021

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 2: Marketing

April 26, 2021

Marketing

Board Members Did Not Personally Participate in Marketing

- Board did not approve the content of any marketing material
- Board relied on approval of all marketing material by (1) Medical, (2) Legal, and (3) Regulatory Affairs
- Board relied on outside counsel's audits and positive endorsement of Purdue's Compliance Program
- Board relied on OIG's and IRO's confirmations of compliance (2007-12)
- Board relied on management's confirmations marketing complied with state and federal laws (2007-18)
- Board relied on monitoring of sales calls by District Managers, Legal and Compliance
- Board Relied on compliance audits of key risk activities

"In performing his duties, a director shall be entitled to rely on information, opinions, reports or statements … prepared or presented by … officers or employees of the corporation … whom the director believes to be reliable and competent in the matters presented …."

N.Y. Bus. Corp. Law §717

Board Knew Purdue Submitted All Marketing Materials to FDA

Code of Federal Regulations

Title 21 - Food and Drugs

Volume: 5
Date: 1997-04-01
Original Date: 1997-04-01

Code of Federal Regulations

Title 21 - Food and Drugs

Context: - . - . SUBCHAPTER D - DRUGS FOR HUMAN USE. PART 314 - APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG. Subpart B - Applications.

(ii) Information concerning any bacteriological contn, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application.

§ 314.81 Other postmarketing reports.

(3) *Other reporting*—(i) *Advertisements and promotional labeling.* The applicant **shall submit** specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product…

(iv) *Chemistry, manufacturing, and controls changes.* (a) Reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product.

(*b*) A full description of the manufacturing and controls changes not requiring a supplemental application under § 314.70 (b) and (c), listed by date in the order in which they were implemented.

(v) *Nonclinical laboratory studies.* Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. The applicant shall submit a copy of a published report if requested by FDA.

(vi) *Clinical data.* (*a*) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(*b*) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

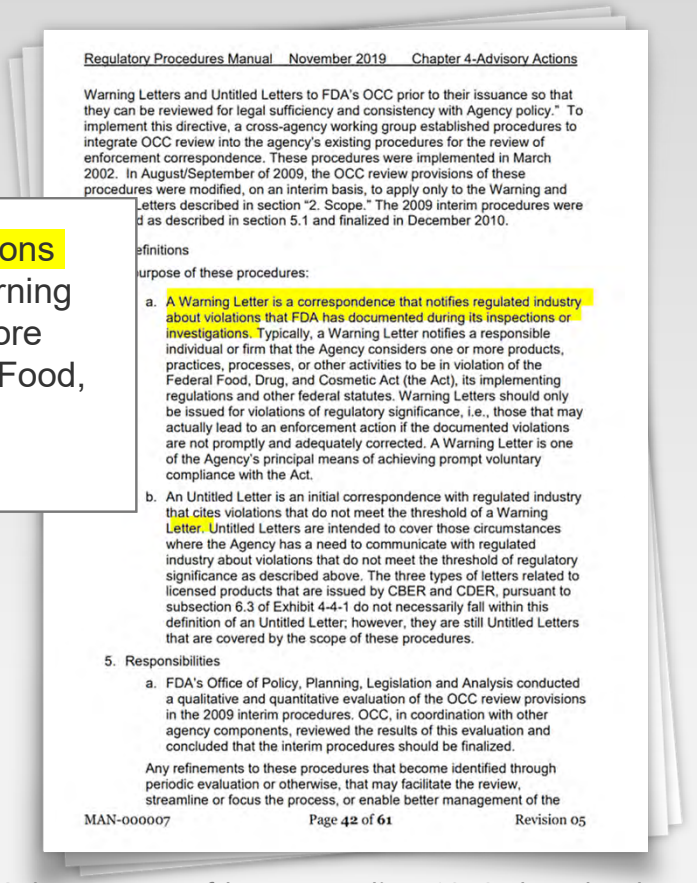
(vii) *Status reports.* A statement on the current status of any postmarketing studies performed by, or on behalf of, the applicant. To facilitate communications between FDA and the applicant, the

https://www.govinfo.gov/content/pkg/CFR-1997-title21-vol5/xml/CFR-1997-title21-vol5-sec314-81.xml

Board Knew FDA Issues Warning Letters for Non-Compliant Marketing Material

FDA U.S. FOOD & DRUG ADMINISTRATION

a. A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. ….



Regulatory Procedures Manual November 2019 Chapter 4-Advisory Actions

Warning Letters and Untitled Letters to FDA's OCC prior to their issuance so that they can be reviewed for legal sufficiency and consistency with Agency policy." To implement this directive, a cross-agency working group established procedures to integrate OCC review into the agency's existing procedures for the review of enforcement correspondence. These procedures were implemented in March 2002. In August/September of 2009, the OCC review provisions of these procedures were modified, on an interim basis, to apply only to the Warning and Letters described in section "2. Scope." The 2009 interim procedures were d as described in section 5.1 and finalized in December 2010.

efinitions

urpose of these procedures:

a. A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.

b. An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter. Untitled Letters are intended to cover those circumstances where the Agency has a need to communicate with regulated industry about violations that do not meet the threshold of regulatory significance as described above. The three types of letters related to licensed products that are issued by CBER and CDER, pursuant to subsection 6.3 of Exhibit 4-4-1 do not necessarily fall within this definition of an Untitled Letter; however, they are still Untitled Letters that are covered by the scope of these procedures.

5. Responsibilities

a. FDA's Office of Policy, Planning, Legislation and Analysis conducted a qualitative and quantitative evaluation of the OCC review provisions in the 2009 interim procedures. OCC, in coordination with other agency components, reviewed the results of this evaluation and concluded that the interim procedures should be finalized.

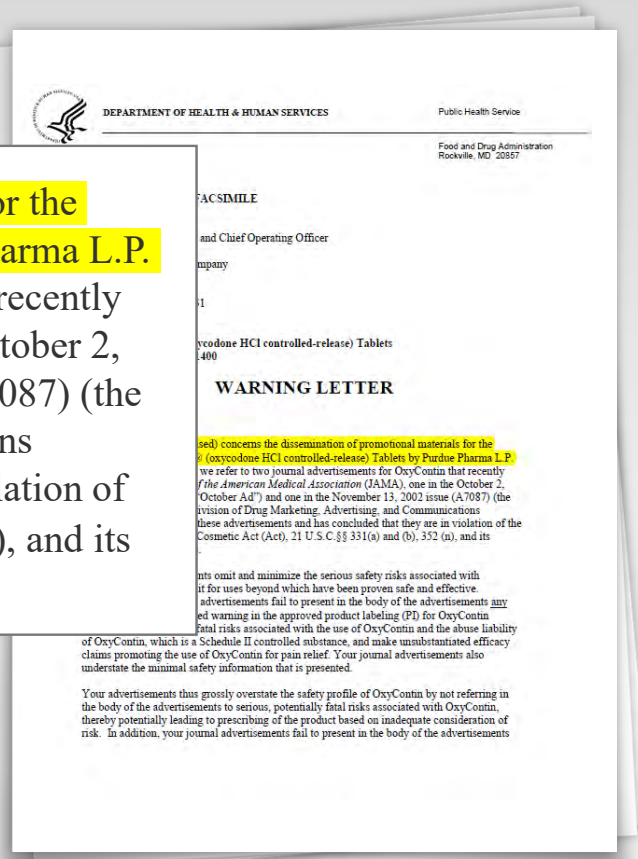
Any refinements to these procedures that become identified through periodic evaluation or otherwise, that may facilitate the review, streamline or focus the process, or enable better management of the

MAN-000007 Page 42 of 61 Revision 05

FDA Regulatory Procedures Manual at 42, https://www.fda.gov/media/71878/download

Board Knew Only 2 Warning Letters Were Sent to Purdue About OxyContin Marketing — And None after 2003

This Warning Letter (revised) concerns the dissemination of promotional materials for the marketing of OxyContin® (oxycodone HCI controlled-release) Tablets by Purdue Pharma L.P. ("Purdue"). Specifically, we refer to two journal advertisements for OxyContin that recently appeared in the *Journal of the American Medical Association* (JAMA), one in the October 2, 2002 issue (A7038) (the "October Ad") and one in the November 13, 2002 issue (A7087) (the "November Ad"). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these advertisements and has concluded that they are in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C.§§ 331(a) and (b), 352 (n), and its implementing regulations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

ACSIMILE

and Chief Operating Officer

mpany

ycodone HCl controlled-release) Tablets
400

WARNING LETTER

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(oxycodone HCl controlled-release) Tablets by Purdue Pharma L.P.
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nts omit and minimize the serious safety risks associated with
it for uses beyond which have been proven safe and effective.
advertisements fail to present in the body of the advertisements any
ed warning in the approved product labeling (PI) for OxyContin
tal risks associated with the use of OxyContin and the abuse liability
of OxyContin, which is a Schedule II controlled substance, and make unsubstantiated efficacy
claims promoting the use of OxyContin for pain relief. Your journal advertisements also
understate the minimal safety information that is presented.

Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in
the body of the advertisements to serious, potentially fatal risks associated with OxyContin,
thereby potentially leading to prescribing of the product based on inadequate consideration of
risk. In addition, your journal advertisements fail to present in the body of the advertisements

2003 FDA Warning Letter, *available at* http://wayback.archive-it.org/7993/20170112065652/http:/www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168946.pdf

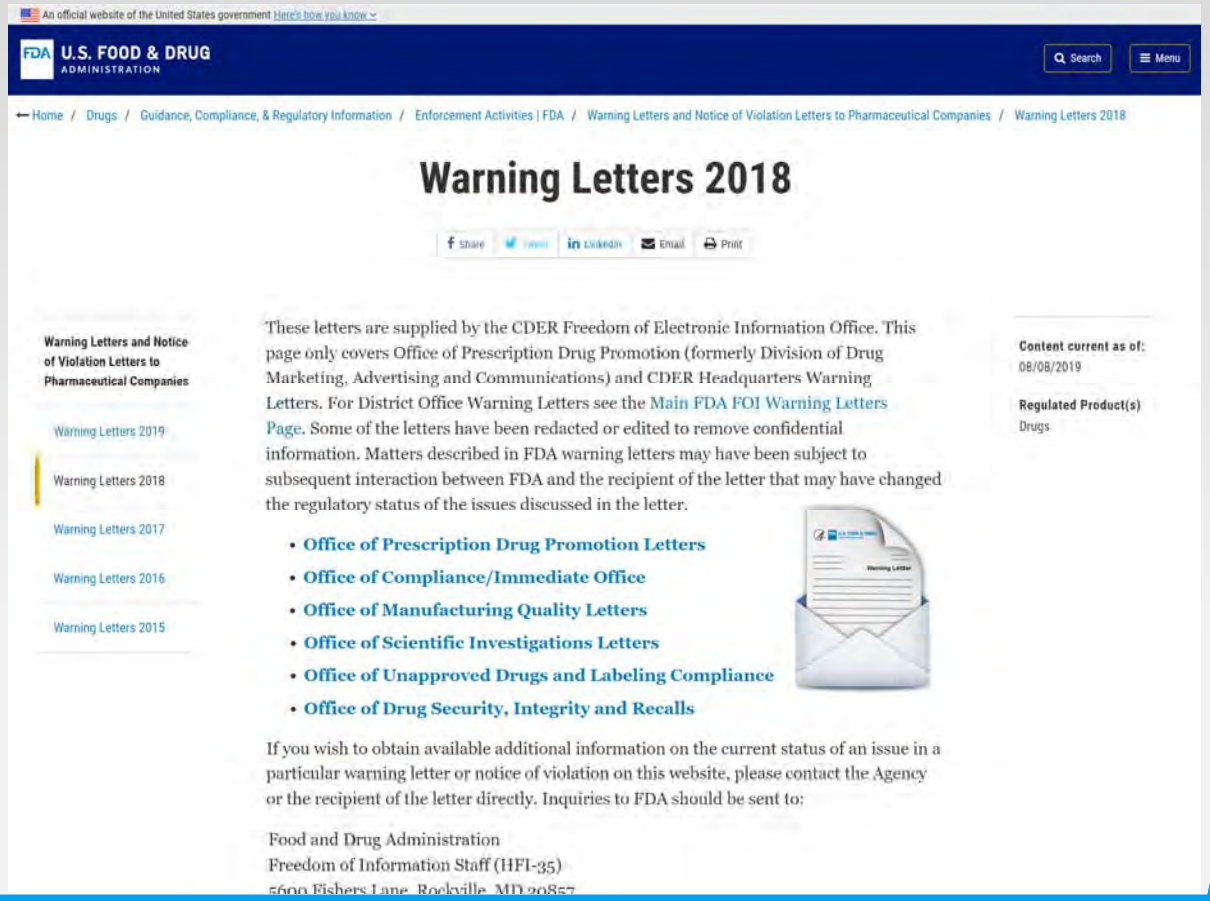
Since 2003, The FDA Has Issued over 1000 Warning Letters to Others

More in Warning Letters and Notice of Violation Letters to Pharmaceutical Companies

- Warning Letters 2016
- Warning Letters 2015
- Warning Letters 2014
- Warning Letters 2013
- Warning Letters 2012
- Warning Letters 2011
- Warning Letters 2010
- Warning Letters 2009
- Warning Letters 2008
- Warning Letters 2007
- Warning Letters 2006
- Warning Letters 2005
- Warning Letters 2004
- Warning Letters 2003
- Warning Letters 2002

wayback.archive-it.org/7993/20170110233145/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/warning-letters-2018



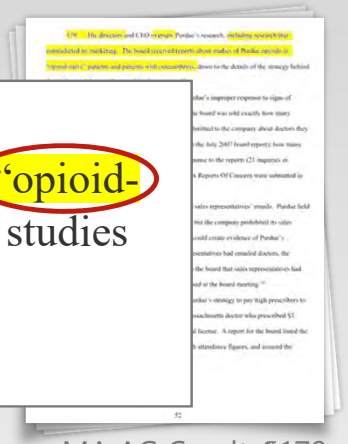
Allegations Are Unsupported by Cited Documents

Allegation: Board Received Research Contradicting Marketing Material

Massachusetts AG OC ¶179:

179. **The directors and CEO oversaw Purdue's research, including research that contradicted its marketing**. The board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.[12]

[12] July 2007.

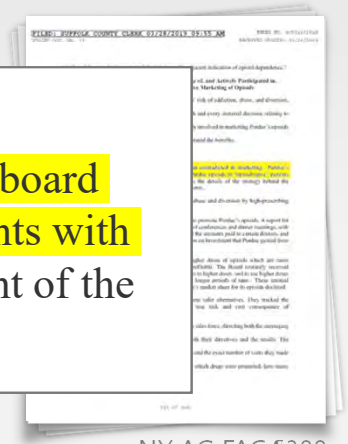


MA AG Cmplt. ¶179

New York AG FAC ¶388:

388. **For example, the Sacklers oversaw…**

- **Purdue's research, including research that contradicted its marketing**. Purdue's board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.



NY AG FAC ¶388

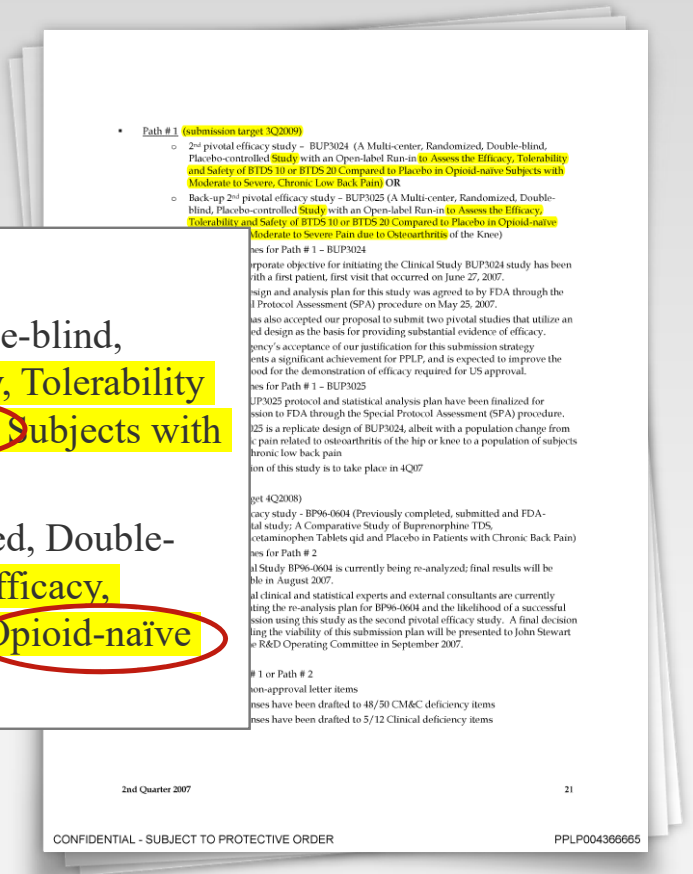
Cited Research Did Not Contradict Purdue's Marketing — It Assessed The Safety of An Unlaunched New Product (Butrans)

July 2007 Board Report:

Norspan – US Submission

Path #1 (submission target 3Q2009)

- 2nd pivotal efficacy study – BUP3024 (A Multi-center, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naïve Subjects with Moderate to Severe, Chronic Low Back Pain) **OR**
- Back-up 2nd pivotal efficacy study – BUP3025 (A Multi-center, Randomized, Double-blind, placebo-controlled Study with an Open-label Run-in to Assess the Efficacy, Tolerability and Safety of BTDS 10 or BTDS 20 Compared to Placebo in Opioid-naïve Subjects with Moderate Severe Pain due to Osteoarthritis of the Knee)



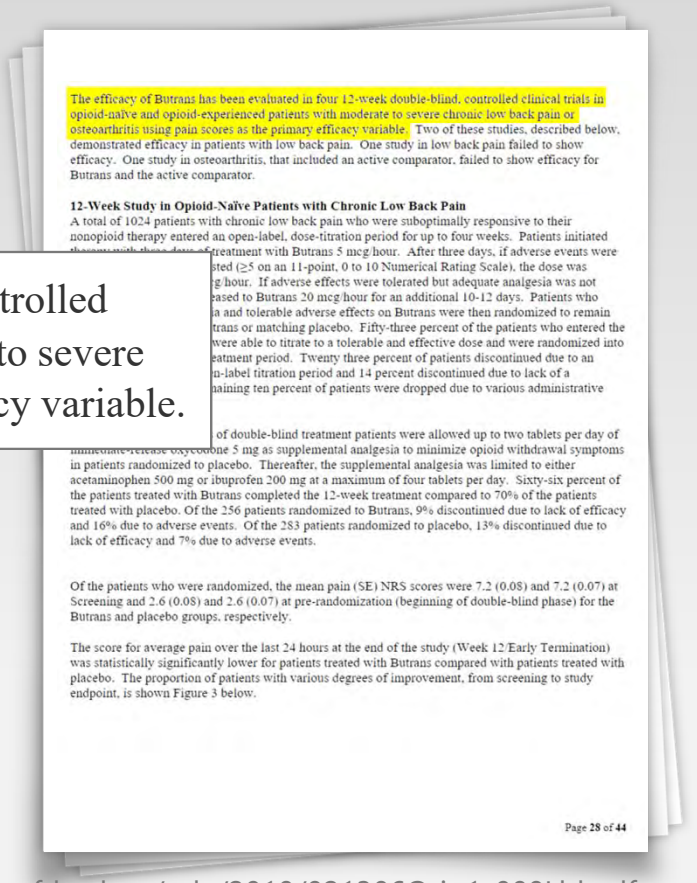
July 2007 Board Report, p. 21 (PPLP004366645)

The Research Was Used on The FDA-Approved Label When Butrans Was Launched

2010 Butrans Label:

The efficacy of Butrans has been evaluated in four 12-week double-blind, controlled clinical trials in ***opioid-naïve*** and opioid-experienced patients with moderate to severe chronic low back pain or osteoarthritis using pain scores as the primary efficacy variable.

The Office of Inspector General <u>confirmed compliance</u> for this period



The efficacy of Butrans has been evaluated in four 12-week double-blind, controlled clinical trials in opioid-naïve and opioid-experienced patients with moderate to severe chronic low back pain or osteoarthritis using pain scores as the primary efficacy variable. Two of these studies, described below, demonstrated efficacy in patients with low back pain. One study in low back pain failed to show efficacy. One study in osteoarthritis, that included an active comparator, failed to show efficacy for Butrans and the active comparator.

12-Week Study in Opioid-Naïve Patients with Chronic Low Back Pain

A total of 1024 patients with chronic low back pain who were suboptimally responsive to their nonopioid therapy entered an open-label, dose-titration period for up to four weeks. Patients initiated treatment with Butrans 5 mcg/hour. After three days, if adverse events were sted (≥5 on an 11-point, 0 to 10 Numerical Rating Scale), the dose was g/hour. If adverse effects were tolerated but adequate analgesia was not eased to Butrans 20 mcg/hour for an additional 10-12 days. Patients who a and tolerable adverse effects on Butrans were then randomized to remain trans or matching placebo. Fifty-three percent of the patients who entered the were able to titrate to a tolerable and effective dose and were randomized into eatment period. Twenty three percent of patients discontinued due to an n-label titration period and 14 percent discontinued due to lack of a haining ten percent of patients were dropped due to various administrative

of double-blind treatment patients were allowed up to two tablets per day of ne 5 mg as supplemental analgesia to minimize opioid withdrawal symptoms in patients randomized to placebo. Thereafter, the supplemental analgesia was limited to either acetaminophen 500 mg or ibuprofen 200 mg at a maximum of four tablets per day. Sixty-six percent of the patients treated with Butrans completed the 12-week treatment compared to 70% of the patients treated with placebo. Of the 256 patients randomized to Butrans, 9% discontinued due to lack of efficacy and 16% due to adverse events. Of the 283 patients randomized to placebo, 13% discontinued due to lack of efficacy and 7% due to adverse events.

Of the patients who were randomized, the mean pain (SE) NRS scores were 7.2 (0.08) and 7.2 (0.07) at Screening and 2.6 (0.08) and 2.6 (0.07) at pre-randomization (beginning of double-blind phase) for the Butrans and placebo groups, respectively.

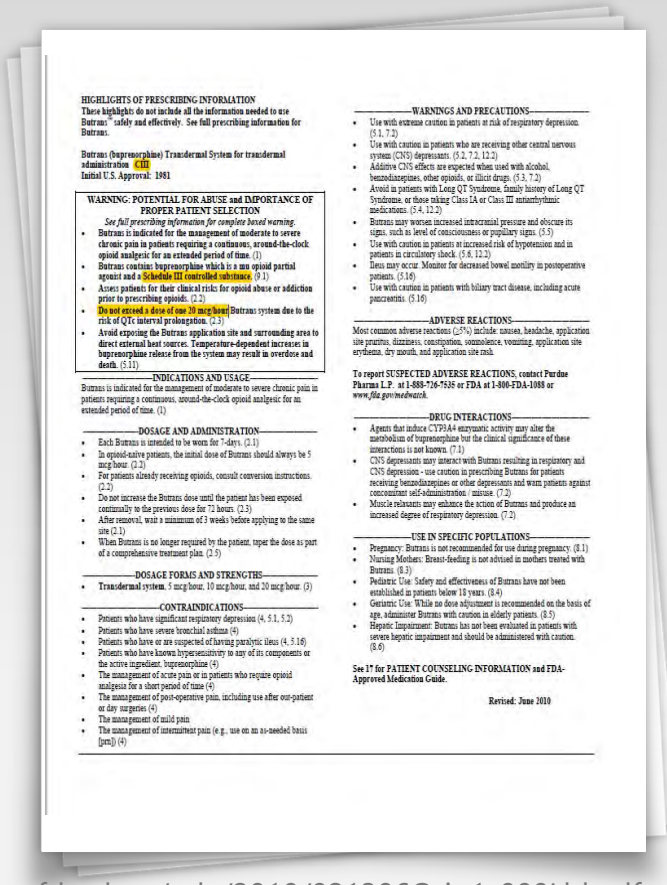
The score for average pain over the last 24 hours at the end of the study (Week 12/Early Termination) was statistically significantly lower for patients treated with Butrans compared with patients treated with placebo. The proportion of patients with various degrees of improvement, from screening to study endpoint, is shown Figure 3 below.

Page 28 of 44

2010 Butrans Label, p. 28, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021306Orig1s000Lbl.pdf

Claimants Rely Heavily on Butrans Allegations, But Butrans Does Not Support Their Claims

- Claimants' theory is that Purdue aggressively promoted higher and higher doses of opioids
- That cannot be done with Butrans
- Butrans is not oxycodone — it is buprenorphine
- Butrans is a transdermal patch, not a pill
- It has a ceiling effect
- There is a maximum dose, and it is far lower than high doses of OxyContin
- It is a Schedule III drug (like testosterone) — not a Schedule II drug (like OxyContin)
- Schedule III drugs are less addictive than Schedule II



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Butrans™ safely and effectively. See full prescribing information for Butrans.

Butrans (buprenorphine) Transdermal System for transdermal administration CIII

Initial U.S. Approval: 1981

WARNING: POTENTIAL FOR ABUSE and IMPORTANCE OF PROPER PATIENT SELECTION

See full prescribing information for complete boxed warning.

- Butrans is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)
- Butrans contains buprenorphine which is a mu opioid partial agonist and a Schedule III controlled substance. (9.1)
- Assess patients for their clinical risks for opioid abuse or addiction prior to prescribing opioids. (2.2)
- Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation. (2.3)
- Avoid exposing the Butrans application site and surrounding area to direct external heat sources. Temperature-dependent increases in buprenorphine release from the system may result in overdose and death. (5.11)

INDICATIONS AND USAGE

Butrans is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)

DOSAGE AND ADMINISTRATION

- Each Butrans is intended to be worn for 7-days. (2.1)
- In opioid-naïve patients, the initial dose of Butrans should always be 5 mcg/hour. (2.2)
- For patients already receiving opioids, consult conversion instructions. (2.2)
- Do not increase the Butrans dose until the patient has been exposed continually to the previous dose for 72 hours. (2.3)
- After removal, wait a minimum of 3 weeks before applying to the same site (2.1)
- When Butrans is no longer required by the patient, taper the dose as part of a comprehensive treatment plan. (2.5)

DOSAGE FORMS AND STRENGTHS

- Transdermal system. 5 mcg/hour, 10 mcg/hour, and 20 mcg/hour. (3)

CONTRAINDICATIONS

- Patients who have significant respiratory depression (4, 5.1, 5.2)
- Patients who have severe bronchial asthma (4)
- Patients who have or are suspected of having paralytic ileus (4, 5.16)
- Patients who have known hypersensitivity to any of its components or the active ingredient, buprenorphine (4)
- The management of acute pain or in patients who require opioid analgesia for a short period of time (4)
- The management of post-operative pain, including use after out-patient or day surgeries (4)
- The management of mild pain
- The management of intermittent pain (e.g., use on an as-needed basis [prn]) (4)

WARNINGS AND PRECAUTIONS

- Use with extreme caution in patients at risk of respiratory depression. (5.1, 7.2)
- Use with caution in patients who are receiving other central nervous system (CNS) depressants. (5.2, 7.2, 12.2)
- Additive CNS effects are expected when used with alcohol, benzodiazepines, other opioids, or illicit drugs. (5.3, 7.2)
- Avoid in patients with Long QT Syndrome, family history of Long QT Syndrome, or those taking Class IA or Class III antiarrhythmic medications. (5.4, 12.2)
- Butrans may worsen increased intracranial pressure and obscure its signs, such as level of consciousness or pupillary signs. (5.5)
- Use with caution in patients at increased risk of hypotension and in patients in circulatory shock. (5.6, 12.2)
- Ileus may occur. Monitor for decreased bowel motility in postoperative patients. (5.16)
- Use with caution in patients with biliary tract disease, including acute pancreatitis. (5.16)

ADVERSE REACTIONS

Most common adverse reactions (≥5%) include: nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth, and application site rash.

To report SUSPECTED ADVERSE REACTIONS, contact Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

- Agents that induce CYP3A4 enzymatic activity may alter the metabolism of buprenorphine but the clinical significance of these interactions is not known. (7.1)
- CNS depressants may interact with Butrans resulting in respiratory and CNS depression - use caution in prescribing Butrans for patients receiving benzodiazepines or other depressants and warn patients against concomitant self-administration / misuse. (7.2)
- Muscle relaxants may enhance the action of Butrans and produce an increased degree of respiratory depression. (7.2)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Butrans is not recommended for use during pregnancy. (8.1)
- Nursing Mothers: Breast-feeding is not advised in mothers treated with Butrans. (8.3)
- Pediatric Use: Safety and effectiveness of Butrans have not been established in patients below 18 years. (8.4)
- Geriatric Use: While no dose adjustment is recommended on the basis of age, administer Butrans with caution in elderly patients. (8.5)
- Hepatic Impairment: Butrans has not been evaluated in patients with severe hepatic impairment and should be administered with caution. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and FDA-Approved Medication Guide.

Revised: June 2010

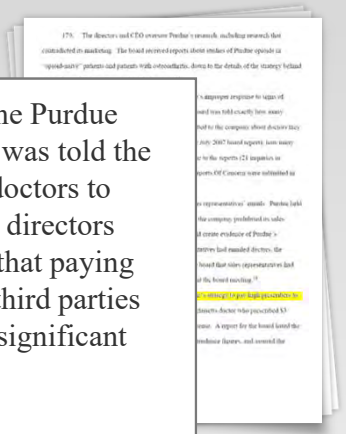
2010 Butrans Label, p. 1, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021306Orig1s000Lbl.pdf

Allegation: Directors Oversaw Payments To High Prescribers

Massachusetts AG OC ¶182:

182. **The directors … oversaw Purdue's strategy to pay high prescribers to promote Purdue's opioids** … A report for the Purdue board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors…[15] The board was told the amounts paid to certain doctors …, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs. The board was told that Purdue would allow a 'spending limit for gifts' of $750 per doctor per year;[16] and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs.[17] The board was told explicitly that paying doctors to promote opioids was 'a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities.'[18] When Congress required disclosure of drug company payments to doctors, the board was told there were "significant compliance implications" for Purdue.[19]

[15] November 2011.
[16] July 2007.
[17] July 2013.
[18] August 2011, November 2011.
[19] April 2010.

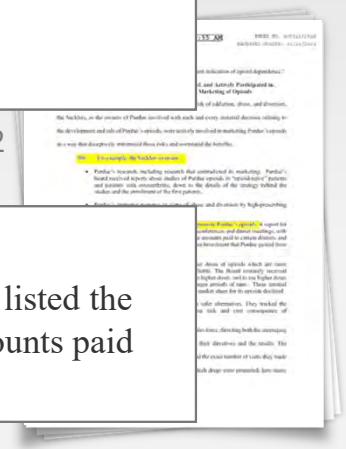


MA AG OC ¶182

New York AG FAC ¶388:

388. For example, **the Sacklers oversaw…**

- **Purdue's strategy to pay high prescribers to promote Purdue's opioids**. A report for the Purdue board listed the exact number of conferences and dinner meetings, with attendance figures and the board was told the amounts paid to certain doctors….



NY AG FAC ¶388

Cited Reports Say Nothing About a Strategy to "Pay High Prescribers"

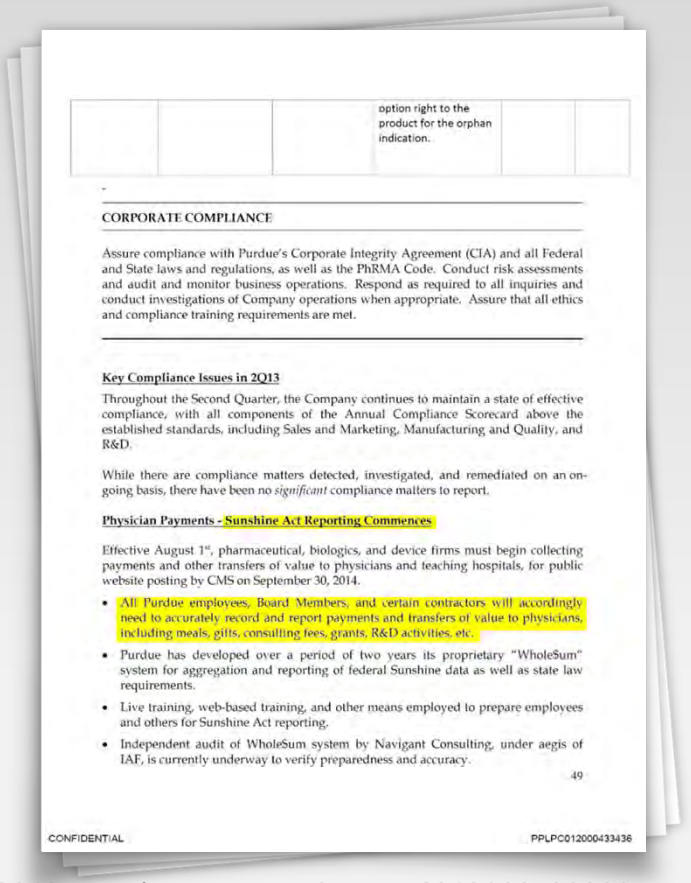
- The reports informed Board of new reporting requirements and spending limits

Physician Payments - Sunshine Act Reporting Commences

Effective August 1st, pharmaceutical, biologics, and device firms must begin collecting payments and other transfers of value to physicians and teaching hospitals, for public website posting by CMS on September 30, 2014.

- All Purdue employees, Board Members, and certain contractors will accordingly need to accurately record and report payments and transfers of value to physicians, including meals, gifts, consulting fees, grants, R&D activities, etc.

- They advised the Board that all payments were in compliance with law



option right to the product for the orphan indication.

CORPORATE COMPLIANCE

Assure compliance with Purdue's Corporate Integrity Agreement (CIA) and all Federal and State laws and regulations, as well as the PhRMA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

Key Compliance Issues in 2Q13

Throughout the Second Quarter, the Company continues to maintain a state of effective compliance, with all components of the Annual Compliance Scorecard above the established standards, including Sales and Marketing, Manufacturing and Quality, and R&D.

While there are compliance matters detected, investigated, and remediated on an on-going basis, there have been no *significant* compliance matters to report.

Physician Payments - Sunshine Act Reporting Commences

Effective August 1st, pharmaceutical, biologics, and device firms must begin collecting payments and other transfers of value to physicians and teaching hospitals, for public website posting by CMS on September 30, 2014.

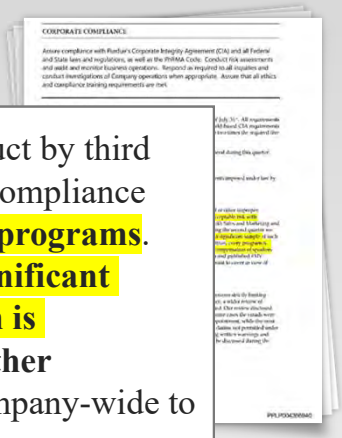
- All Purdue employees, Board Members, and certain contractors will accordingly need to accurately record and report payments and transfers of value to physicians, including meals, gifts, consulting fees, grants, R&D activities, etc.
- Purdue has developed over a period of two years its proprietary "WholeSum" system for aggregation and reporting of federal Sunshine data as well as state law requirements.
- Live training, web-based training, and other means employed to prepare employees and others for Sunshine Act reporting.
- Independent audit of WholeSum system by Navigant Consulting, under aegis of IAF, is currently underway to verify preparedness and accuracy.

49

CONFIDENTIAL PPLPC012000433436

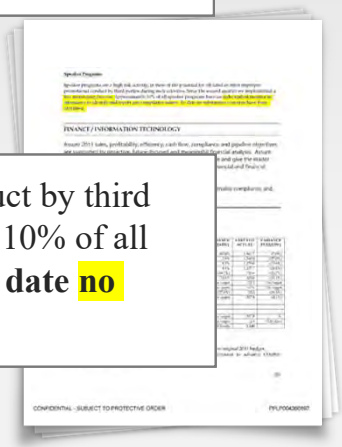
July 2013 Board Report, p. 49 (PPLPC012000433388)

Cited Reports Informed Board Speaker Programs Had Appropriate Controls And Were Monitored For Compliance



Speaker programs are a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities, but **they are an acceptable risk with appropriate safeguards in place**. Corporate Compliance has worked closely with Sales and Marketing and others to implement **appropriate controls for Butrans speaker programs**. During the second quarter we implemented **a live monitoring process**, so that **independent monitors attend a significant sample of such programs nation-wide** to evaluate and report to us on these programs. In addition, **every program is monitored by Purdue attendees**. An **expert consultant on Fair Market Value compensation of speakers and other Healthcare professionals has completed analysis** of Purdue's HCPs and published FMV criteria to be applied company-wide to all such arrangements, an important point to cover in view of Government requirements for such arrangements.

August 2011 Board Report, p. 28
(PPLP004366913)



Speaker programs are a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities. Since the second quarter we implemented a **live monitoring process**. Approximately 10% of all speaker programs have an **independent monitor in attendance to identify and report any compliance issues. To date no substantive concerns have been identified.**

November 2011 Board Report, p. 26
(PPLP004366871)

Allegation: Board Informed Of Strategy To Push Higher Doses, Reverse Public Health Initiatives

Massachusetts AG OC ¶183:

183. **The directors … oversaw Purdue's strategy to push patients to higher doses of opioids** —which are more dangerous, more addictive, and more profitable. The board routinely received reports on Purdue's efforts to push patients to higher doses. A report alerted the board that "Net sales of the 40 and 80 mg strengths of OxyContin had fallen below Purdue's targets in the fall of 2010 and were $85 million below budget.[20] … The board dug into the issue. **Multiple reports to the board identified as a 'threat' an initiative by public health authorities** to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day.[23] **The CEO and directors oversaw Purdue's effort to push back against that public health "threat."**[24] Executives were pleased to report to the directors in 2013 that "initiatives to validate increased total daily doses are having impact in the field."[25]

[20] January 2011.
[21] August 2011.
[22] November 2011.
[23] April 2010, July 2010, October 2010, November 2011.
[24] April 2010, July 2010, October 2010, November 2011.
[25] May 2013 email for board meeting in June 2013

MA AG OC ¶183

New York AG FAC ¶388:

388. For example, **the Sacklers oversaw…**

- **Purdue's strategy to push patients to higher doses of opioids** which are more dangerous, more addictive, and more profitable ….

NY AG FAC ¶388

Cited Reports Informed Board Only Of Declining Sales — Not A Strategy To Push Higher Doses

Net sales of the 40 and 80 mg strengths of OxyContin ended 2010 $85 mm less than budget. Sales of these strengths were over budget through the end of October, but sales in November and December were substantially less than budget.

January 2011 Board Report, p. 2 (PPLP004366955)

2Q 2011 year to date net sales of $1,174.1 mm were lower than budget by $416.5 mm or 26 %. This variance was driven by: (i) OxyContin gross sales of $1,399.4 mm that were $517 mm or 27% below budget mainly due to declining sales in the 40 mg and 80 mg strengths.

August 2011 Board Report, p. 3 (PPLP004366913)

3Q 2011 year to date actual net sales of $2,213.7 mm were lower than budget by $848. 9 mm or 28 %. This variance was driven by: (i) OxyContin gross sales of $2,077.6 mm that were $813.4 mm or 28 % below budget mainly due to declining sales in the 40 mg and 80 mg strengths.

November 2011 Board Report, p. 2 (PPLP004366871)

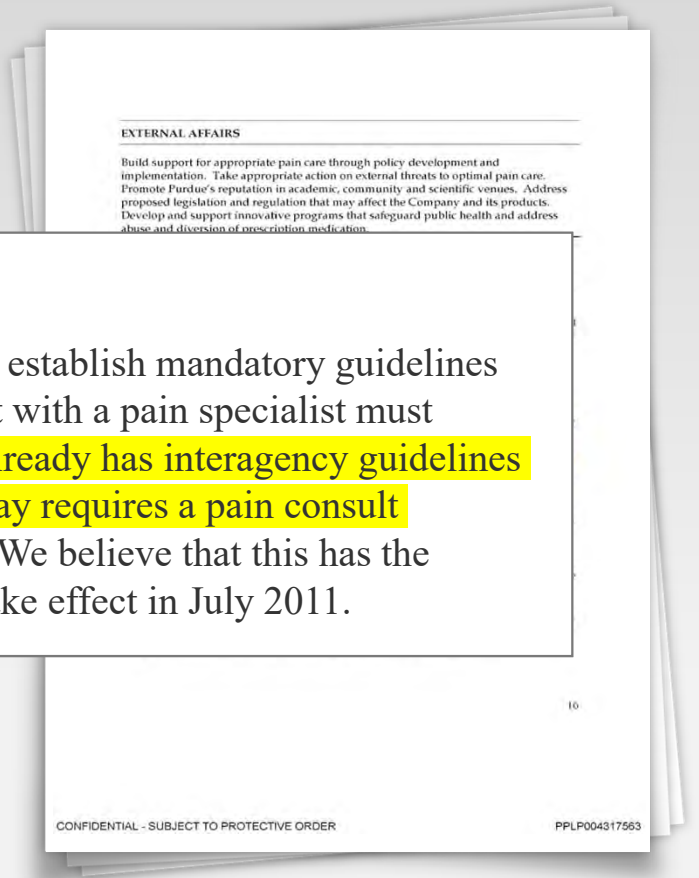
- **OIG <u>confirmed compliance</u> for this period (2010-2011)**

Cited Reports Informed The Board Of A Legislative Threat To Optimal Pain Care

April 2010 Board Report:

Take appropriate action on external threats to optimal pain care.

- Important state activity in Washington where legislation was passed that would establish mandatory guidelines for the treatment of pain and sets a prescribing threshold above which a consult with a pain specialist must occur in order to continue treatment. This action is concerning since the state already has interagency guidelines for State Medical Directors (AMDG) where above 80 total mg of oxycodone/day requires a pain consult however there are only 15 pain management consultants identified by AMDG. We believe that this has the potential to be a model that will be pushed out to other states. The guidelines take effect in July 2011.


EXTERNAL AFFAIRS

Build support for appropriate pain care through policy development and implementation. Take appropriate action on external threats to optimal pain care. Promote Purdue's reputation in academic, community and scientific venues. Address proposed legislation and regulation that may affect the Company and its products. Develop and support innovative programs that safeguard public health and address abuse and diversion of prescription medication.

16

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004317563

April 2010 Board Report, p. 16 (PPLP004317547)

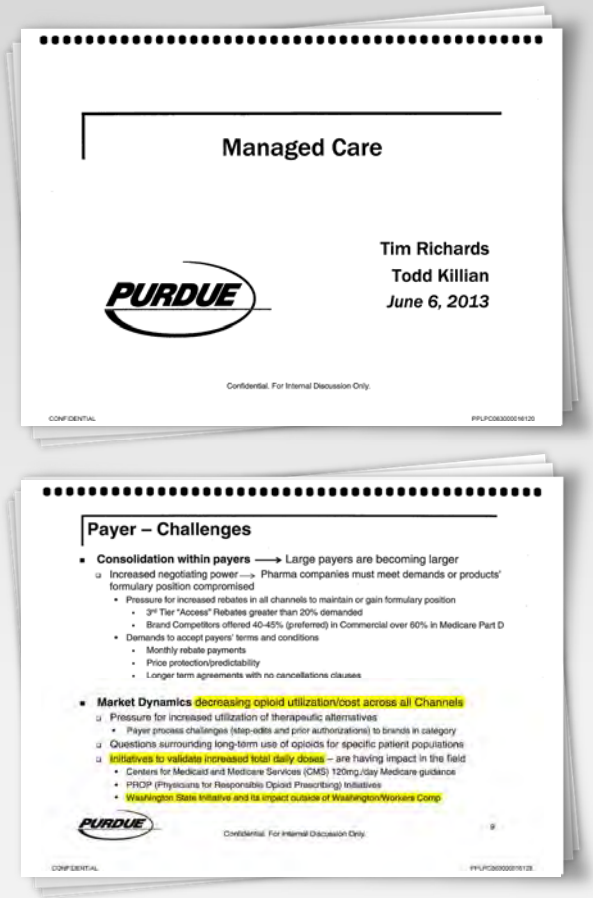
Cited Reports Informed The Board That Legislation Required Validation of Higher Daily Doses — Not Purdue Initiatives To Increase Doses

Board was told market dynamics were driving sales down

- **Market Dynamics** decreasing opioid utilization/cost across all Channels
  - Pressure for increased utilization of therapeutic alternatives
    - Payer process challenges (step-edits and prior authorizations) to brands in category.

Washington legislation requiring consultation with pain expert for prescriptions above a certain dose was part of this:

- Initiatives to validate increased total daily doses – are having impact in the field
  - Centers for Medicaid and Medicare Services (CMS) 120mg./day Medicare guidance
  - PROP (Physicians for Responsible Opioid Prescribing) Initiatives
  - Washington State Initiative and its impact outside of Washington/Workers Comp



June 2013 Managed Care Board Slides, p. 9 (PPLPC063000016119)

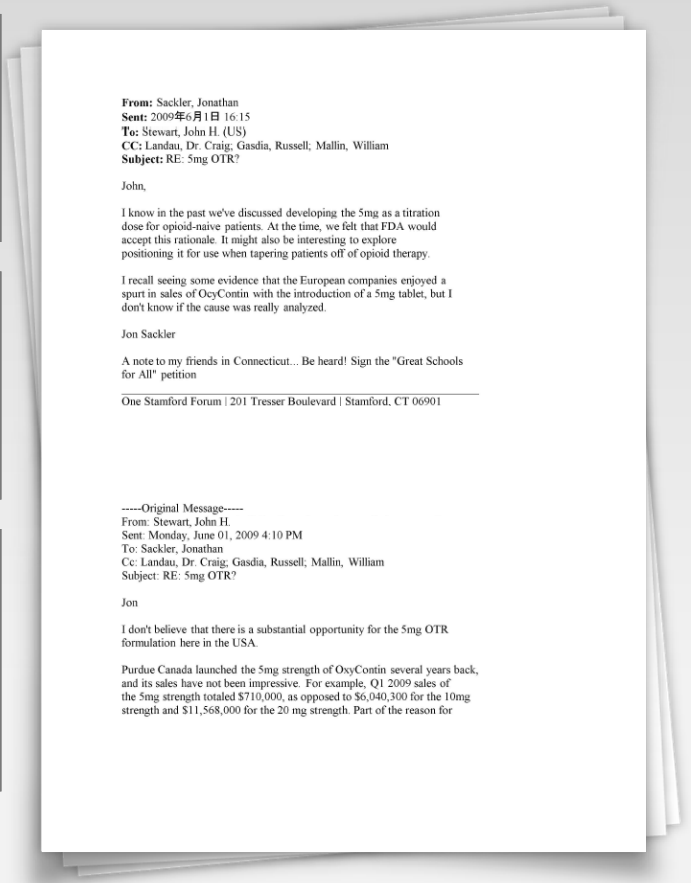
Rather Than Promoting Higher Doses, Jonathan Sackler Proposed A Lower-Dose Tablet — Management Said Prescribers Were Not Interested

From: Sackler, Jonathan
Sent: Thursday, May 28, 2009 5:47 PM
To: Stewart, John H. (US)
Subject: RE: 5mg OTR?
What do you think?

From: Stewart, John H. (US)
Sent: Monday, June 01, 2009 4:10 PM
To: Sackler, Jonathan
Cc: Landau, Dr. Craig; Gasdia, Russell; Mallin, William
Subject: RE: 5mg OTR?

I don't believe there is a substantial opportunity for the 5 mg OTR formulation here in the USA. . . .

Part of the reason for the low sales is that the 5mg strength never received listing on the provincial drug benefit formularies, but that is because they wanted it priced lower than 50% of the price of the 10mg strength. However, the general response to the strength from prescribers as to the therapeutic importance of a lower strength was also not particularly strong.



From: Sackler, Jonathan
Sent: 2009年6月1日 16:15
To: Stewart, John H. (US)
CC: Landau, Dr. Craig; Gasdia, Russell; Mallin, William
Subject: RE: 5mg OTR?

John,

I know in the past we've discussed developing the 5mg as a titration dose for opioid-naive patients. At the time, we felt that FDA would accept this rationale. It might also be interesting to explore positioning it for use when tapering patients off of opioid therapy.

I recall seeing some evidence that the European companies enjoyed a spurt in sales of OcyContin with the introduction of a 5mg tablet, but I don't know if the cause was really analyzed.

Jon Sackler

A note to my friends in Connecticut... Be heard! Sign the "Great Schools for All" petition

One Stamford Forum | 201 Tresser Boulevard | Stamford, CT 06901

-----Original Message-----
From: Stewart, John H.
Sent: Monday, June 01, 2009 4:10 PM
To: Sackler, Jonathan
Cc: Landau, Dr. Craig; Gasdia, Russell; Mallin, William
Subject: RE: 5mg OTR?

Jon

I don't believe that there is a substantial opportunity for the 5mg OTR formulation here in the USA.

Purdue Canada launched the 5mg strength of OxyContin several years back, and its sales have not been impressive. For example, Q1 2009 sales of the 5mg strength totaled $710,000, as opposed to $6,040,300 for the 10mg strength and $11,568,000 for the 20 mg strength. Part of the reason for

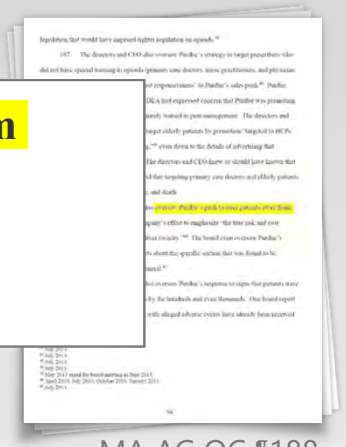
5/28/09 - 6/1/09 Email Chain (PPLPC012000225228)

Allegation: Board Oversaw Push Away From Safer Alternatives

Massachusetts AG OC ¶188:

188. **The directors and CEO also oversaw Purdue's push to steer patients away from safer alternatives**. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity."[43]

[43] May 2013 email for board meeting in June 2013.

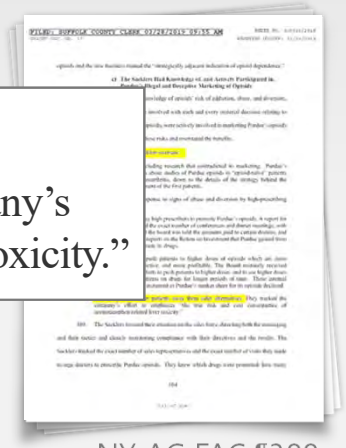


MA AG OC ¶188

New York AG FAC ¶388:

388. For example, **the Sacklers oversaw…**

- **Purdue's push to steer patients away from safer alternatives**. They tracked the company's efforts to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity."

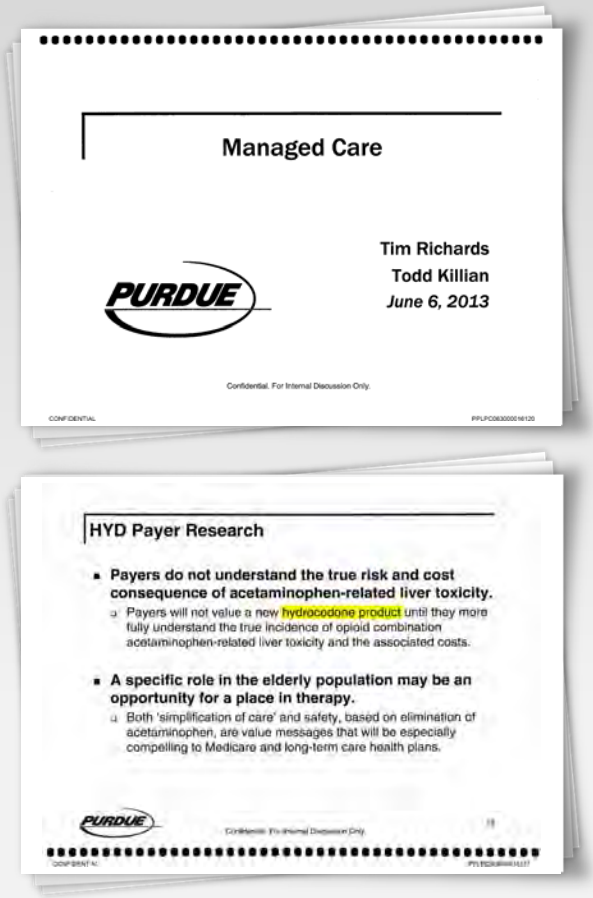


NY AG FAC ¶388

No "Push Away From Safer Alternatives"

- Cited report compared two opioids
- It explained why some insurers would not cover the unlaunched one, Hysingla
- Nothing to do with marketing

- **Payers do not understand the true risk and cost consequence of acetaminophen-related liver toxicity.**
  - Payers will not value a new hydrocodone product until they more fully understand the true incidence of opioid combination acetaminophen-related liver toxicity and the associated costs.



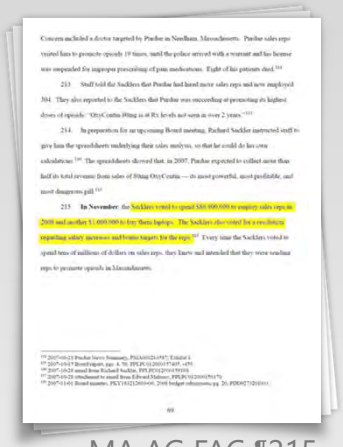
June 2013 Managed Care Board Slides, p. 18 (PPLPC063000016119)

Allegation: Board Decisions To Compensate, Hire & Equip Sales Reps With Laptops

Massachusetts AG FAC ¶215:

215. **In November**, the Sacklers voted to spend $86,900,000 to employ sales reps in 2008 and another $1,000,000 to buy them laptops. The Sacklers also voted for a resolution regarding salary increases and bonus targets for the reps.[118] Every time the Sacklers voted to spend tens of millions of dollars on sales reps, they knew and intended that they were sending reps to promote opioids in Massachusetts.

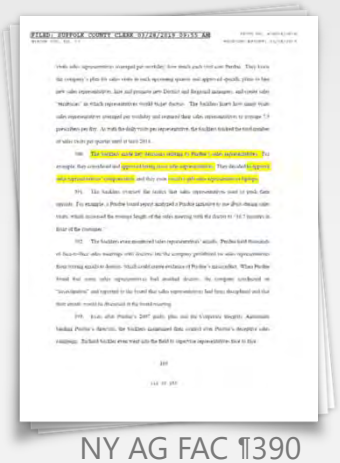
[118] 2007-11-01 Board minutes, PKY183212603-06; 2008 budget submission, pg. 20, PDD9273201033.



MA AG FAC ¶215

New York AG FAC ¶390:

390. The Sacklers made key decisions relating to Purdue's sales representatives. For example, they considered and approved hiring more sales representatives. They decided to approve sales representatives' compensation, and they even voted to gift sales representatives laptops.



NY AG FAC ¶390

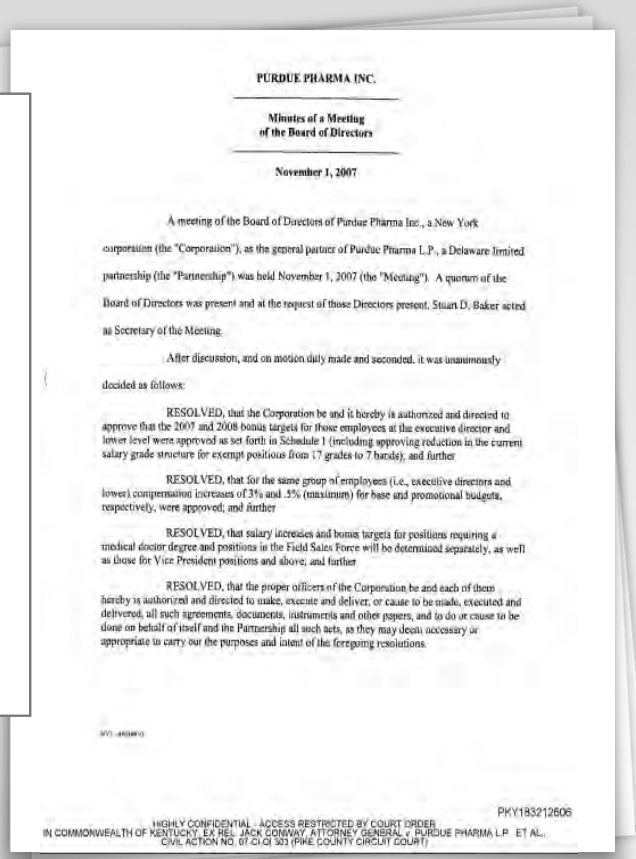
Cited Board Minutes Did Not Address Compensation For Sales Reps, Said Nothing About "Gifting" Laptops

November 1, 2007 Board Minutes:

RESOLVED, that the Corporation be and it hereby is authorized and directed to approve that the 2007 and 2008 bonus targets for those employees at the executive director and lower level were approved as set forth in Schedule 1 (including approving reduction in the current salary grade structure for exempt positions from 17 grades to 7 bands); and further

RESOLVED, that for the same group of employees (i.e., executive directors and lower) compensation increases of 3% and .5% (maximum) for base and promotional budgets, respectively, were approved; and further

RESOLVED, that salary increases and bonus targets for positions requiring a medical doctor degree and positions in the Field Sales Force will be determined separately, as well as those for Vice President positions and above . . . .



PURDUE PHARMA INC.

Minutes of a Meeting of the Board of Directors

November 1, 2007

A meeting of the Board of Directors of Purdue Pharma Inc., a New York corporation (the "Corporation"), as the general partner of Purdue Pharma L.P., a Delaware limited partnership (the "Partnership") was held November 1, 2007 (the "Meeting"). A quorum of the Board of Directors was present and at the request of those Directors present, Stuart D. Baker acted as Secretary of the Meeting.

After discussion, and on motion duly made and seconded, it was unanimously decided as follows:

RESOLVED, that the Corporation be and it hereby is authorized and directed to approve that the 2007 and 2008 bonus targets for those employees at the executive director and lower level were approved as set forth in Schedule 1 (including approving reduction in the current salary grade structure for exempt positions from 17 grades to 7 bands); and further

RESOLVED, that for the same group of employees (i.e., executive directors and lower) compensation increases of 3% and .5% (maximum) for base and promotional budgets, respectively, were approved; and further

RESOLVED, that salary increases and bonus targets for positions requiring a medical doctor degree and positions in the Field Sales Force will be determined separately, as well as those for Vice President positions and above; and further

RESOLVED, that the proper officers of the Corporation be and each of them hereby is authorized and directed to make, execute and deliver, or cause to be made, executed and delivered, all such agreements, documents, instruments and other papers, and to do or cause to be done on behalf of itself and the Partnership all such acts, as they may deem necessary or appropriate to carry out the purposes and intent of the foregoing resolutions.

PKY183212606

HIGHLY CONFIDENTIAL - ACCESS RESTRICTED BY COURT ORDER
IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P. ET AL.,
CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

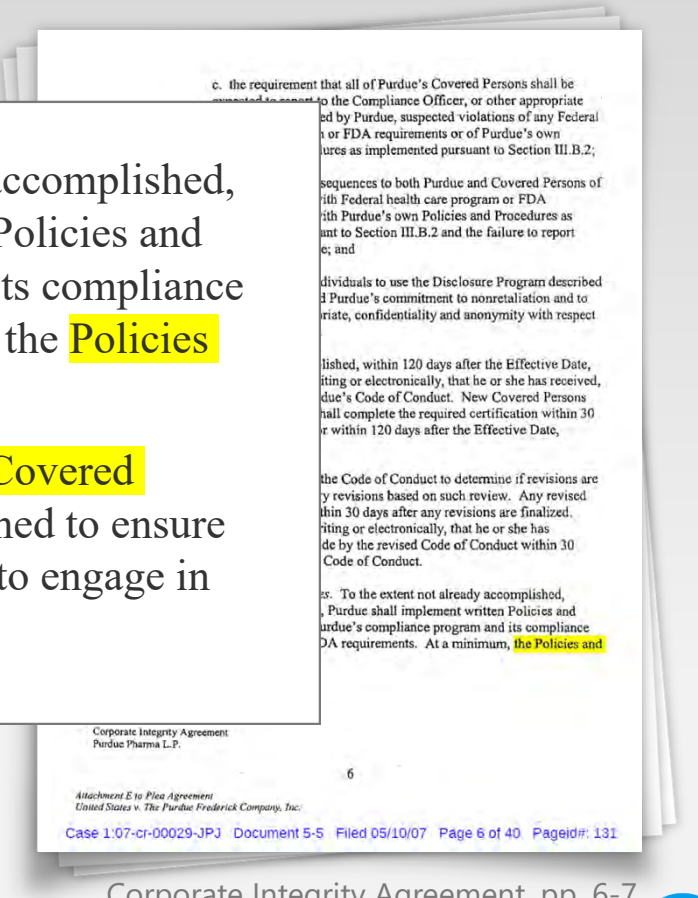
11/1/07 Board Minutes (PKY183212603 at -606)

The CIA Governed Decisions About Compensation For Sales Reps

Corporate Integrity Agreement:

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Purdue shall implement written Policies and Procedures regarding the operation of Purdue's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

d. Compensation (including salaries and bonuses) for Relevant Covered Persons engaged in promoting and selling Purdue products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products;


c. the requirement that all of Purdue's Covered Persons shall be
to the Compliance Officer, or other appropriate
ed by Purdue, suspected violations of any Federal
or FDA requirements or of Purdue's own
ures as implemented pursuant to Section III.B.2;
sequences to both Purdue and Covered Persons of
ith Federal health care program or FDA
ith Purdue's own Policies and Procedures as
nt to Section III.B.2 and the failure to report
e; and
dividuals to use the Disclosure Program described
Purdue's commitment to nonretaliation and to
riate, confidentiality and anonymity with respect
lished, within 120 days after the Effective Date,
iting or electronically, that he or she has received,
due's Code of Conduct. New Covered Persons
hall complete the required certification within 30
r within 120 days after the Effective Date,
the Code of Conduct to determine if revisions are
y revisions based on such review. Any revised
hin 30 days after any revisions are finalized.
iting or electronically, that he or she has
de by the revised Code of Conduct within 30
Code of Conduct.
s. To the extent not already accomplished,
, Purdue shall implement written Policies and
rdue's compliance program and its compliance
DA requirements. At a minimum, the Policies and
Corporate Integrity Agreement
Purdue Pharma L.P.
6
Attachment E to Plea Agreement
United States v. The Purdue Frederick Company, Inc.
Case 1:07-cr-00029-JPJ Document 5-5 Filed 05/10/07 Page 6 of 40 Pageid#: 131

- **OIG <u>confirmed compliance</u> for this period**

Corporate Integrity Agreement, pp. 6-7

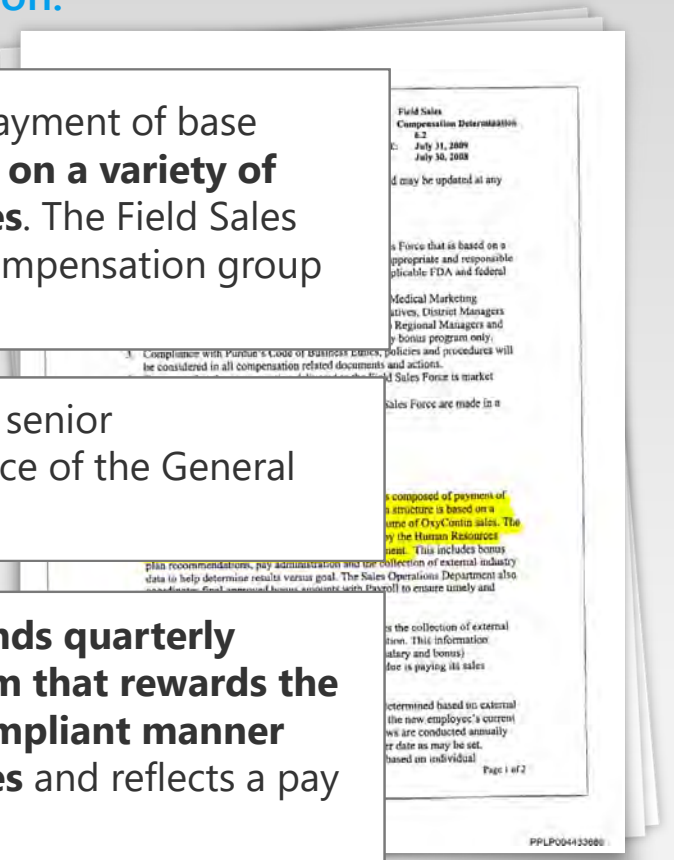
The CIA Governed Decisions About Compensation For Sales Reps

HR Standard Business Practices Field Sales Compensation Determination:

1.1 The compensation system for the Field Sales Force is composed of payment of base salary and a quarterly bonus. **The compensation structure is based on a variety of factors and is not based exclusively on volume of OxyContin sales**. The Field Sales Force compensation system is managed by the Human Resources Compensation group with input from Sales Management.

1.4 There is a Field Force Bonus Review Committee comprised of Purdue senior management from: Sales, Marketing, Finance, Human Resources, Office of the General Counsel and Sales Operations.

1.6 **The Field Force Bonus Review Committee reviews and recommends quarterly bonus plan proposals in an effort to provide for a bonus program that rewards the Field Sales Force's efforts to promote Company products in a compliant manner within applicable FDA and federal health care program guidelines** and reflects a pay philosophy that is market competitive.



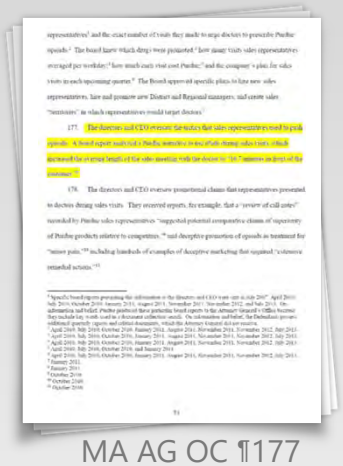
2009 HR SOP (PPLP004433671)

Allegation: Board Oversaw Sales Force Tactics, Including iPad Use, In Meetings With Prescribers

Massachusetts AG OC ¶177:

177. **The directors and CEO oversaw the tactics that sales representatives used to push opioids**. A board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer."[8]

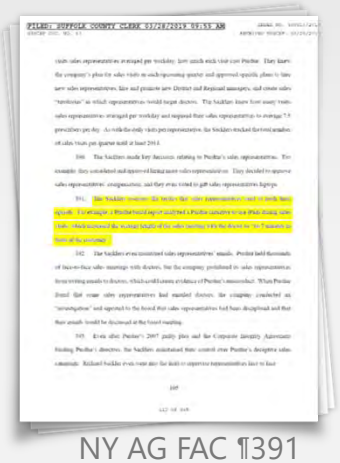
[8] **January 2011.**



MA AG OC ¶177

New York AG FAC ¶391:

391. **The Sacklers oversaw the tactics that sales representatives used to push their opioids**. For example, a Purdue board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer."



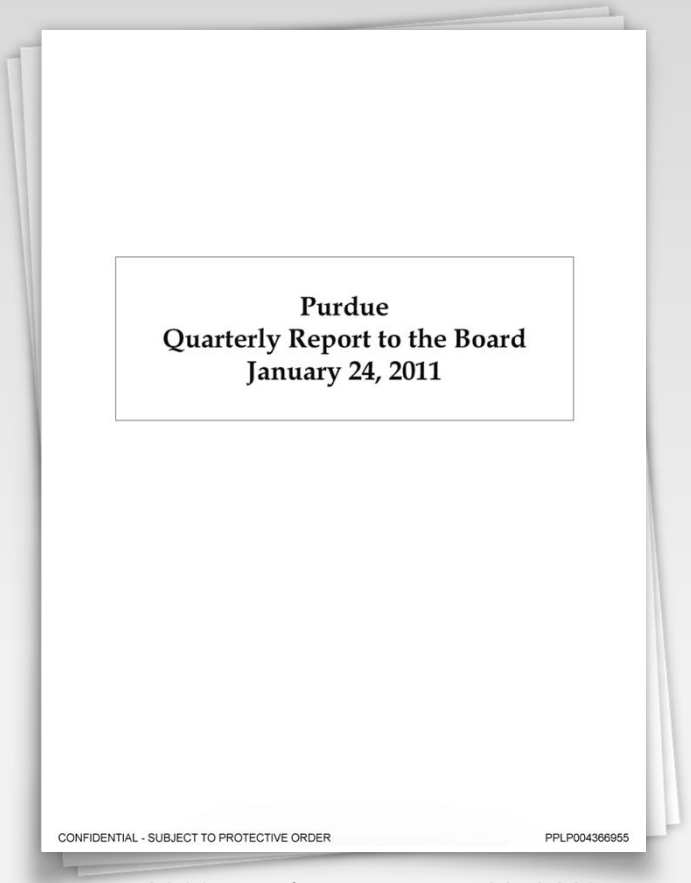
NY AG FAC ¶391

Cited Report Does Not Show Board Oversight Of Sales Force Or Sales Tactics

The January 2011 Report to the Board:

- Seeks no Board input on the marketing initiatives
- Informs directors about existing marketing initiatives
- Makes no reference to iPads
- Does not describe the substance of any marketing presentation

- OIG confirmed compliance for 2011



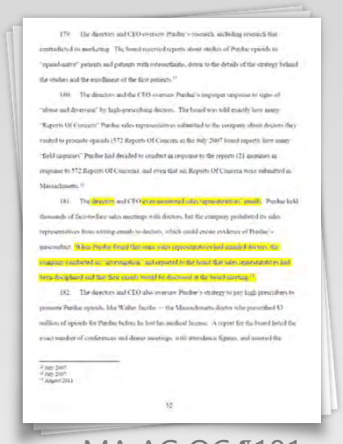
January 2011 Board Report (PPLP004366955)

Allegation: Board Monitored Sales Reps' Emails

Massachusetts AG OC ¶181:

181. **The directors … even monitored sales representatives' emails**. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting."[14]

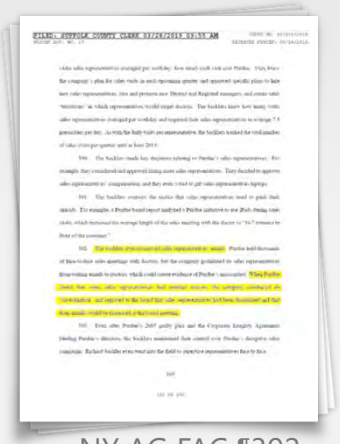
[14] August 2011.



MA AG OC ¶181

New York AG FAC ¶392:

392. **The Sacklers even monitored sales representatives' emails**. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting."



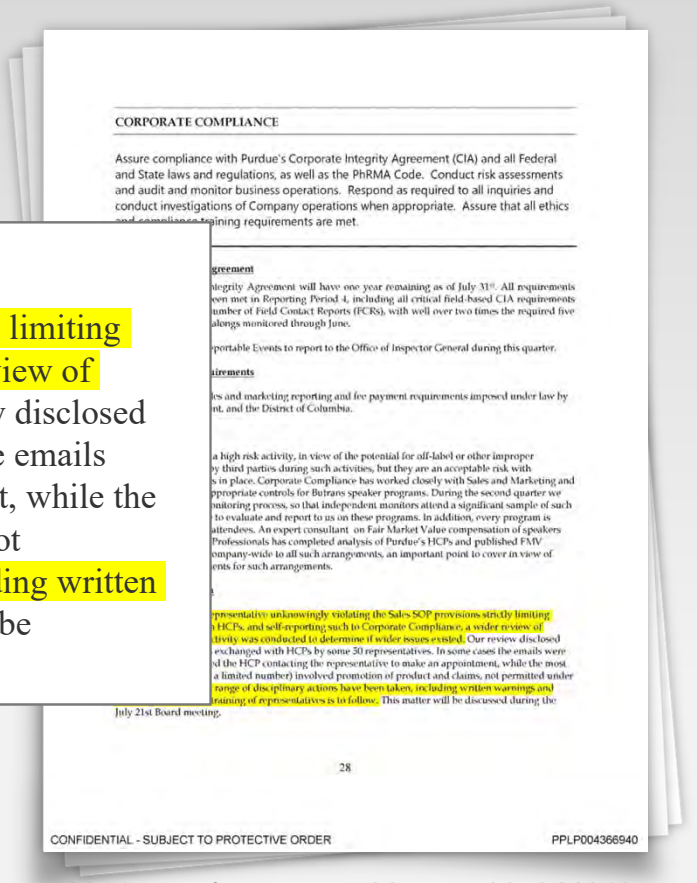
NY AG FAC ¶392

Management Monitored Emails To Prevent And Remediate Marketing Violations

August 2011 Board Report:

"Email" Investigation

As a result of a sales representative unknowingly violating the Sales SOP provisions strictly limiting emails exchanged with HCPs, and self-reporting such to Corporate Compliance, a wider review of representative email activity was conducted to determine if wider issues existed. Our review disclosed the existence of emails exchanged with HCPs by some 50 representatives. In some cases the emails were innocuous and involved the HCP contacting the representative to make an appointment, while the most problematic (and only a limited number) involved promotion of product and claims, not permitted under Purdue's Sales SOP. A range of disciplinary actions have been taken, including written warnings and coaching, and further training of representatives is to follow. This matter will be discussed during the July 21st Board meeting.



CORPORATE COMPLIANCE

Assure compliance with Purdue's Corporate Integrity Agreement (CIA) and all Federal and State laws and regulations, as well as the PhRMA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

greement

ntegrity Agreement will have one year remaining as of July 31st. All requirements een met in Reporting Period 4, including all critical field-based CIA requirements umber of Field Contact Reports (FCRs), with well over two times the required five alongs monitored through June.

portable Events to report to the Office of Inspector General during this quarter.

irements

les and marketing reporting and fee payment requirements imposed under law by nt, and the District of Columbia.

a high risk activity, in view of the potential for off-label or other improper y third parties during such activities, but they are an acceptable risk with s in place. Corporate Compliance has worked closely with Sales and Marketing and ppropriate controls for Butrans speaker programs. During the second quarter we nitoring process, so that independent monitors attend a significant sample of such to evaluate and report to us on these programs. In addition, every program is attendees. An expert consultant on Fair Market Value compensation of speakers Professionals has completed analysis of Purdue's HCPs and published FMV ompany-wide to all such arrangements, an important point to cover in view of ents for such arrangements.

presentative unknowingly violating the Sales SOP provisions strictly limiting HCPs, and self-reporting such to Corporate Compliance, a wider review of tivity was conducted to determine if wider issues existed. Our review disclosed exchanged with HCPs by some 50 representatives. In some cases the emails were d the HCP contacting the representative to make an appointment, while the most a limited number) involved promotion of product and claims, not permitted under range of disciplinary actions have been taken, including written warnings and raining of representatives is to follow. This matter will be discussed during the July 21st Board meeting.

28

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004366940

August 2011 Board Report, p. 28 (PPLP004366913)

Board Knew That Management Monitored Emails To Prevent And Remediate Marketing Violations

How Does the Sales Monitoring "System" Work in Practice?

An Example…

PURDUE 22

CONFIDENTIAL PPLPC012000335554

Emails to Customers

- A newer sales representative was speaking with a more tenured representative and indicated that she had sent emails to some of her customers.
- Tenured representative reminded new representative that this is a violation of Sales SOP:

Correspondence with HCPs

Sales Representatives generally are not permitted to draft and/or send correspondence to any Health Care Professional (HCP) that has not previously gone through the internal Material Review Process and received written approval for distribution, except as provided below.

Individualized email communications may be drafted and sent solely for purposes of arranging and/or confirming an office visit. In such cases, the Representative is required to copy his/her District Manager on such correspondence and must avoid any mention of product, product attributes, competitor products, disease states, and/or specific patients. Model language for such emails is provided in the "Email Communications by Representatives" document on the Phoenix homepage in the Desktop Library.

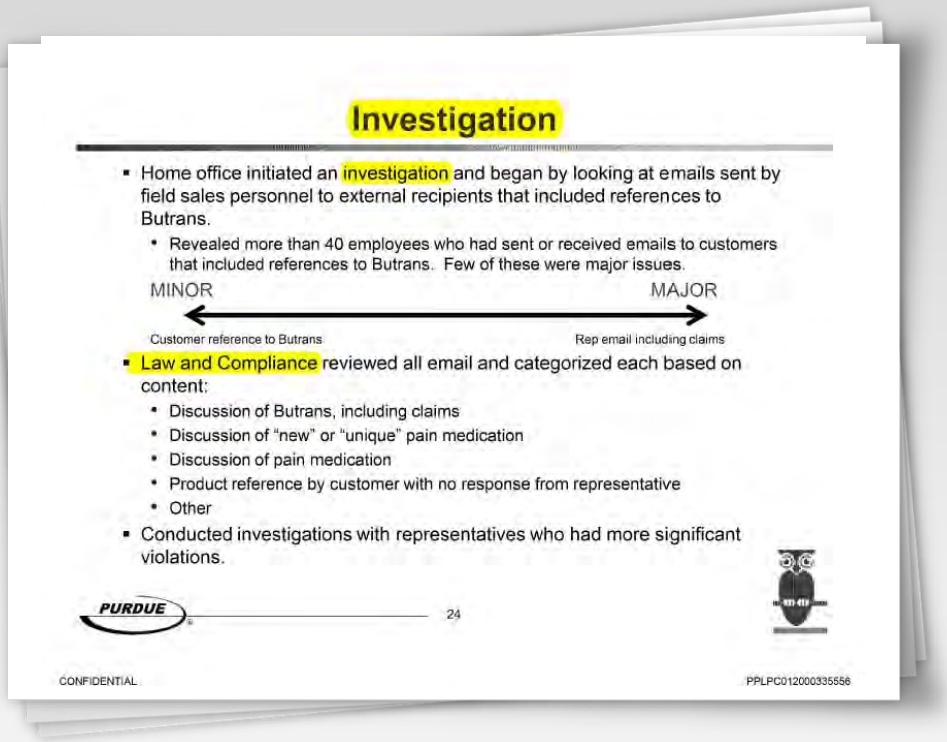
- New representative self-reported the violation to her Manager.
- Manager alerted home office, which kicked off an investigation.

PURDUE 23

CONFIDENTIAL PPLPC012000335555

Quarterly Compliance Report 2Q 2011, pp. 22-23 (PPLPC012000335414)

Board Knew That Management Monitored Emails To Prevent And Remediate Marketing Violations



Investigation

- Home office initiated an investigation and began by looking at emails sent by field sales personnel to external recipients that included references to Butrans.
  - Revealed more than 40 employees who had sent or received emails to customers that included references to Butrans. Few of these were major issues.

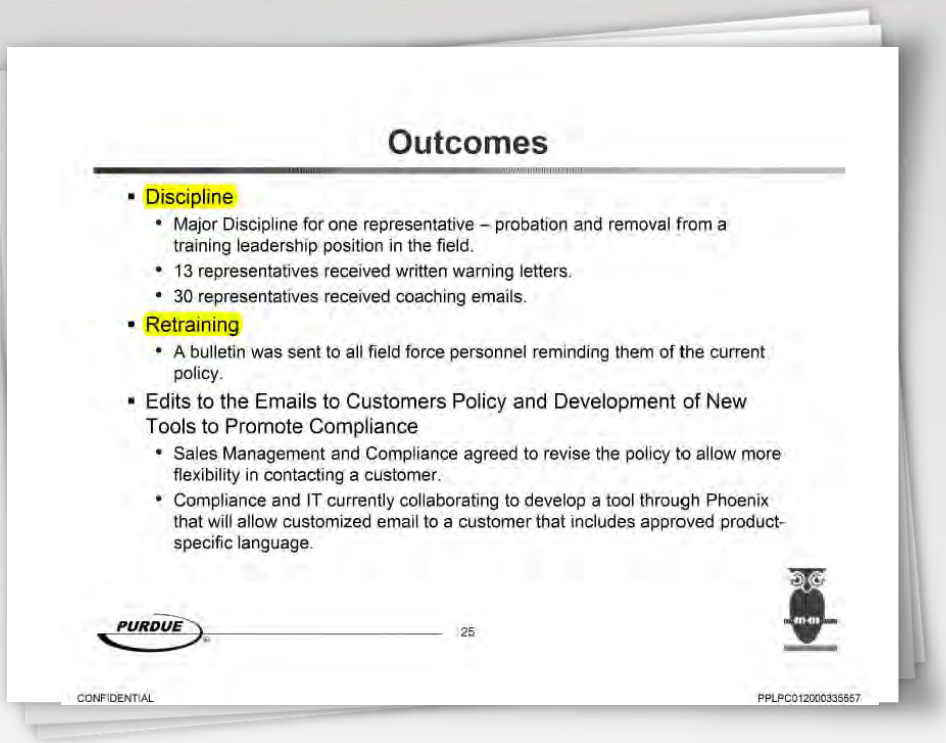
MINOR ⟷ MAJOR

Customer reference to Butrans — Rep email including claims

- Law and Compliance reviewed all email and categorized each based on content:
  - Discussion of Butrans, including claims
  - Discussion of "new" or "unique" pain medication
  - Discussion of pain medication
  - Product reference by customer with no response from representative
  - Other
- Conducted investigations with representatives who had more significant violations.

PURDUE 24

CONFIDENTIAL PPLPC012000335556



Outcomes

- Discipline
  - Major Discipline for one representative – probation and removal from a training leadership position in the field.
  - 13 representatives received written warning letters.
  - 30 representatives received coaching emails.
- Retraining
  - A bulletin was sent to all field force personnel reminding them of the current policy.
- Edits to the Emails to Customers Policy and Development of New Tools to Promote Compliance
  - Sales Management and Compliance agreed to revise the policy to allow more flexibility in contacting a customer.
  - Compliance and IT currently collaborating to develop a tool through Phoenix that will allow customized email to a customer that includes approved product-specific language.

PURDUE 25

CONFIDENTIAL PPLPC012000335557

- **OIG confirmed compliance for 2011**

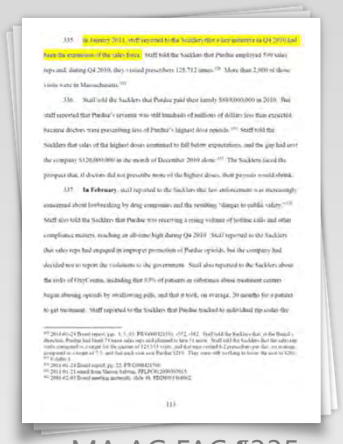
Quarterly Compliance Report 2Q 2011, p. 24-25 (PPLPC012000335414)

Allegation: Board Approved Expansion Of Sales Force

Massachusetts AG FAC ¶335:

335. In January 2011, staff reported to the Sacklers that a key initiative in Q4 2010 had been the expansion of the sales force. Staff told the Sacklers that Purdue employed 590 sales reps and, during Q42010, they visited prescribers 12,715 times.[328]

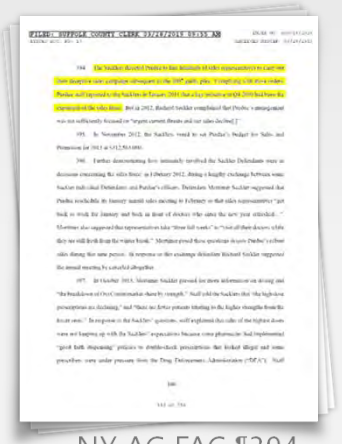
[328] 2011-01-24 Board report, pgs. 4, 5, 35, PWG000421551, -552, -582.



MA AG FAC ¶335

New York AG FAC ¶394:

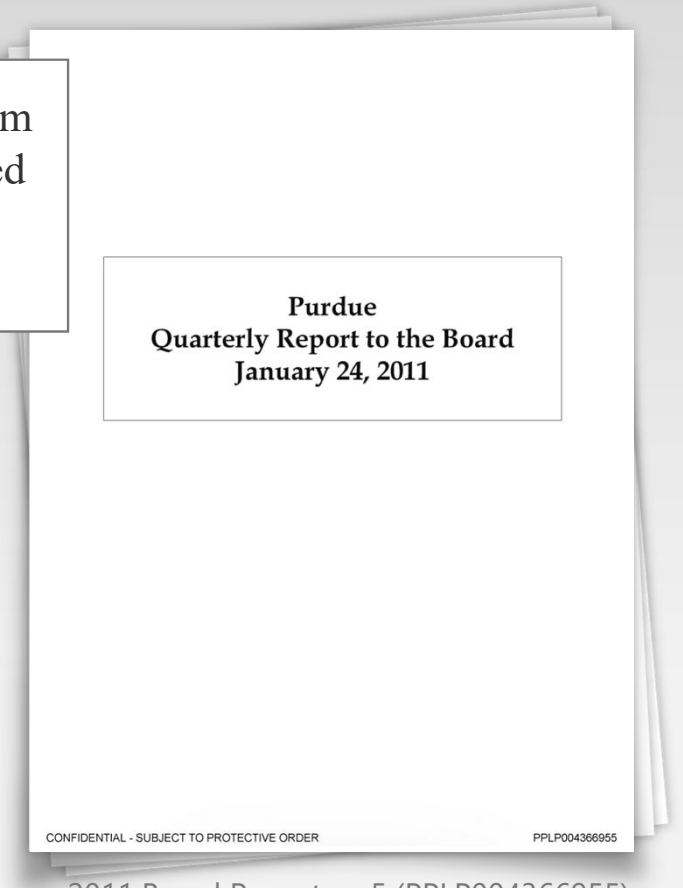
394. The Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign subsequent to the 2007 guilty plea. Complying with those orders, Purdue staff reported to the Sacklers in January 2011 that a key initiative in Q4 2010 had been the expansion of the sales force. …"



NY AG FAC ¶394

Cited Report Shows Expanded Sales Force Was To Launch Butrans

> Recruiting has gone well. In fact, 90 individuals were hired and trained from September through November. An additional 45 individuals have been hired and will attend the Butrans Launch Meeting in January, and receive Level 100 training the week after the launch meeting.



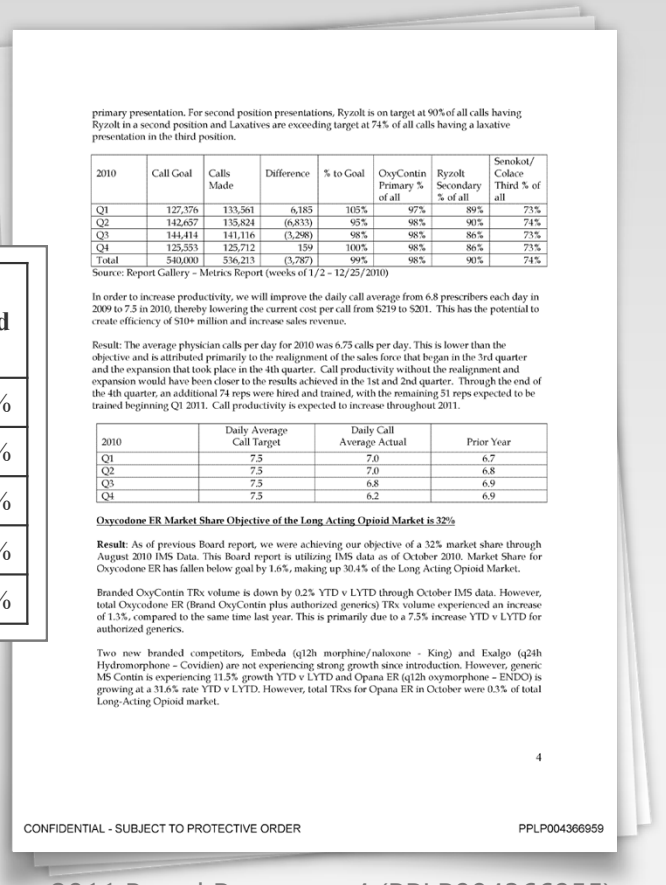
January 2011 Board Report, p. 5 (PPLP004366955)

- Adjusting sales force size is not deceptive marketing
- Butrans, not OxyContin
- OIG confirmed compliance for 2011

Cited Report Shows Sales Force "Realignment" In Q4 2010 Reduced OxyContin Marketing Calls

January 2011 Board Report:

2010	Call Goal	Calls Made	Difference	% to Goal	OxyContin Primary % of all	Ryzolt Secondary % of all	Senokot Colace Third % of all
Q1	127,376	**133,561**	6,185	105%	97%	89%	73%
Q2	142,657	**135,824**	(6,833)	95%	98%	90%	74%
Q3	144,414	**141,116**	(3,298)	98%	98%	86%	73%
Q4	125,553	**125,712**	159	100%	98%	86%	73%
Total	540,000	**536,213**	(3,787)	99%	98%	90%	74%



primary presentation. For second position presentations, Ryzolt is on target at 90% of all calls having Ryzolt in a second position and Laxatives are exceeding target at 74% of all calls having a laxative presentation in the third position.

2010	Call Goal	Calls Made	Difference	% to Goal	OxyContin Primary % of all	Ryzolt Secondary % of all	Senokot/ Colace Third % of all
Q1	127,376	133,561	6,185	105%	97%	89%	73%
Q2	142,657	135,824	(6,833)	95%	98%	90%	74%
Q3	144,414	141,116	(3,298)	98%	98%	86%	73%
Q4	125,553	125,712	159	100%	98%	86%	73%
Total	540,000	536,213	(3,787)	99%	98%	90%	74%

Source: Report Gallery – Metrics Report (weeks of 1/2 – 12/25/2010)

In order to increase productivity, we will improve the daily call average from 6.8 prescribers each day in 2009 to 7.5 in 2010, thereby lowering the current cost per call from $219 to $201. This has the potential to create efficiency of $10+ million and increase sales revenue.

Result: The average physician calls per day for 2010 was 6.75 calls per day. This is lower than the objective and is attributed primarily to the realignment of the sales force that began in the 3rd quarter and the expansion that took place in the 4th quarter. Call productivity without the realignment and expansion would have been closer to the results achieved in the 1st and 2nd quarter. Through the end of the 4th quarter, an additional 74 reps were hired and trained, with the remaining 51 reps expected to be trained beginning Q1 2011. Call productivity is expected to increase throughout 2011.

2010	Daily Average Call Target	Daily Call Average Actual	Prior Year
Q1	7.5	7.0	6.7
Q2	7.5	7.0	6.8
Q3	7.5	6.8	6.9
Q4	7.5	6.2	6.9

Oxycodone ER Market Share Objective of the Long Acting Opioid Market is 32%

Result: As of previous Board report, we were achieving our objective of a 32% market share through August 2010 IMS Data. This Board report is utilizing IMS data as of October 2010. Market Share for Oxycodone ER has fallen below goal by 1.6%, making up 30.4% of the Long Acting Opioid Market.

Branded OxyContin TRx volume is down by 0.2% YTD v LYTD through October IMS data. However, total Oxycodone ER (Brand OxyContin plus authorized generics) TRx volume experienced an increase of 1.3%, compared to the same time last year. This is primarily due to a 7.5% increase YTD v LYTD for authorized generics.

Two new branded competitors, Embeda (q12h morphine/naloxone - King) and Exalgo (q24h Hydromorphone – Covidien) are not experiencing strong growth since introduction. However, generic MS Contin is experiencing 11.5% growth YTD v LYTD and Opana ER (q12h oxymorphone – ENDO) is growing at a 31.6% rate YTD v LYTD. However, total TRxs for Opana ER in October were 0.3% of total Long-Acting Opioid market.

4

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004366959

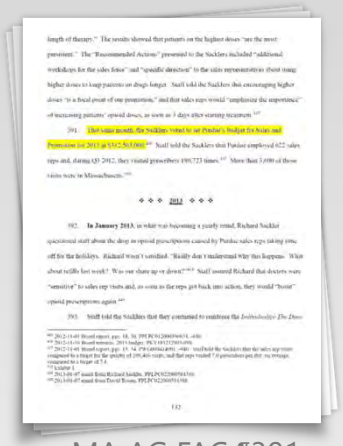
January 2011 Board Report, p. 4 (PPLP004366955)

Allegation: Board Set Sales Budget

Massachusetts AG FAC ¶391:

391. That same month, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000.[436]

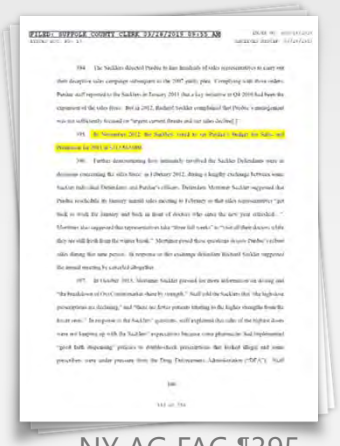
[436] 2012-11-26 Board minutes, 2013 budget, PKY183212995-998.



MA AG FAC ¶391

New York AG FAC ¶395:

395. In November 2012, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000.



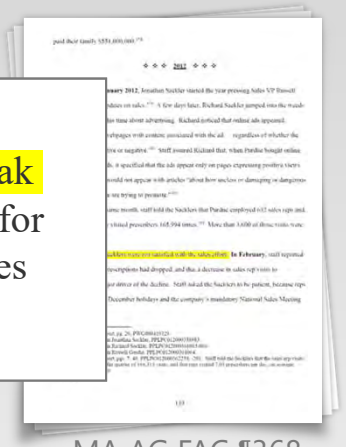
NY AG FAC ¶395

- Setting a budget is not deceptive marketing

Allegation: Board Was "Intimately Involved" in Sales Force Decisions

Massachusetts AG FAC ¶368:

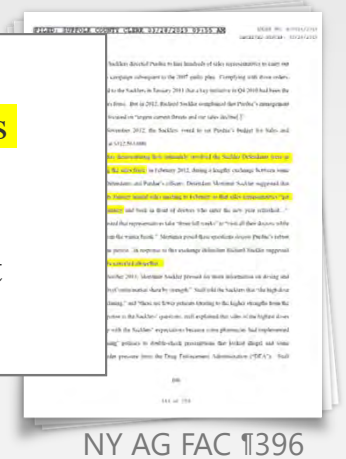
368. The Sacklers were not satisfied with the sales effort. In February, … [Mortimer Sackler] suggested that, "in future years we should not plan the national sales meeting so close to the winter break as it extends the period of time since the doctors last saw our rep … Staff replied to Mortimer, arguing for "balance." Richard Sackler replied within minutes that, since the National Sales Meeting prevented sales reps from visiting doctors, "Maybe the thing to have done was not have the meeting at all."



MA AG FAC ¶368

New York AG FAC ¶396:

396. Further demonstrating how intimately involved the Sackler Defendants were in decisions concerning the sales force: in February 2012, … Mortimer Sackler suggested that Purdue reschedule its January annual sales meeting to February so that sales representatives "get back to work for January and back in front of doctors who enter the new year refreshed ..." … Mortimer posed these questions despite Purdue's robust sales during that time period. In response to this exchange defendant Richard Sackler suggested the annual meeting be canceled altogether.



NY AG FAC ¶396

Cited Email Shows Board Questions About Timing Of Annual Sales Meeting

From: Sackler, Mortimer D.A.
Sent: Tuesday, February 07, 2012 6:35 PM

Russ,

Do you feel based on these results that in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep? …

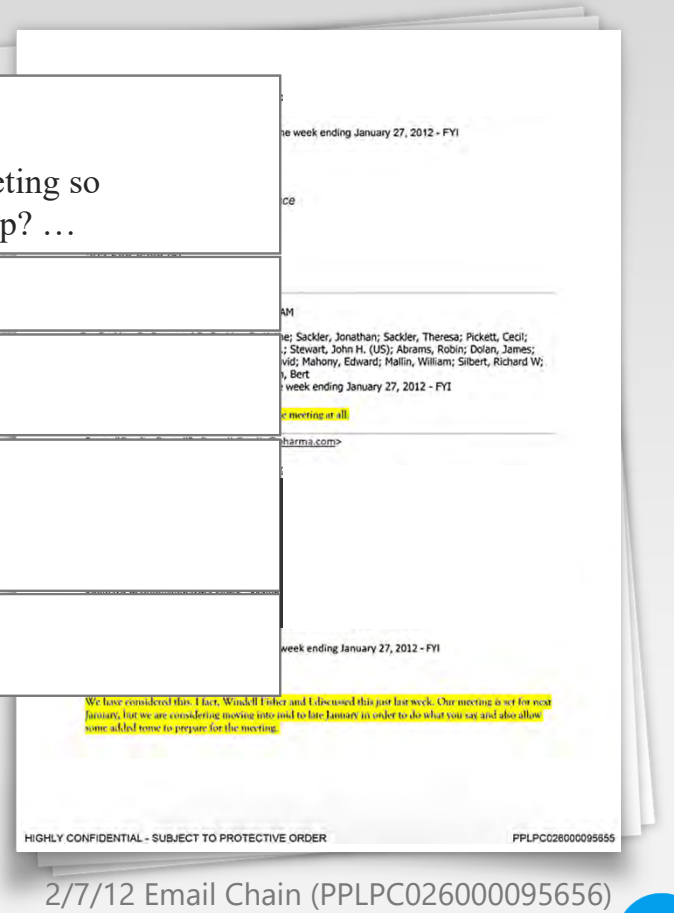
What do other companies do?

From: "Gasdia, Russell"
Date: Wed, 8 Feb 2012 09:38:33-0500

We have considered this. I[n] fact, Windell Fisher and I discussed this just last week. Our meeting is set for next January, but we are considering moving into mid to late January in order to do what you say and also allow some added tome to prepare for the meeting.

From: Sackler, Dr Richard
Date: Wednesday, February 08, 2012 9:45 AM

Maybe the thing to have done was not have the meeting at all.



2/7/12 Email Chain (PPLPC026000095656)

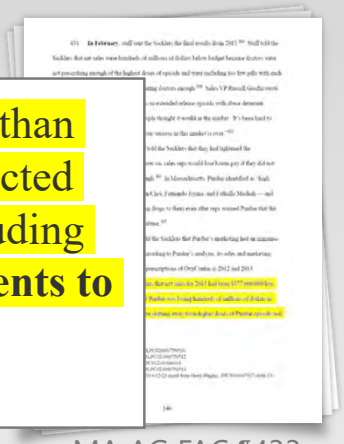
- **OIG confirmed compliance for 2012**

Allegation: Board Agreed To "Key Initiative" To Keep Patients On Therapy Longer

Massachusetts AG FAC ¶433:

433. … staff reported to the Sacklers that net sales for 2013 had been $377 million less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. **Staff told the Sacklers that a "Key Initiative" was to get patients to "stay on therapy longer."**[508]

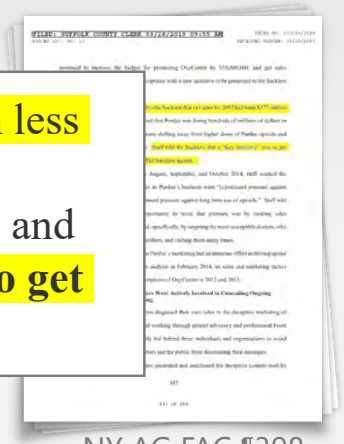
[508] 2014-02-04 Board report, pgs. 3, 5, 9, 22, PPLPC002000181037, -039, -043, -056.



MA AG FAC ¶433

New York AG FAC ¶398:

398. In 2013, staff reported to the Sacklers that net sales for 2013 had been $377 million less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. **Staff told the Sacklers that a "Key Initiative" was to get patients to "stay on therapy longer." The Sacklers agreed**.



NY AG FAC ¶398

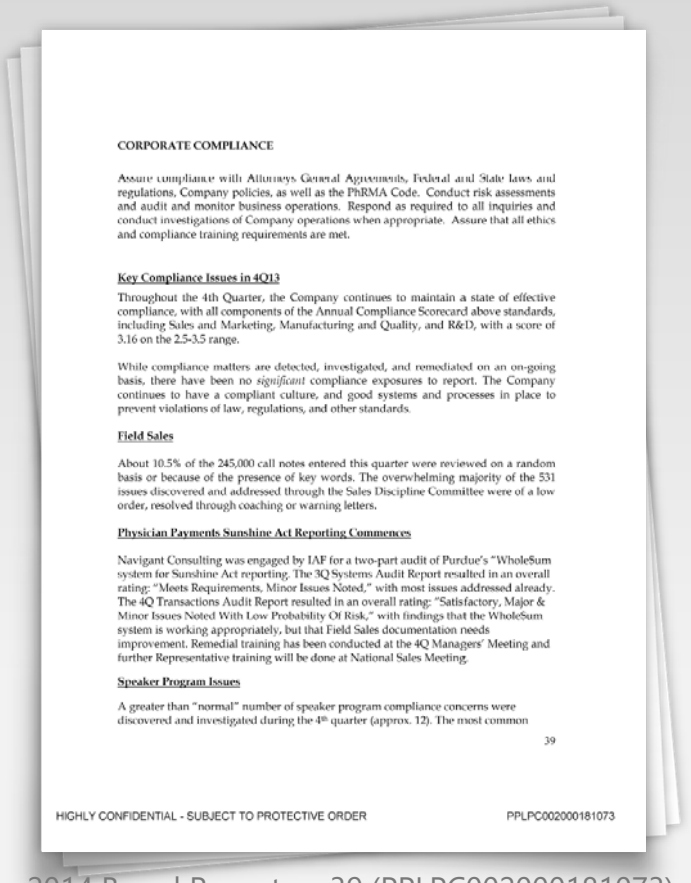
Allegation Juxtaposes Unrelated Passages On Net Sales And An Initiative To Help Patients Take Butrans As Prescribed ("Adherence Program")

- This allegation juxtaposes unrelated snippets – about net sales and Butrans – from a 48-page Board Report
- No allegation Butrans Adherence Program was deceptive
- Board was informed in the same Report:

[T]he Company **continues to maintain a state of effective compliance**.

[T]here have been **no significant compliance exposures** to report.

The Company continues to have a compliant culture, and **good systems and processes in place to prevent violations of law**, regulations, and other standards.



CORPORATE COMPLIANCE

Assure compliance with Attorneys General Agreements, Federal and State laws and regulations, Company policies, as well as the PhRMA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

Key Compliance Issues in 4Q13

Throughout the 4th Quarter, the Company continues to maintain a state of effective compliance, with all components of the Annual Compliance Scorecard above standards, including Sales and Marketing, Manufacturing and Quality, and R&D, with a score of 3.16 on the 2.5-3.5 range.

While compliance matters are detected, investigated, and remediated on an on-going basis, there have been no *significant* compliance exposures to report. The Company continues to have a compliant culture, and good systems and processes in place to prevent violations of law, regulations, and other standards.

Field Sales

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Speaker Program Issues

A greater than "normal" number of speaker program compliance concerns were discovered and investigated during the 4th quarter (approx. 12). The most common

39

HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLPC002000181073

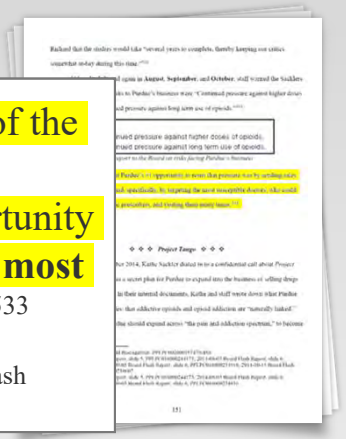
February 2014 Board Report, p. 39 (PPLPC002000181073)

Allegation: Board Informed Purdue Was Targeting "Susceptible" Doctors

Massachusetts AG FAC ¶444:

444. **In July** and again in **August, September,** and **October,** staff warned the Sacklers that two of the greatest risks to Purdue's business were "Continued pressure against higher doses of opioids," and "Continued pressure against long term use of opioids."[532] Staff told the Sacklers that Purdue's #1 opportunity to resist that pressure was by sending sales reps to visit prescribers; and, **specifically, by targeting the most susceptible doctors,** who could be convinced to be prolific prescribers, and visiting them many times.[533]

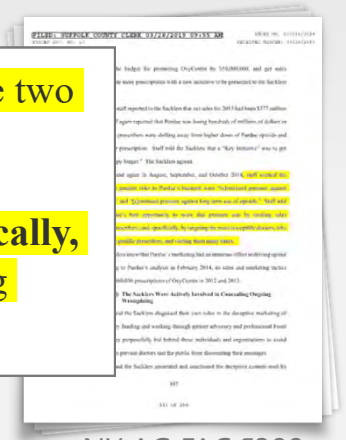
[533] 2014-07-01 Board Flash Report, slide 5, PPLPC016000244173; 2014-08-05 Board Flash Report, slide 6, PPLPC016000250753; 2014-09-05 Board Flash Report, slide 6, PPLPC016000254916.



MA AG FAC ¶444

New York AG FAC ¶399:

399. In July and again in August, September, and October 2014, staff warned the Sacklers that the two greatest risks to Purdue's business were '[c]ontinued pressure against higher doses of opioids,' and '[c]ontinued pressure against long term use of opioids.' Staff told the Sacklers that Purdue's best opportunity to resist that pressure was by sending sales representatives to visit prescribers; and, **specifically, by targeting more susceptible doctors**, who could be convinced to be prolific prescribers, and visiting them many times.



NY AG FAC ¶399

Cited Flash Reports Say Nothing About Targeting "Susceptible" Doctors

Purdue U.S. September 2014 YTD – OxyContin Risks and Opportunities

OPPORTUNITIES

i. OxyContin AG bottles may sell in slower than Budget. Net sales value of $180 million of AG product was shipped by Purdue to the counterparties in Q3 2014. The budget assumed that the entire $180 million would impact Purdue sales in 2014 - our current estimate is that only $85 million will impact 2014, with $95 million of net sales impact shifting from 2014 to 2015.

ii. Medicaid line extension rebate final regulations may be decided favorable to Purdue saving $243 million. We now expect this matter to be resolved in Q2 2015.

iii. The E2E effort has resulted in on or very close to budget performance on (1) primary sales call split between products (OxyContin/Butrans), (2) # of sales calls, and (3) % calls on target HCP's (Q3 Actual of 90% vs. budget of 85%). These are all significant improvements since 2013.

iv. Improved patient access - Purdue is employing many tactics to address patient access issues including collaborating with the National Association of Boards of Pharmacy to develop standard dispensing guidelines, working with wholesalers/retailers to establish thresholds for orders/scripts based on NDC # versus API, and more. Most recently Purdue has been successful with Walgreens in moving to NDC # quotas thereby separating OxyContin from oxycodone IR and other non-abuse deterrent products.

v. R2R has delivered improved tools such as customer segmentation and contract profitability that will help ensure profitable access and optimization of rebates in the Managed care area (more likely to impact 2015).

vi. IDN, call center, savings card optimization, prior authorization assistance programs and other initiatives are underway or being evaluated (more likely to impact 2015).

RISKS

i. Continued pressure against higher doses of opioids,

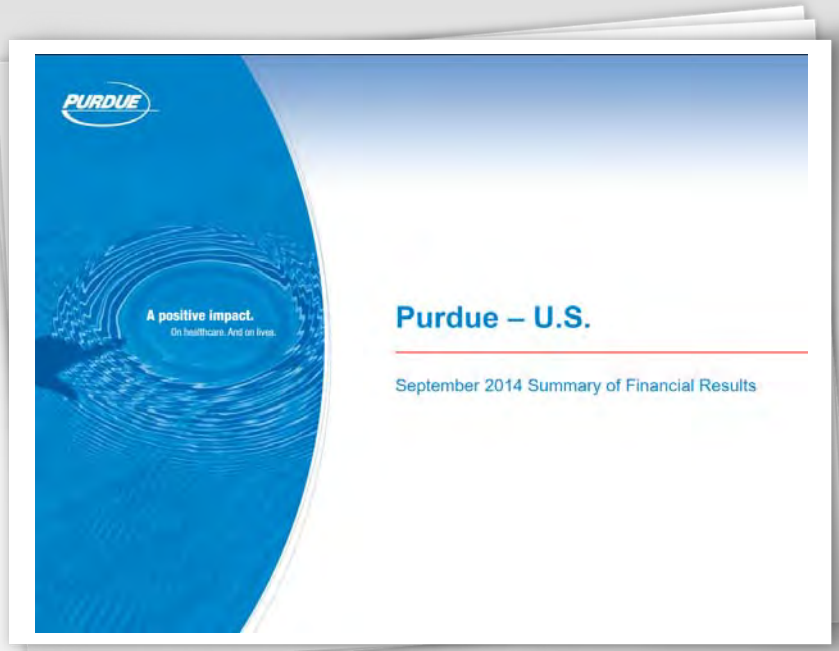
ii. Continued pressure against long term use of opioids,

iii. A new class label for ER opioids includes the following language "reserve OxyContin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate …".

iv. OxyContin rebates will run higher than budget due to an unanticipated contract re-negotiation initiated by United Healthcare. This is reflected in our latest estimates.

v. The budget does not include any impact that a Teva settlement may have on 2014 results.

PURDUE 7



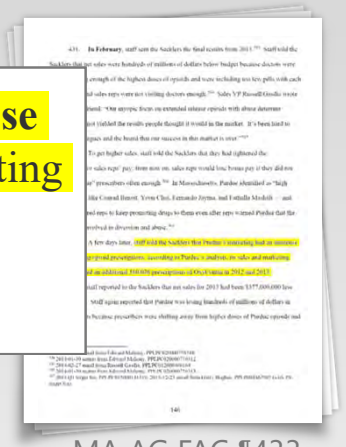
2014-10-15 Board Flash Report, slide 7 (PPLPC016000259607).
See also 2014-07-01 Board Flash Report, slide 5 (PPLPC016000244173);
2014-08-05 Board Flash Report, slide 6 (PPLPC016000250753); 2014-09-05 Board Flash Report, slide 6 (PPLPC016000254916).

Allegation: Board Knew Marketing Generated Increased Prescriptions

Massachusetts AG FAC ¶433:

433. A few days later, **staff told the Sacklers that Purdue's marketing had an immense effect on driving opioid prescriptions**: According to Purdue's analysis, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013. … [508]

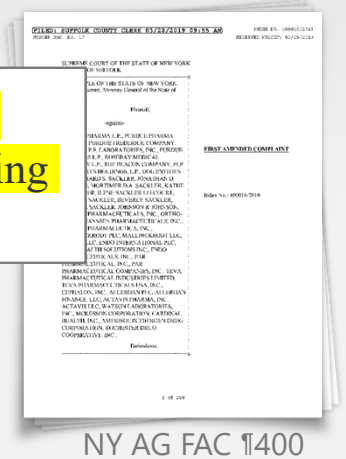
[508] 2014-02-04 Board report, pgs. 3, 5, 9, 22, PPLPC002000181037, -039, -043, -056.



MA AG FAC ¶433

New York AG FAC ¶400:

400. **The Sacklers knew that Purdue's marketing had an immense effect in driving opioid prescriptions.** According to Purdue's analysis in February 2014, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013.



NY AG FAC ¶400

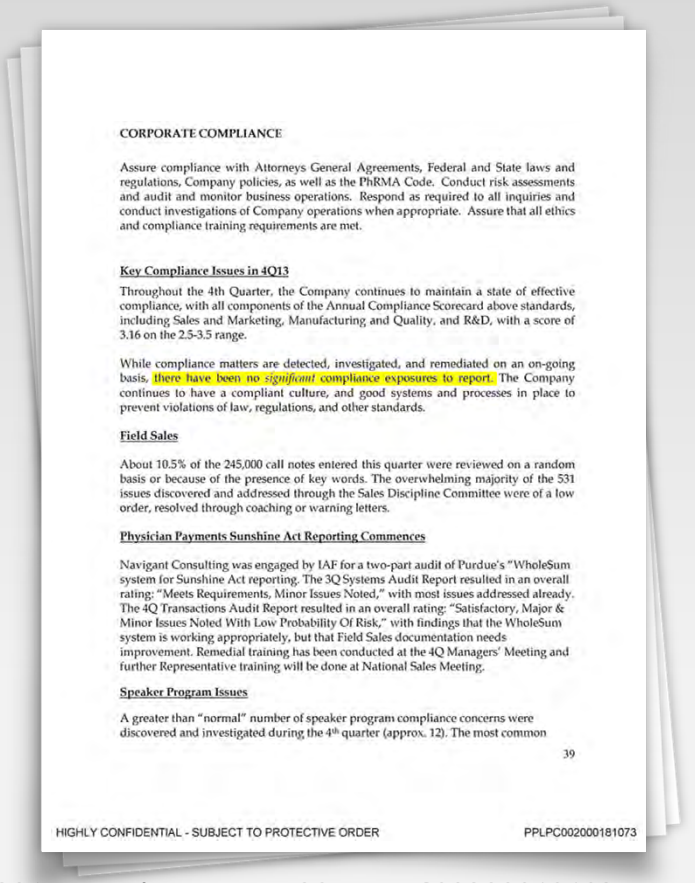
Reports Of Increased Prescriptions Accompanied By Confirmation Of Compliance

February 2014 Board Report:

[T]he Company continues to maintain a state of effective compliance.

[T]here have been no *significant* compliance exposures to report.

The Company continues to have a compliant culture, and good systems and processes in place to prevent violations of law, regulations, and other standards.



CORPORATE COMPLIANCE

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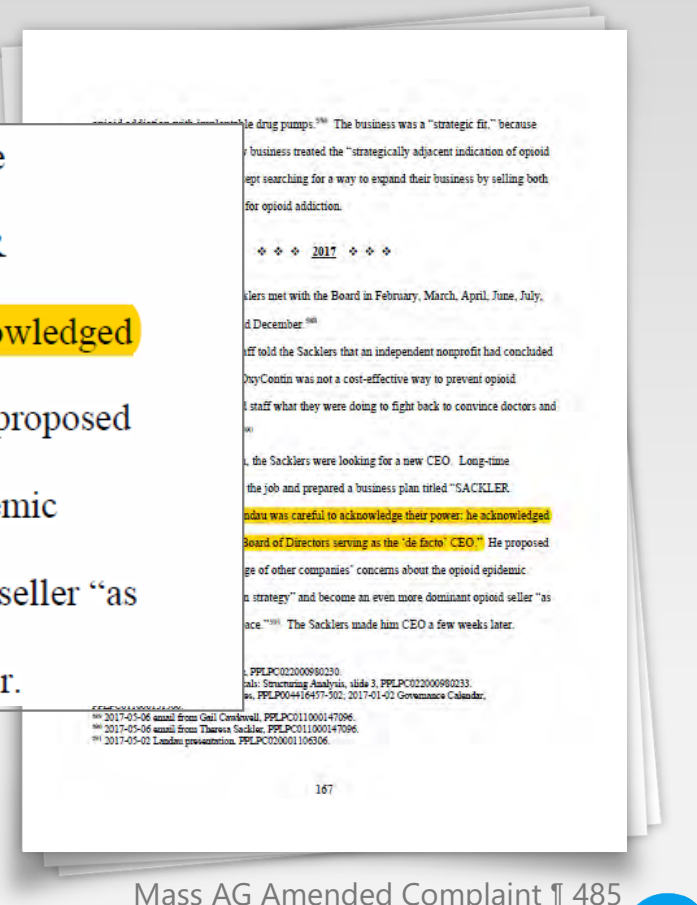
HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLPC002000181073

February 2014 Board Report, p. 39 (PPLPC002000181035)

Allegation: The Board Served As "De Facto CEO" of Purdue

Massachusetts AG FAC ¶485:

485. That same month, the Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled "SACKLER PHARMA ENTERPRISE." Landau was careful to acknowledge their power: he acknowledged that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." He proposed that Purdue should take advantage of other companies' concerns about the opioid epidemic through an "opioid consolidation strategy" and become an even more dominant opioid seller "as other companies abandon the space."[591] The Sacklers made him CEO a few weeks later.

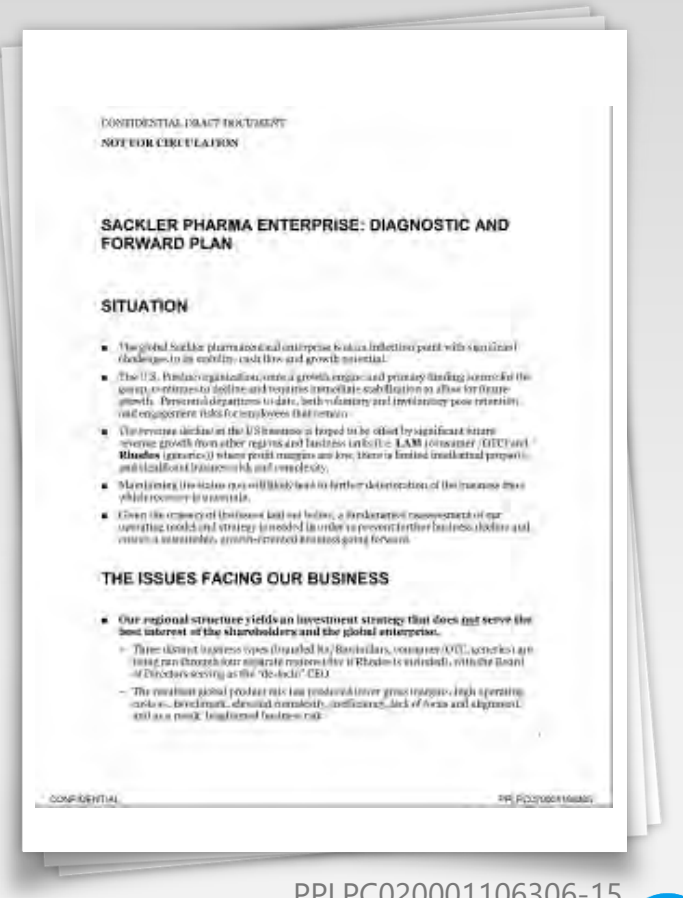


Mass AG Amended Complaint ¶ 485

Cited Report Addresses Global Organization, Says Nothing About Directors Serving As "De Facto" CEO Of Purdue

- Landau's was one of several memos prepared in connection with a strategy session on the **global** business
- The global business consisted of companies doing business in **49 countries** — and had no CEO
- **All** of the memos proposed a **global CEO** to relieve the **global board**

(*See, e.g.,* PPPLPC051000317758 at -63, -64; PPLPC051000317750 at -52, -53; PPLPC051000317768 at -72)



CONFIDENTIAL DRAFT DOCUMENT
NOT FOR CIRCULATION

SACKLER PHARMA ENTERPRISE: DIAGNOSTIC AND FORWARD PLAN

SITUATION

THE ISSUES FACING OUR BUSINESS

- **Our regional structure yields an investment strategy that does not serve the best interest of the shareholders and the global enterprise.**

CONFIDENTIAL

PPLPC020001106306-15

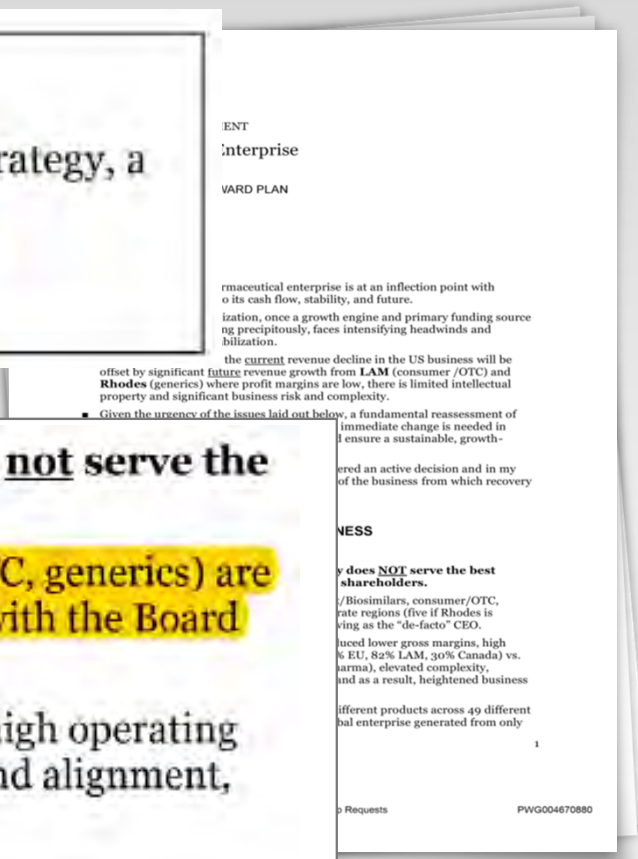
Landau Was Explicit He Was Discussing The Global Business, Not The US

SUMMARY

In the face of significant market pressures, our current investment strategy, a weak organic innovation pipeline, limited success in BD and limited resources for external assets, the global business as it stands is not sustainable.

Our regional structure yields an investment strategy that does not serve the best interest of the shareholders and the global enterprise.

- Three distinct business types (branded Rx/Biosimilars, consumer/OTC, generics) are being run through four separate regions (five if Rhodes is included), with the Board of Directors serving as the "de-facto" CEO.
- The resultant global product mix has produced lower gross margins, high operating costs vs. benchmark, elevated complexity, inefficiency, lack of focus and alignment, and as a result, heightened business risk.



PWG004670879

The Other Memos Were Also Explicit They Were Discussing The Global Business, Not The US

POTENTIAL IDEAS TO UNLOCK SHAREHOLDER VALUE THROUGH AN INTEGRATED GLOBAL ORGANISATION

***

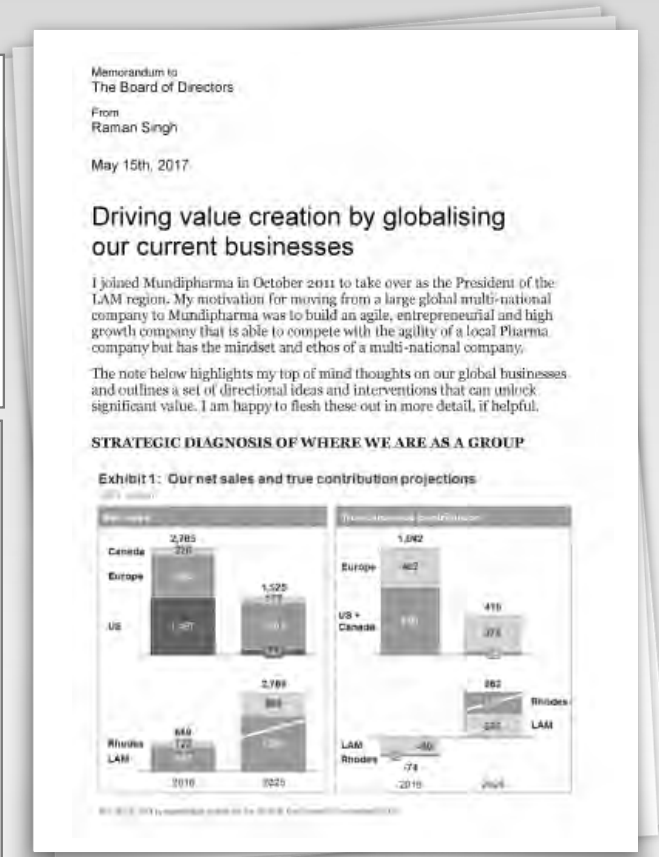
We should globalise our businesses with a CEO running them, and integrate our ethical business into 4 geographic units

WE NEED A GLOBAL STRUCTURE ALIGNED WITH GOVERNANCE AND PRIORITIES

***

What we should do:

I recommend a global business unit structure, as shown in the Attachment at the end of this document. In this proposed model, we create a global CEO, in a flat organization with all functions and businesses reporting in directly. We also



Memorandum to
The Board of Directors

From
Raman Singh

May 15th, 2017

Driving value creation by globalising our current businesses

I joined Mundipharma in October 2011 to take over as the President of the LAM region. My motivation for moving from a large global multi-national company to Mundipharma was to build an agile, entrepreneurial and high growth company that is able to compete with the agility of a local Pharma company but has the mindset and ethos of a multi-national company.

The note below highlights my top of mind thoughts on our global businesses and outlines a set of directional ideas and interventions that can unlock significant value. I am happy to flesh these out in more detail, if helpful.

STRATEGIC DIAGNOSIS OF WHERE WE ARE AS A GROUP

Exhibit 1: Our net sales and true contribution projections

PPLPC05100317752, PPLPC051000317764

Marketing Allegations About Richard, Jonathan, Beverly & David Sackler

Claimants' Allegations Fall Into 3 Categories

1. False
2. True but irrelevant
3. Decades old, distorted and released

True But Irrelevant Allegations

1. **Directors received or requested information from management**

See, e.g., NY AG FAC ¶393; MA AG FAC ¶¶214, 219, 220, 229, 230, 232, 240, 266, 270, 293, 304, 328, 358, 363, 366, 468.

2. **Directors were concerned about sales performance**

See, e.g., NY AG FAC ¶394; MA AG FAC ¶¶198, 226, 234, 258, 260, 261, 269, 318, 341-42, 344, 353.

3. **Directors knew OxyContin carried a risk of abuse and addiction**

See, e.g., NY AG FAC ¶¶367, 374, 377-78, 382-83, 386, 492; MA AG FAC ¶226.

Risk Of Abuse And Addiction Always Prominently Disclosed

WARNING: May be Habit Forming

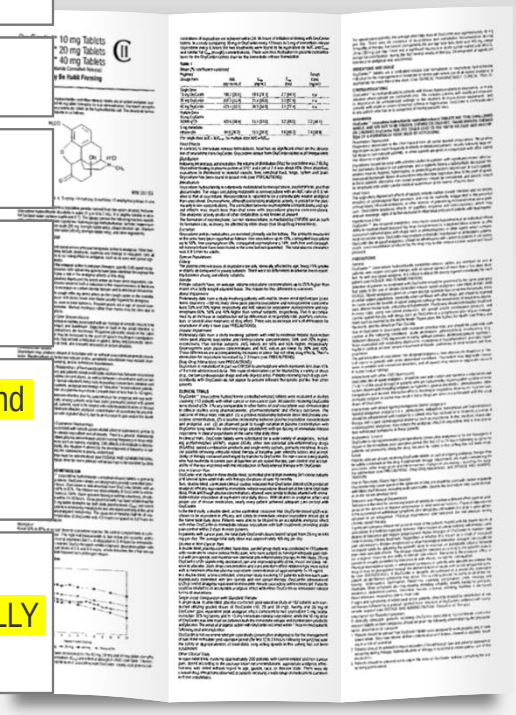
OxyContin is a mu-agonist with an abuse liability similar to morphine, and is a Schedule II controlled substance.

Oxycodone products are common targets for both drug abusers and addicts.

Patients should be advised that OxyContin is a potential drug of abuse. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed.

Physicians should be aware that psychological dependence may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true psychological dependence and is characterized by misuse for non-medical purposes.

OxyContin … TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO … A POTENTIALLY TOXIC DOSE OF OXYCODONE.



Original 1995 OxyContin Label

1995 OxyContin Label (PDD1501070001)

Schedule II: "High Potential For Abuse"

The Schedule II Ⓒ symbol appears prominently.

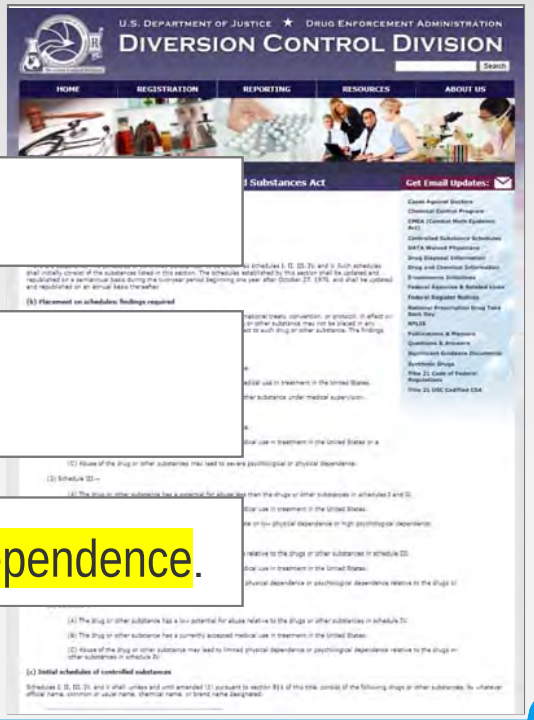
1995 OxyContin Label (PDD1501070001)

Schedule II:

(A) The drug … has a high potential for abuse.

(B) The drug … has a currently accepted medical use in treatment … with severe restrictions..

(C) Abuse of the drug … may lead to severe psychological or physical dependence.



https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm; 21 USC §812(b)(2)

2001 Label Added Black Box Warning

WARNING:

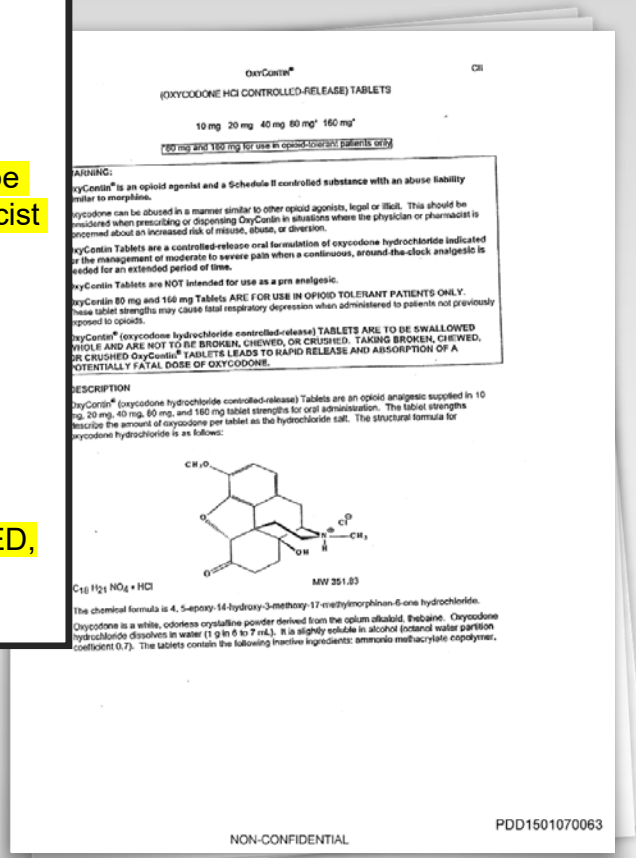
OxyContin ® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

***

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These label strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin ® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin ® TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.


OxyContin®

(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

10 mg 20 mg 40 mg 80 mg* 160 mg*

*80 mg and 160 mg for use in opioid-tolerant patients only

WARNING:

OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin® TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

DESCRIPTION

OxyContin® (oxycodone hydrochloride controlled-release) Tablets are an opioid analgesic supplied in 10 mg, 20 mg, 40 mg, 80 mg, and 160 mg tablet strengths for oral administration. The tablet strengths describe the amount of oxycodone per tablet as the hydrochloride salt. The structural formula for oxycodone hydrochloride is as follows:

MW 351.83

The chemical formula is 4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.

Oxycodone is a white, odorless crystalline powder derived from the opium alkaloid, thebaine. Oxycodone hydrochloride dissolves in water (1 g in 6 to 7 mL). It is slightly soluble in alcohol (ethanol and water partition coefficient 0.7). The tablets contain the following inactive ingredients: ammonio methacrylate copolymer,

NON-CONFIDENTIAL

PDD1501070063

July 2001 OxyContin Label, p. 1 (PDD1501070063)

"A boxed warning is the most serious warning placed in the labeling of a prescription medication"

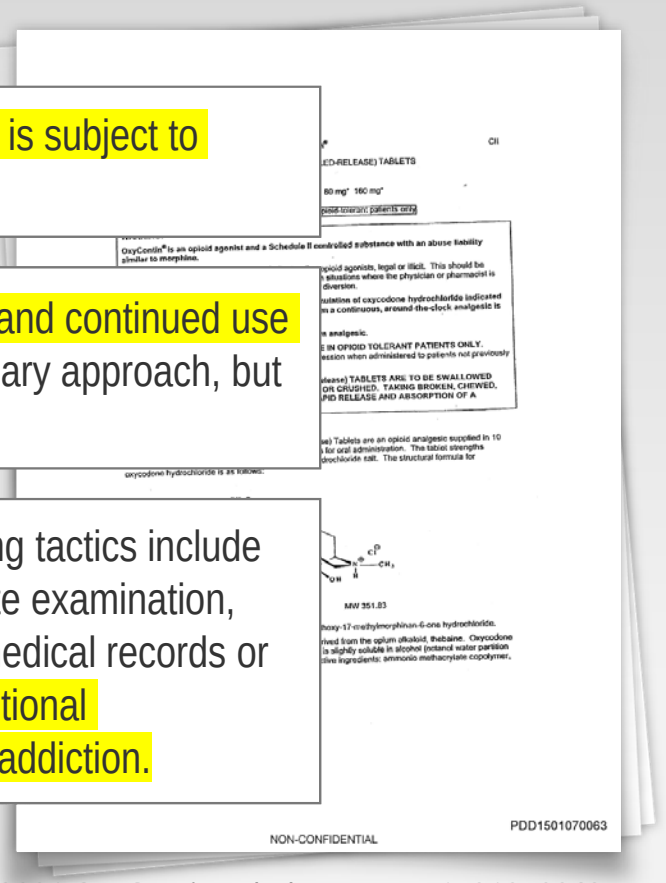
FDA Denial of AG Richard Blumenthal Petition (Sept. 9, 2008)
FDA Docket No. FDA-2004-P-0294, at p. 2

2001 Label Expanded Prior Warnings About Abuse And Diversion

Oxycodone, like morphine and other opioids used in analgesia, can be abused and is subject to criminal diversion.

Drug addiction is characterized by compulsive use, use for non-medical purposes, and continued use despite risk of harm. Drug addiction is a treatable disease, utilizing a multi-disciplinary approach, but relapse is common.

"Drug-seeking" behavior is very common in addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated "loss" of prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction.

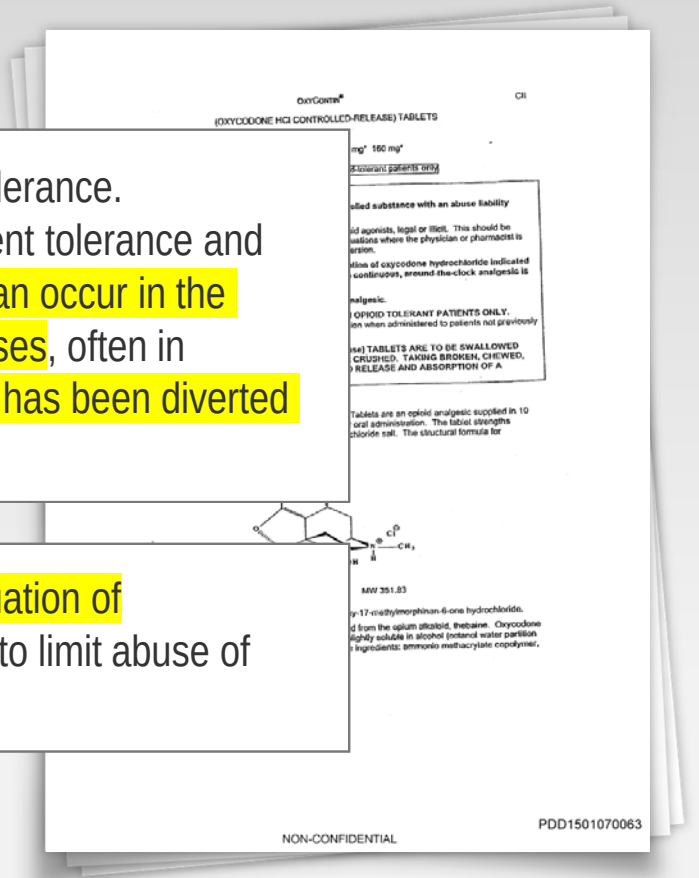


July 2001 OxyContin Label, p. 7 (PDD1501070063)

2001 Label Expanded Prior Warnings About Abuse And Diversion

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances. OxyContin, like other opioids, has been diverted for non-medical use.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

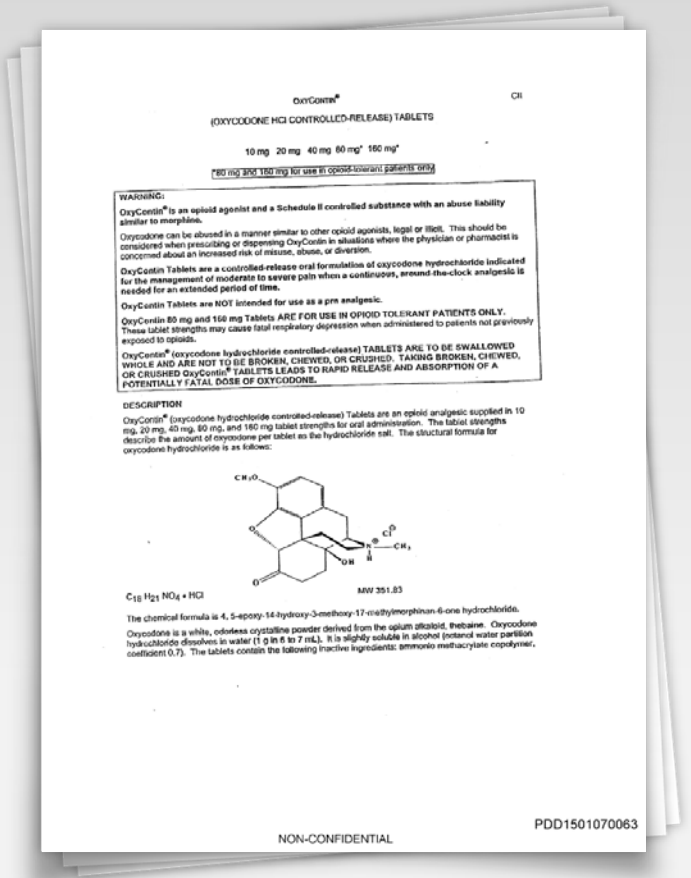


July 2001 OxyContin Label, pp. 7-8 (PDD1501070063)

2001 Label Removed And Revised Prior Statements

- **Removed** statements that "**Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug**" and that "**Iatrogenic 'addiction' to opioids legitimately used in the management of pain is very rare.**"

- **Revised** label to say that **OxyContin is not appropriate for "as needed" pain relief or in the immediate-post operative period if pain is mild or not expected to persist for an extended period of time**



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OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin® TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

DESCRIPTION

OxyContin® (oxycodone hydrochloride controlled-release) Tablets are an opioid analgesic supplied in 10 mg, 20 mg, 40 mg, 80 mg, and 160 mg tablet strengths for oral administration. The tablet strengths describe the amount of oxycodone per tablet as the hydrochloride salt. The structural formula for oxycodone hydrochloride is as follows:

$C_{18}H_{21}NO_4 \cdot HCl$ MW 351.83

The chemical formula is 4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.

Oxycodone is a white, odorless crystalline powder derived from the opium alkaloid, thebaine. Oxycodone hydrochloride dissolves in water (1 g in 6 to 7 mL). It is slightly soluble in alcohol (octanol water partition coefficient 0.7). The tablets contain the following inactive ingredients: ammonio methacrylate copolymer,

PDD1501070063

NON-CONFIDENTIAL

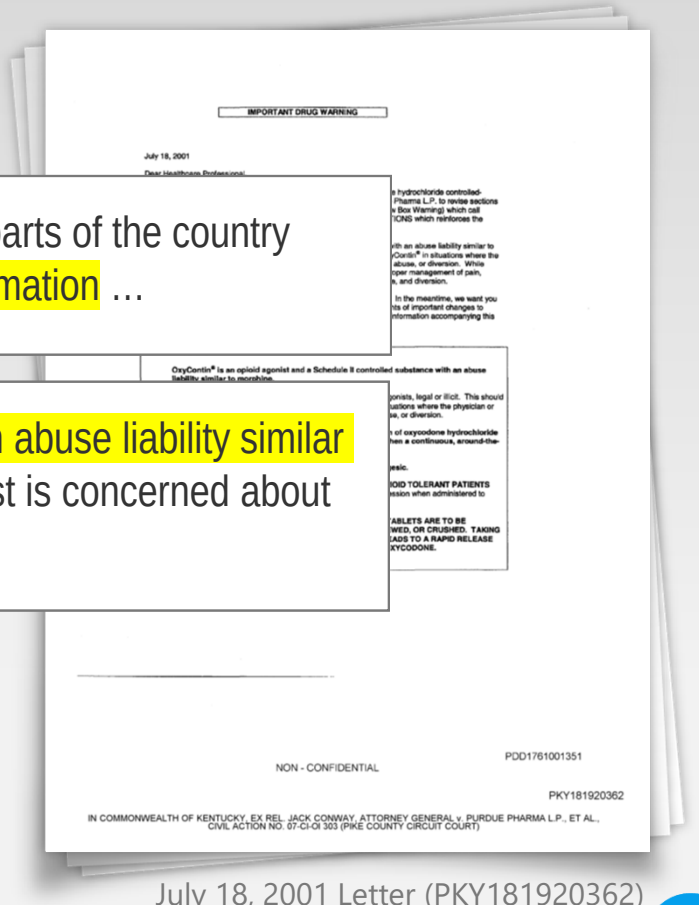
July 2001 OxyContin Label (PDD1501070063)

2001 Letter From Purdue To Prescribers Alerting Them To Label Changes

- **Purdue sent over a half million letters to HCPs alerting them to the 2001 label changes**

Reports of illegal misuse, abuse and diversion of OxyContin … from various parts of the country have prompted Purdue Pharma L.P. to revise sections of the prescribing information …

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. This should be considered … where the prescriber or pharmacist is concerned about an increased risk of misuse, abuse or diversion. …


IMPORTANT DRUG WARNING

July 18, 2001

NON - CONFIDENTIAL

PDD1761001351

PKY181920362

IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL., CIVIL ACTION NO. 07-CI-OI 303 (PIKE COUNTY CIRCUIT COURT)

July 18, 2001 Letter (PKY181920362)

Black Box Warnings On Every OxyContin Label Since 2001

2010 Label

WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE

See full prescribing information for complete boxed warning.

- OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (9)
- OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)
- OxyContin is NOT intended for use on an as-needed basis. (1)
- OxyContin 60 mg and 80 mg Tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in opioid-tolerant patients to avoid fatal respiratory depression. (2.7)
- Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. (2.2)
- OxyContin tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved which can lead to rapid release and absorption of a potentially fatal dose of oxycodone. (2.1)
- The concomitant use with cytochrome P450 3A4 inhibitors such as macrolide antibiotics and protease inhibitors may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. (7.2)

2010 OxyContin Label, p. 1, (PDD8901035967)

2014 Label

WARNING: ADDICTION, ABUSE and MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION

See full prescribing information for complete boxed warning.

- OXYCONTIN exposes users to risks of addictions, abuse and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing and monitor regularly for development of these behaviors and conditions. (5.1)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole to avoid exposure to a potentially fatal dose of oxycodone. (5.2)
- Accidental ingestion of OXYCONTIN, especially in children, can result in a fatal overdose of oxycodone. (5.2)
- Prolonged use of OXYCONTIN during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.3)
- Initiation of CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycodone from OXYCONTIN. (5.14)

April 2014 OxyContin Label, p. 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2016 Label

WARNING: ADDICTION, ABUSE AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole to avoid exposure to a potentially fatal dose of oxycodone. (5.2)
- Accidental ingestion of OXYCONTIN, especially by children, can result in a fatal overdose of oxycodone. (5.2)
- Prolonged use of OXYCONTIN during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.3)
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycodone. (5.4, 7, 12.3)
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.5, 7)

2016 OxyContin Label, p. 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2018 Label

WARNING: ADDICTION, ABUSE AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for these products. (5.2)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole to avoid exposure to a potentially fatal dose of oxycodone. (5.3)
- Accidental ingestion of OXYCONTIN, especially by children, can result in a fatal overdose of oxycodone. (5.3)
- Prolonged use of OXYCONTIN during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.4)
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycodone. (5.5, 7, 12.3)
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.6, 7)

September 2018 OxyContin Label, p. 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf

Risks Of Addiction, Overdose And Death Continuously Disclosed

2010 Label

The following adverse reactions have been identified during post-approval use of controlled-release oxycodone. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: abuse, addiction, overdose, death, amenorrhea, symptoms associated with an anaphylactic or anaphylactoid reaction, increased hepatic enzymes, muscular hypertonia, hyponatremia, ileus, palpitations (in the context of withdrawal), seizures, syndrome of inappropriate antidiuretic hormone secretion, and urticaria

2010 OxyContin Label, p. 14, (PDD8901035967)

2014 Label

The following adverse reactions have been identified during post-approval use of controlled-release oxycodone: abuse, addiction, amenorrhea, cholestasis, death, dental caries, increased hepatic enzymes, hyperalgesia, hypogonadism, hyponatremia, ileus, muscular hypertonia, overdose, palpitations (in the context of withdrawal), seizures, syndrome of inappropriate antidiuretic hormone secretion, and urticaria.

April 2014 OxyContin Label, p.13, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2016 Label

Abuse, addiction, aggression, amenorrhea, cholestasis, completed suicide, death, dental caries, increased hepatic enzymes, hyperalgesia, hypogonadism, hyponatremia, ileus, intentional overdose, mood altered, muscular hypertonia, overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria.

2016 OxyContin Label, p. 20, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2018 Label

Abuse, addiction, aggression, amenorrhea, cholestasis, completed suicide, death, dental caries, increased hepatic enzymes, hyperalgesia, hypogonadism, hyponatremia, ileus, intentional overdose, mood altered, muscular hypertonia, overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria.

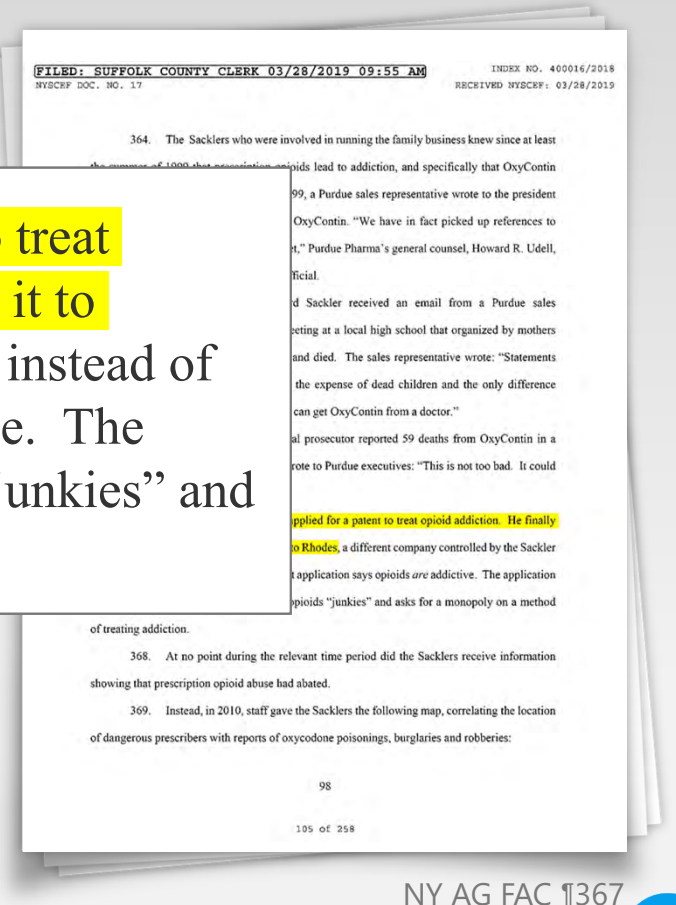
September 2018 OxyContin Label, p. 21, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf

Post-2007 Allegations About Richard Sackler

Allegation: Richard Applied For Patent To Treat Addiction

New York AG FAC ¶367:

367. In 2007, Richard Sackler applied for a patent to treat addiction. He finally received it in January 2018 and assigned it to Rhodes, a different company controlled by the Sackler family, instead of Purdue. Richard's patent application says opioids *are* addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

364. The Sacklers who were involved in running the family business knew since at least
oids lead to addiction, and specifically that OxyContin
99, a Purdue sales representative wrote to the president
OxyContin. "We have in fact picked up references to
t," Purdue Pharma's general counsel, Howard R. Udell,
ficial.
d Sackler received an email from a Purdue sales
eting at a local high school that organized by mothers
and died. The sales representative wrote: "Statements
the expense of dead children and the only difference
can get OxyContin from a doctor."
al prosecutor reported 59 deaths from OxyContin in a
rote to Purdue executives: "This is not too bad. It could
pplied for a patent to treat opioid addiction. He finally
o Rhodes, a different company controlled by the Sackler
t application says opioids *are* addictive. The application
pioids "junkies" and asks for a monopoly on a method
of treating addiction.

368. At no point during the relevant time period did the Sacklers receive information showing that prescription opioid abuse had abated.

369. Instead, in 2010, staff gave the Sacklers the following map, correlating the location of dangerous prescribers with reports of oxycodone poisonings, burglaries and robberies:

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NY AG FAC ¶367

- **False, irrelevant and released**

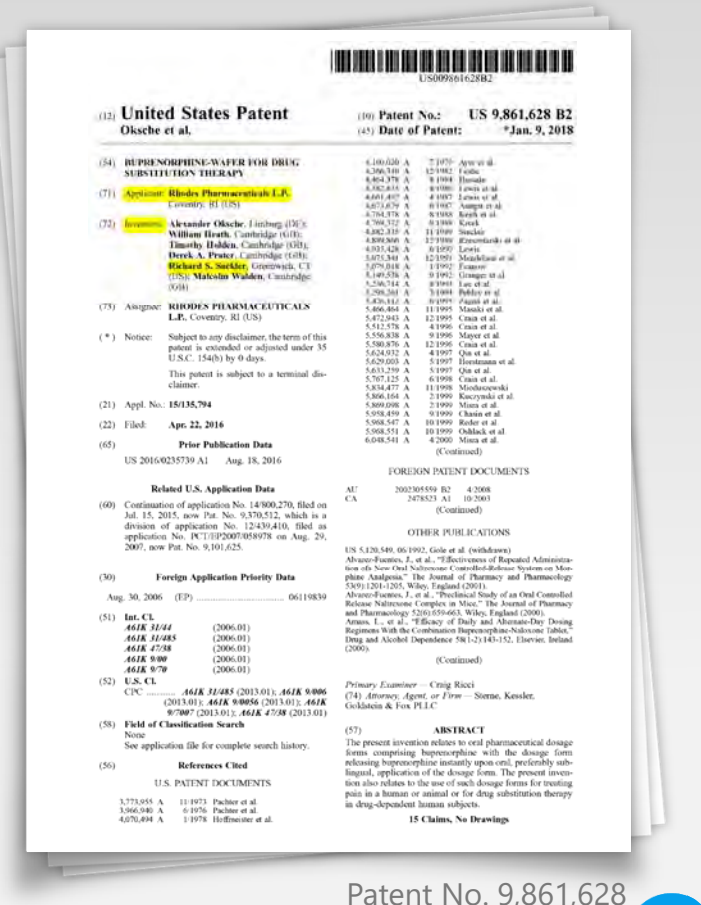
Inventor, Not Applicant

(72) Inventors: **Alexander Oksche**, Limburg (DE); **William Heath**, Cambridge (GB); **Timothy Holden**, Cambridge (GB); **Derek A. Prater**, Cambridge (GB); **Richard S. Sackler**, Greenwich, CT (US); **Malcolm Walden**, Cambridge (GB)

(71) Applicant: **Rhodes Pharmaceuticals L.P.**, Coventry, RI (US)

- His contribution: the idea of the fast-dissolving wafer

3/8/19 MDL R. Sackler Tr. 371:8-9



US009861628B2

(12) **United States Patent**
Oksche et al.

(10) **Patent No.: US 9,861,628 B2**
(45) **Date of Patent: *Jan. 9, 2018**

(54) **BUPRENORPHINE-WAFER FOR DRUG SUBSTITUTION THERAPY**

(71) Applicant: **Rhodes Pharmaceuticals L.P.**, Coventry, RI (US)

(72) Inventors: **Alexander Oksche**, Limburg (DE); **William Heath**, Cambridge (GB); **Timothy Holden**, Cambridge (GB); **Derek A. Prater**, Cambridge (GB); **Richard S. Sackler**, Greenwich, CT (US); **Malcolm Walden**, Cambridge (GB)

(73) Assignee: **RHODES PHARMACEUTICALS L.P.**, Coventry, RI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/135,794**

(22) Filed: **Apr. 22, 2016**

(65) **Prior Publication Data**

US 2016/0235739 A1 Aug. 18, 2016

Related U.S. Application Data

(60) Continuation of application No. 14/800,270, filed on Jul. 15, 2015, now Pat. No. 9,370,512, which is a division of application No. 12/439,410, filed as application No. PCT/EP2007/058978 on Aug. 29, 2007, now Pat. No. 9,101,625.

(30) **Foreign Application Priority Data**

Aug. 30, 2006 (EP) 06119839

(51) **Int. Cl.**

A61K 31/44	(2006.01)
A61K 31/485	(2006.01)
A61K 47/38	(2006.01)
A61K 9/00	(2006.01)
A61K 9/70	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 31/485*** (2013.01); ***A61K 9/006*** (2013.01); ***A61K 9/0056*** (2013.01); ***A61K 9/7007*** (2013.01); ***A61K 47/38*** (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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(Continued)

Primary Examiner — Craig Ricci

(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox PLLC

(57) **ABSTRACT**

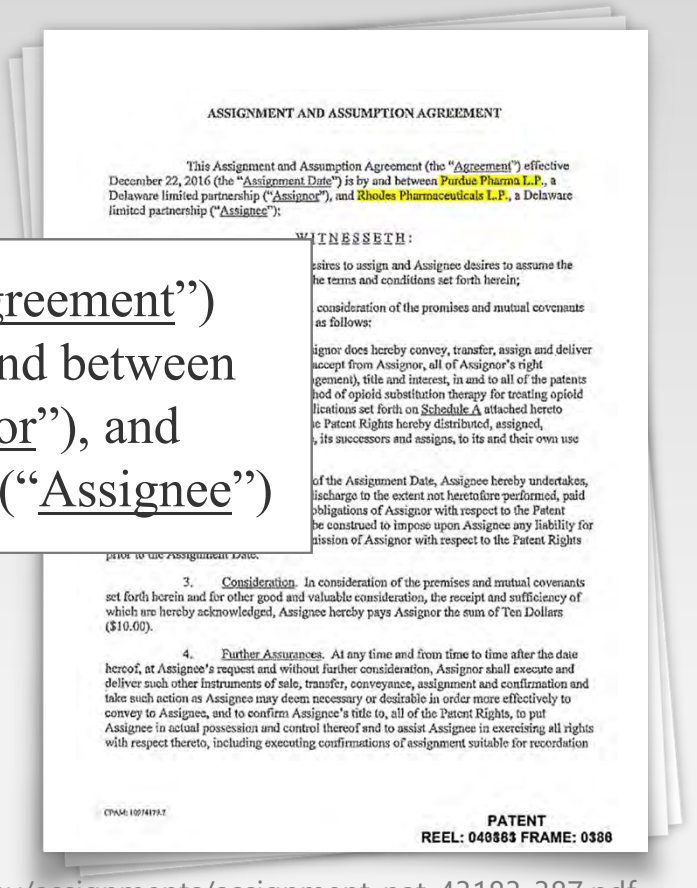
The present invention relates to oral pharmaceutical dosage forms comprising buprenorphine with the dosage form releasing buprenorphine instantly upon oral, preferably sublingual, application of the dosage form. The present invention also relates to the use of such dosage forms for treating pain in a human or animal or for drug substitution therapy in drug-dependent human subjects.

15 Claims, No Drawings

Patent No. 9,861,628

Purdue Assigned Patent To Rhodes

This Assignment and Assumption Agreement (the "Agreement") effective December 22, 2016 (the "Assignment Date") is by and between Purdue Pharma L.P., a Delaware limited partnership ("Assignor"), and Rhodes Pharmaceuticals L.P., a Delaware limited partnership ("Assignee")



ASSIGNMENT AND ASSUMPTION AGREEMENT

This Assignment and Assumption Agreement (the "Agreement") effective December 22, 2016 (the "Assignment Date") is by and between Purdue Pharma L.P., a Delaware limited partnership ("Assignor"), and Rhodes Pharmaceuticals L.P., a Delaware limited partnership ("Assignee"):

WITNESSETH:

sires to assign and Assignee desires to assume the he terms and conditions set forth herein;

consideration of the promises and mutual covenants as follows:

ignor does hereby convey, transfer, assign and deliver accept from Assignor, all of Assignor's right gement), title and interest, in and to all of the patents hod of opioid substitution therapy for treating opioid lications set forth on Schedule A attached hereto e Patent Rights hereby distributed, assigned, , its successors and assigns, to its and their own use

of the Assignment Date, Assignee hereby undertakes, ischarge to the extent not heretofore performed, paid obligations of Assignor with respect to the Patent be construed to impose upon Assignee any liability for nission of Assignor with respect to the Patent Rights

3. Consideration. In consideration of the premises and mutual covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignee hereby pays Assignor the sum of Ten Dollars ($10.00).

4. Further Assurances. At any time and from time to time after the date hereof, at Assignee's request and without further consideration, Assignor shall execute and deliver such other instruments of sale, transfer, conveyance, assignment and confirmation and take such action as Assignee may deem necessary or desirable in order more effectively to convey to Assignee, and to confirm Assignee's title to, all of the Patent Rights, to put Assignee in actual possession and control thereof and to assist Assignee in exercising all rights with respect thereto, including executing confirmations of assignment suitable for recordation

PATENT
REEL: 040883 FRAME: 0388

Irrelevant to deceptive marketing claims

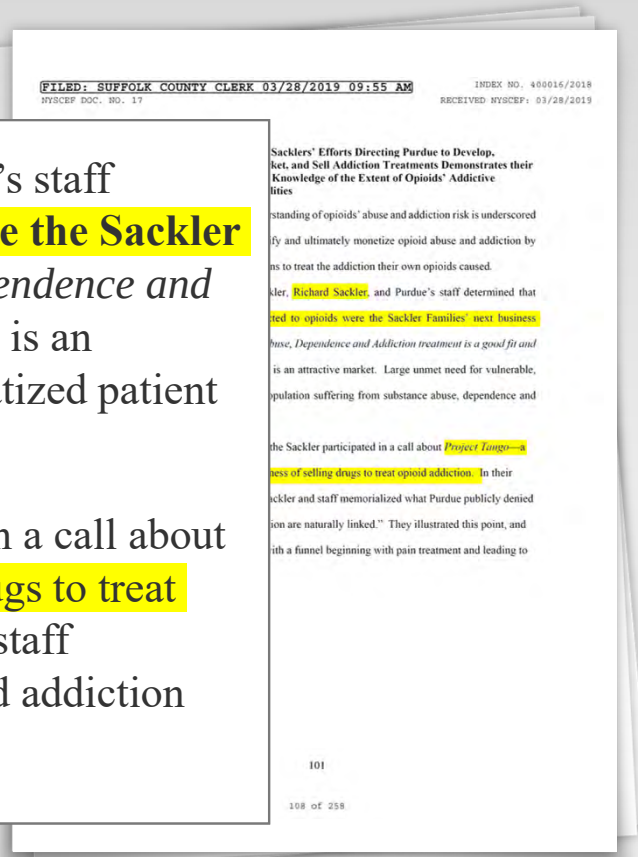
http://legacy-assignments.uspto.gov/assignments/assignment-pat-43183-387.pdf

Allegation: Family Plan To Sell Opioid Addiction Treatment (Project Tango)

New York AG FAC ¶¶377-78:

377. Defendants Kathe Sackler, **Richard Sackler**, and Purdue's staff **determined that millions of people who became addicted to opioids were the Sackler Families' next business opportunity**. A slide titled *Substance Abuse, Dependence and Addiction treatment is a good fit and next natural step for Purdue* states: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction."

378. In September 2014, Kathe Sackler participated in a call about ***Project Tango***—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, defendant Kathe Sackler and staff memorialized what Purdue publicly denied for decades: "Pain treatment and addiction are naturally linked." …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NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

Sacklers' Efforts Directing Purdue to Develop, ket, and Sell Addiction Treatments Demonstrates their Knowledge of the Extent of Opioids' Addictive lities

standing of opioids' abuse and addiction risk is underscored fy and ultimately monetize opioid abuse and addiction by ns to treat the addiction their own opioids caused.

kler, Richard Sackler, and Purdue's staff determined that ted to opioids were the Sackler Families' next business

buse, Dependence and Addiction treatment is a good fit and is an attractive market. Large unmet need for vulnerable, opulation suffering from substance abuse, dependence and

the Sackler participated in a call about Project Tango—a ness of selling drugs to treat opioid addiction. In their ckler and staff memorialized what Purdue publicly denied ion are naturally linked." They illustrated this point, and ith a funnel beginning with pain treatment and leading to

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NY AG FAC ¶¶377-78

Not A Family Plan, Not Pursued, Not Relevant

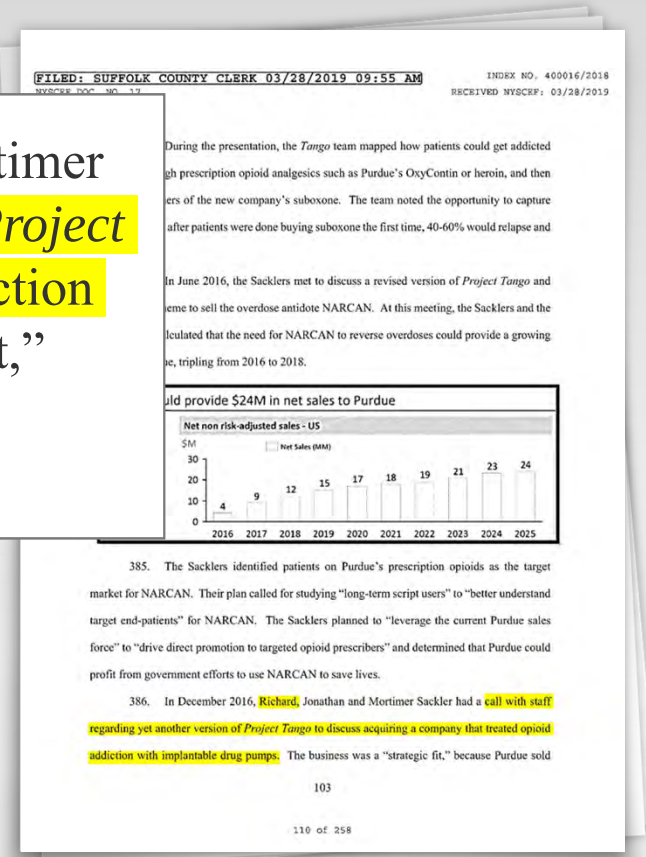
- Proposal from a private equity fund
- Not pursued by Purdue
- Irrelevant to deceptive marketing claims

Allegation: "Another Version Of *Project Tango*" Two Years Later

New York AG FAC ¶386:

386. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of *Project Tango* to discuss acquiring a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."

- Presented to Board by management
- Never materialized
- Irrelevant to deceptive marketing claims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During the presentation, the *Tango* team mapped how patients could get addicted gh prescription opioid analgesics such as Purdue's OxyContin or heroin, and then ers of the new company's suboxone. The team noted the opportunity to capture after patients were done buying suboxone the first time, 40-60% would relapse and

In June 2016, the Sacklers met to discuss a revised version of *Project Tango* and eme to sell the overdose antidote NARCAN. At this meeting, the Sacklers and the lculated that the need for NARCAN to reverse overdoses could provide a growing e, tripling from 2016 to 2018.

uld provide $24M in net sales to Purdue

385. The Sacklers identified patients on Purdue's prescription opioids as the target market for NARCAN. Their plan called for studying "long-term script users" to "better understand target end-patients" for NARCAN. The Sacklers planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use NARCAN to save lives.

386. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of *Project Tango* to discuss acquiring a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold

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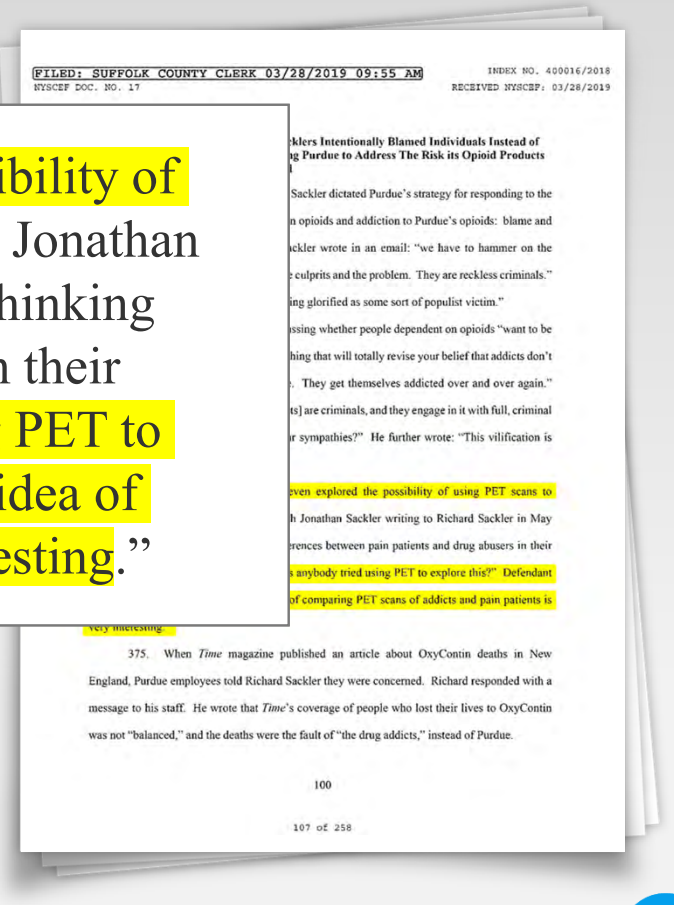
NY AG FAC ¶386

Allegation: Explored Possibility Of Using PET Scans To Identify Abusers

NY AG FAC ¶374:

374. The Sackler Defendants even explored the possibility of using PET scans to distinguish "patients" from "abusers," with Jonathan Sackler writing to Richard Sackler in **May 2008** that he "was thinking about the differences between pain patients and drug abusers in their reaction to opioids." Jonathan asked, "Has anybody tried using PET to explore this?" Defendant Richard Sackler replied: "I think the idea of comparing PET scans of addicts and pain patients is very interesting."


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

klers Intentionally Blamed Individuals Instead of
g Purdue to Address The Risk its Opioid Products

Sackler dictated Purdue's strategy for responding to the
n opioids and addiction to Purdue's opioids: blame and
ckler wrote in an email: "we have to hammer on the
culprits and the problem. They are reckless criminals."
ing glorified as some sort of populist victim."
ssing whether people dependent on opioids "want to be
hing that will totally revise your belief that addicts don't
. They get themselves addicted over and over again."
ts] are criminals, and they engage in it with full, criminal
r sympathies?" He further wrote: "This vilification is

ven explored the possibility of using PET scans to
h Jonathan Sackler writing to Richard Sackler in May
rences between pain patients and drug abusers in their
anybody tried using PET to explore this?" Defendant
of comparing PET scans of addicts and pain patients is

375. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue.

100

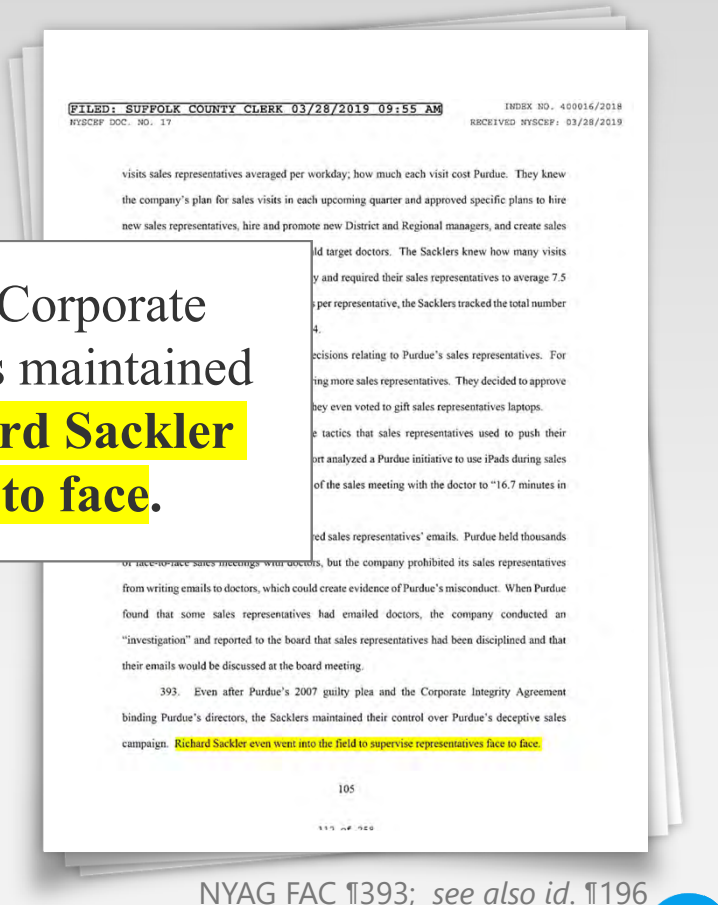
107 of 258

- Speculative email between brothers 13 years ago
- No "exploration", no suggestion of impropriety
- OIG confirmed compliance for 2008

Allegation: 2011 Ride-Along With Sales Rep

New York AG FAC ¶393:

393. Even after Purdue's 2007 guilty plea and the Corporate Integrity Agreement binding Purdue's directors, the Sacklers maintained their control over Purdue's deceptive sales campaign. **Richard Sackler even went into the field to supervise representatives face to face.**


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

visits sales representatives averaged per workday; how much each visit cost Purdue. They knew the company's plan for sales visits in each upcoming quarter and approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales

ld target doctors. The Sacklers knew how many visits

y and required their sales representatives to average 7.5

per representative, the Sacklers tracked the total number

4.

ecisions relating to Purdue's sales representatives. For

ing more sales representatives. They decided to approve

hey even voted to gift sales representatives laptops.

e tactics that sales representatives used to push their

ort analyzed a Purdue initiative to use iPads during sales

of the sales meeting with the doctor to "16.7 minutes in

ed sales representatives' emails. Purdue held thousands

of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

393. Even after Purdue's 2007 guilty plea and the Corporate Integrity Agreement binding Purdue's directors, the Sacklers maintained their control over Purdue's deceptive sales campaign. Richard Sackler even went into the field to supervise representatives face to face.

105

NYAG FAC ¶393; *see also id.* ¶196

2011 Ride-Along With Sales Rep

- Butrans launch in progress
- One ride-along in 2011 in Fairfield County, Connecticut
- Compliance directed him not to say anything
- He did not engage in promotion or marketing
- He did not go on any other ride-along
- Office of Inspector General confirmed compliance for 2011

2011 Ride-Along With Sales Rep Was An Appropriate Directorial Activity

Columbia Law School Millstein Center for Global Markets and Corporate Ownership, *Greater Expectations: Strategies for Effective Board Meeting Preparation* (March 2018):

Directors should ... make efforts to better understand the company's operations outside of the board setting. This is important not just for their own grasp of the organization and its culture, but also as a way to hear different perspectives on the company's products or services. For example, as a director, if your company manufacturers vehicles, make a casual visit to a dealership to see how products are marketed directly to the consumer; as a director of a bank, open a new account or meet with a teller to assess the customer service and process. **Experiencing the company you serve through the lens of the consumer can provide insight and confirmation about the feedback provided from the management's perspective**.

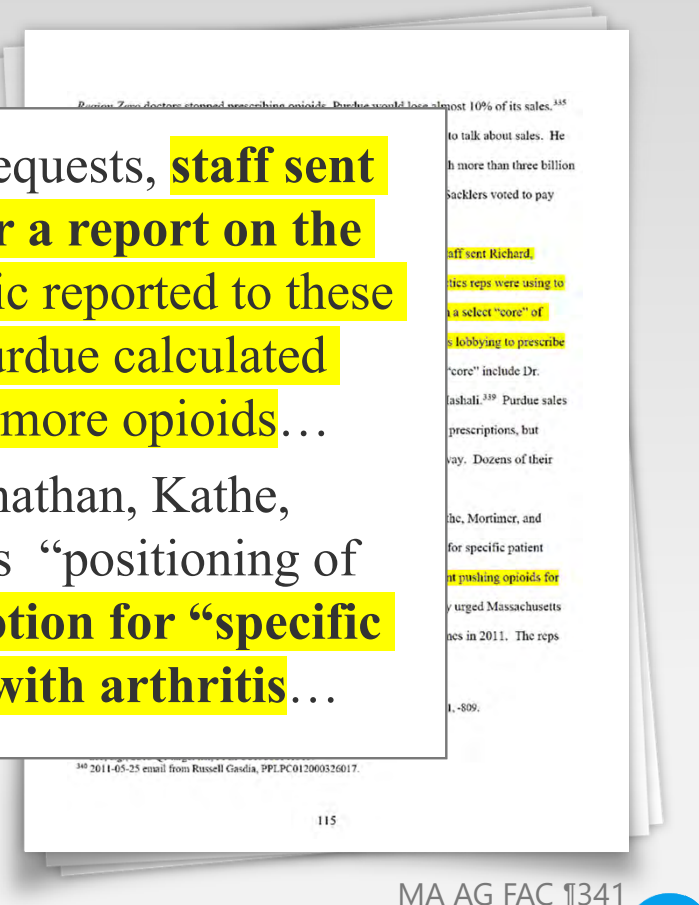
https://millstein.law.columbia.edu/content/millstein-center-publications

Allegation: Report On Tactics To "Push" Butrans Sales

Massachusetts AG FAC ¶¶341-42:

341. In May, in response to the Sacklers' repeated requests, **staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics reps were using to push Butrans.** The first tactic reported to these Sacklers was focusing on a select "core" of physicians that Purdue calculated would be most susceptible to sales reps lobbying to prescribe more opioids…

342. The second tactic staff reported to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler in the May 25, 2011 email was "positioning of Butrans for specific patient types." **In Massachusetts, promotion for "specific patient types" meant pushing opioids for elderly patients with arthritis**…

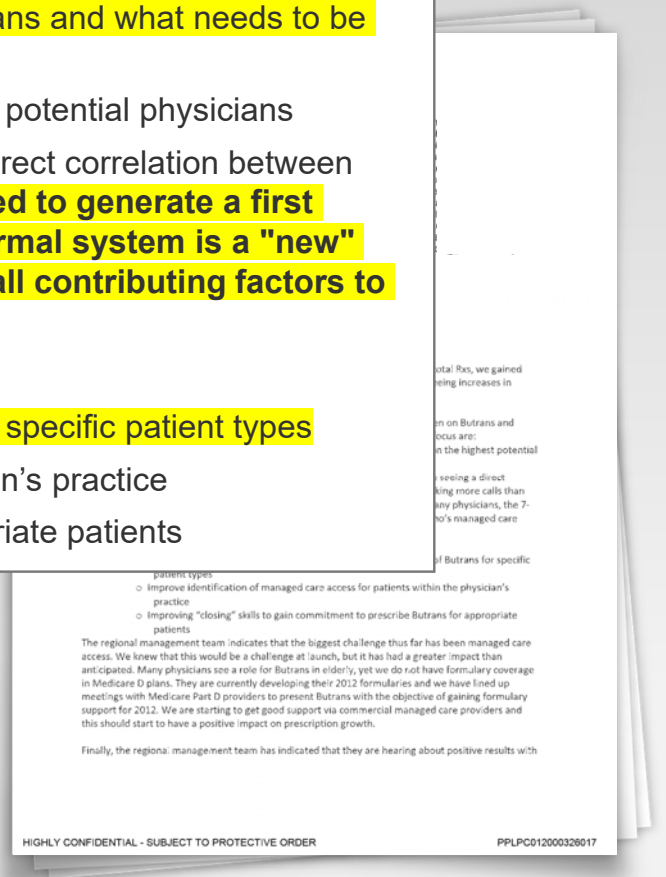


MA AG FAC ¶341

2011 Email: High Level Report On Sales

The regional management team in here this week. A great deal of focus has been on Butrans and what needs to be done to increase growth at a faster pace. The major areas of focus are:

- Improving physician "targeting" to ensure representatives are calling on the highest potential physicians
- Increasing call frequency on a select "super core" of physicians. We are seeing a direct correlation between call activity and results. **The results indicate it is taking more calls than expected to generate a first prescription (buprenorphine is "new" to many physicians, the 7- day transdermal system is a "new" concept and identifying a patient who's managed care plan covers them are all contributing factors to a longer selling cycle)**
- Improving selling skill effectiveness to:
  - Improve specific patient focus on calls and effective positioning of Butrans for specific patient types
  - Improve identification of managed care access for patients within the physician's practice
  - Improving "closing" skills to gain commitment to prescribe Butrans for appropriate patients



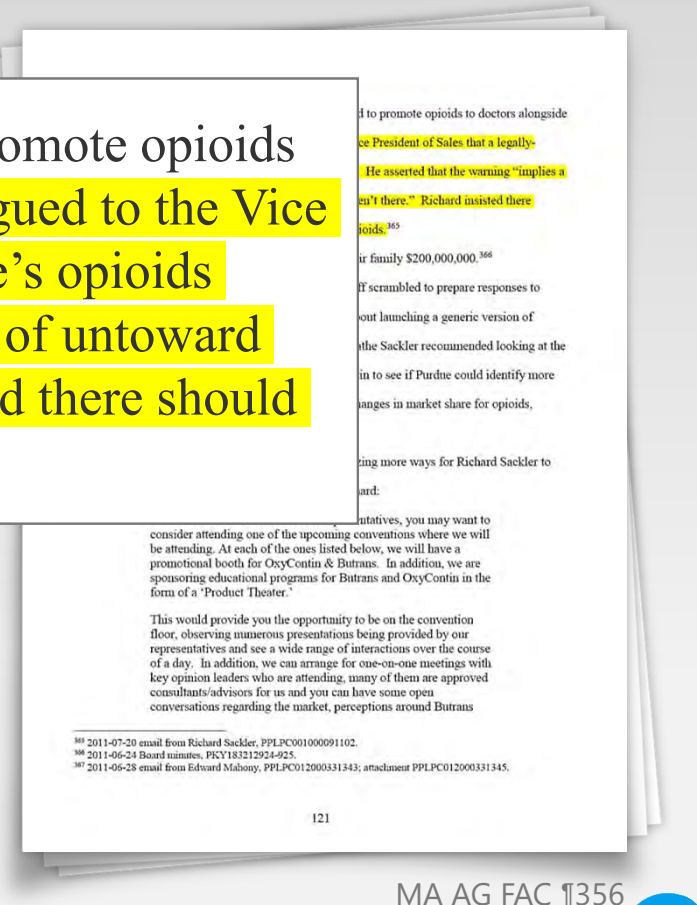
- Butrans, not OxyContin
- No mention of elderly, arthritis or pushing opioids
- Sensible to focus on doctors with proper specialties
- OIG confirmed compliance for 2011

5/25/11 Email from R. Gasdia (PPLPC012000326017)

Allegation: Question About Butrans Warning

Massachusetts AG FAC ¶356:

356. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales rep. When he returned, Richard argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.



- Butrans, not OxyContin
- Richard was told others shared his concern, but the FDA rejected it — that ended the matter
- 2011 email — OIG confirmed compliance for 2011

MA AG FAC ¶356

2011 Email: Question About Butrans Warning

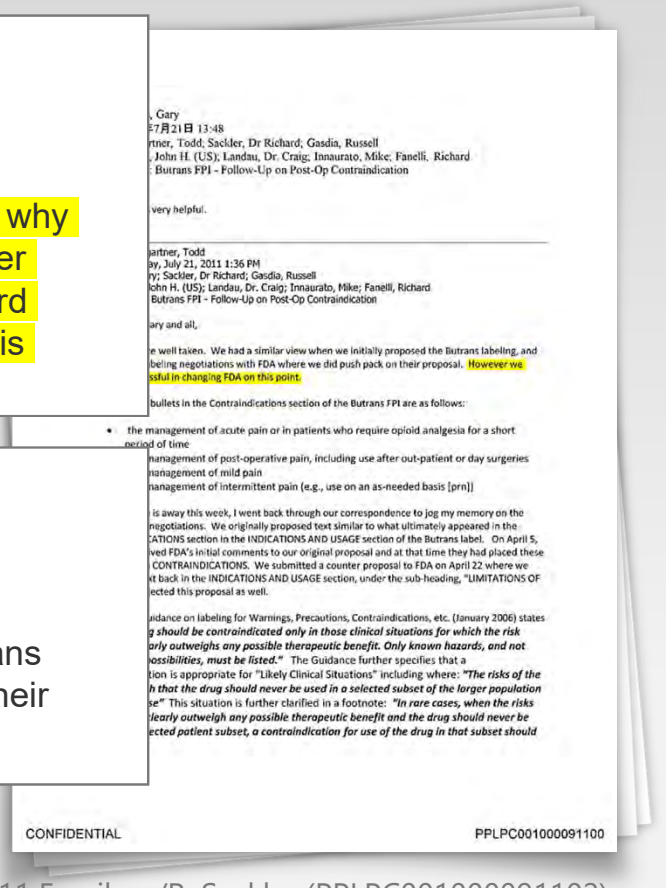
From: Sackler, Dr Richard
Sent: Wednesday, July 20, 2011 9:46 PM
Subject: RE: Butrans FPI – Follow-Up on Post-Op Contraindication

The issue isn't whether we can promote [Butrans for post-operative use]. The issue is why is it "contraindicated" rather than in a less threatening section. It could be in many other sections. Don't you think this is the worst place because it implies a danger of untoward reactions and hazards that simply aren't there to explain when the doctor asks, "what is the hazard?" …

From: Baumgartner, Todd
Sent: Thursday, July 21, 20111:36 PM …

Dr. Richard, Gary and all,

Your points are well taken. We had a similar view when we initially proposed the Butrans labeling, and then during labeling negotiations with FDA where we did push pack on their proposal. However we were unsuccessful in changing FDA on this point.



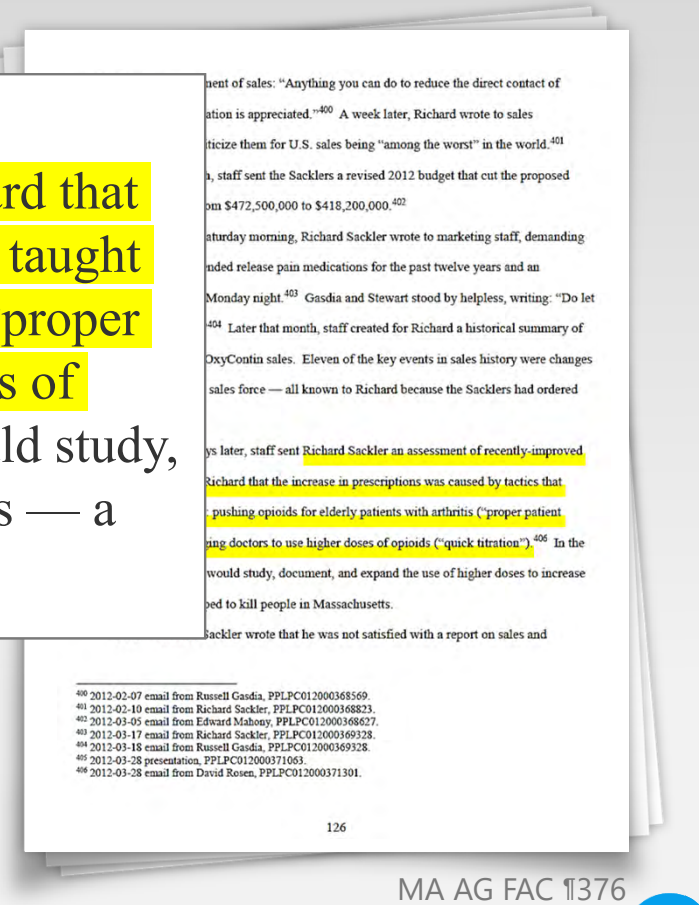
- **No suggestion of impropriety**

7/20/11 Emails w/R. Sackler (PPLPC001000091102)

Allegation: Staff Told Richard Sales Reps Pushed Opioids On Elderly For Arthritis

Massachusetts AG FAC ¶376:

376. A few days later, staff sent Richard Sackler an assessment of recently-improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales reps: pushing opioids for elderly patients with arthritis ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration"). In the coming months, Purdue would study, document, and expand the use of higher doses to increase sales — a tactic that helped to kill people in Massachusetts.

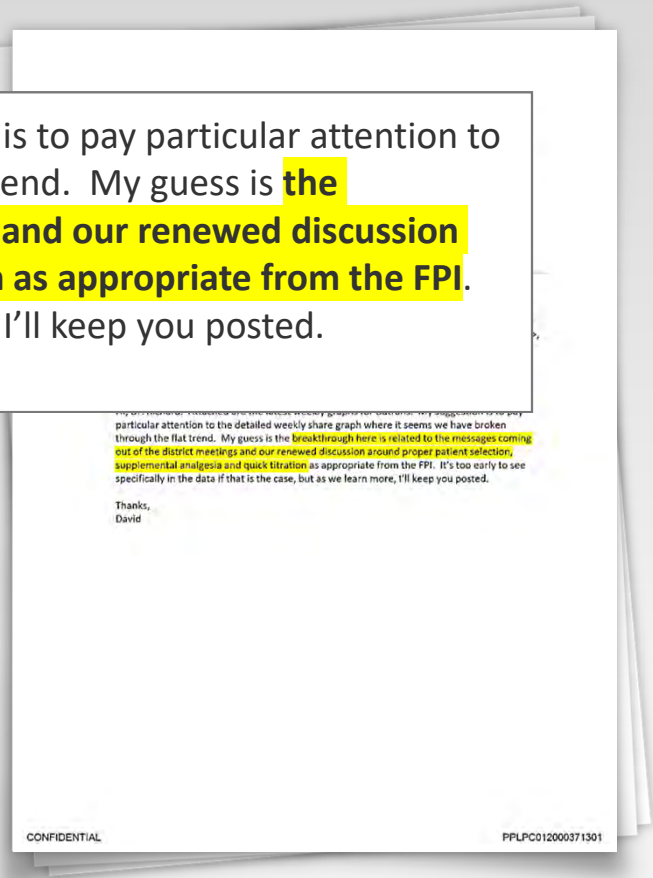

nent of sales: "Anything you can do to reduce the direct contact of
ation is appreciated."[400] A week later, Richard wrote to sales
iticize them for U.S. sales being "among the worst" in the world.[401]
, staff sent the Sacklers a revised 2012 budget that cut the proposed
om $472,500,000 to $418,200,000.[402]
aturday morning, Richard Sackler wrote to marketing staff, demanding
nded release pain medications for the past twelve years and an
Monday night.[403] Gasdia and Stewart stood by helpless, writing: "Do let
[404] Later that month, staff created for Richard a historical summary of
OxyContin sales. Eleven of the key events in sales history were changes
sales force — all known to Richard because the Sacklers had ordered
ys later, staff sent Richard Sackler an assessment of recently-improved
Richard that the increase in prescriptions was caused by tactics that
pushing opioids for elderly patients with arthritis ("proper patient
ing doctors to use higher doses of opioids ("quick titration").[406] In the
would study, document, and expand the use of higher doses to increase
ed to kill people in Massachusetts.
ackler wrote that he was not satisfied with a report on sales and
[400] 2012-02-07 email from Russell Gasdia, PPLPC012000368569.
[401] 2012-02-10 email from Richard Sackler, PPLPC012000368823.
[402] 2012-03-05 email from Edward Mahony, PPLPC012000368627.
[403] 2012-03-17 email from Richard Sackler, PPLPC012000369328.
[404] 2012-03-18 email from Russell Gasdia, PPLPC012000369328.
[405] 2012-03-28 presentation, PPLPC012000371063.
[406] 2012-03-28 email from David Rosen, PPLPC012000371301.
126

MA AG FAC ¶376

2012 Email Concerns Butrans, Does Not Mention Elderly Or Arthritis

HI, Dr. Richard. Attached are the latest weekly graphs for Butrans. My suggestion is to pay particular attention to the detailed weekly share graph where it seems we have broken through the flat trend. My guess is **the breakthrough here is related to the messages coming out of the district meetings and our renewed discussion around proper patient selection, supplemental analgesia and quick quick titration as appropriate from the FPI**. It's too early to see specifically in the data if that is the case, but as we learn more, I'll keep you posted.

- Butrans, not OxyContin
- 2012 email does not mention the elderly or arthritis
- Titration must be per the FDA-approved label ("FPI")
- OIG <u>confirmed compliance</u> for this period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Thanks,
David

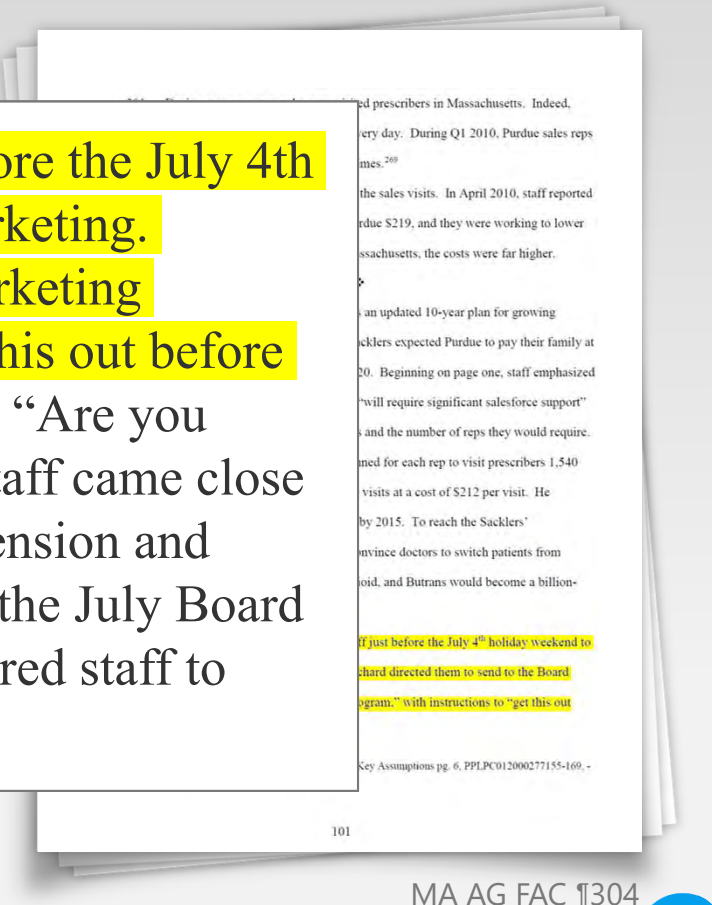
CONFIDENTIAL PPLPC012000371301

3/28/12 Email from D. Rosen (PPLPC012000371301)

Allegation: Demand For Details About Sales And Marketing

Massachusetts AG FAC ¶304:

304. In July, Richard Sackler emailed staff just before the July 4th holiday weekend to demand more details about sales and marketing. Richard directed them to send to the Board plans for "the marketing program" and "the sales program," with instructions to "get this out before the weekend." A despondent staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?" Staff came close to telling Richard Sackler no. Instead, they negotiated an extension and promised to provide full details about sales and marketing at the July Board meeting in Bermuda. To enforce the deal, Kathe Sackler ordered staff to circulate materials before the meeting.


ed prescribers in Massachusetts. Indeed,
ery day. During Q1 2010, Purdue sales reps
mes.[269]
the sales visits. In April 2010, staff reported
rdue $219, and they were working to lower
ssachusetts, the costs were far higher.
an updated 10-year plan for growing
cklers expected Purdue to pay their family at
20. Beginning on page one, staff emphasized
"will require significant salesforce support"
and the number of reps they would require.
ned for each rep to visit prescribers 1,540
visits at a cost of $212 per visit. He
by 2015. To reach the Sacklers'
nvince doctors to switch patients from
oid, and Butrans would become a billion-
f just before the July 4th holiday weekend to
chard directed them to send to the Board
gram," with instructions to "get this out
Key Assumptions pg. 6, PPLPC012000277155-169, -
101

- True but irrelevant

MA AG FAC ¶304

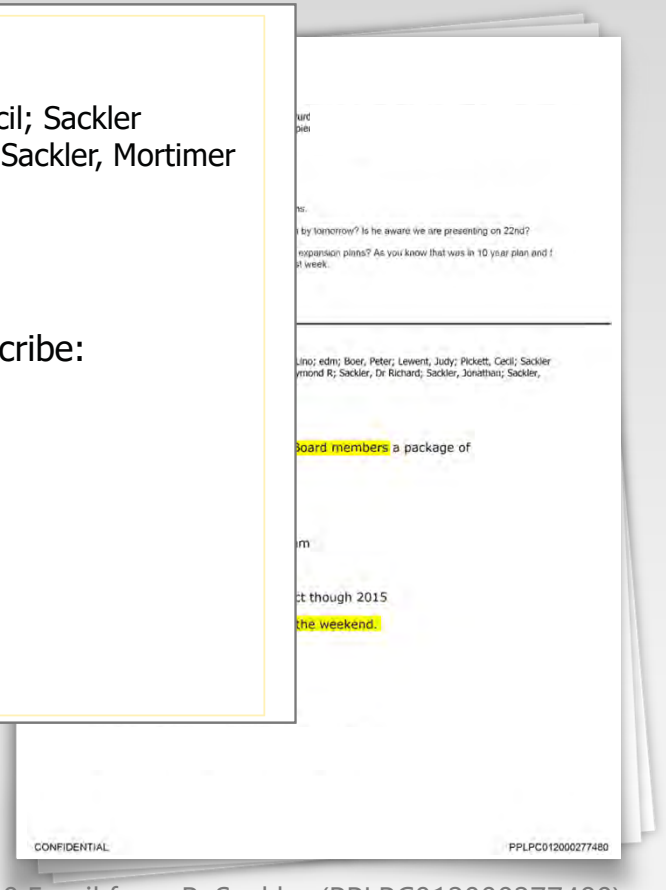
2010 Email: Request For Written Presentation On Five Topics

From: Sackler, Dr Richard
To: JHS (US)
Cc: Gasdia, Russell; Landau, Dr. Craig; Tavares, Lino; edm; Boer, Peter; Lewent, Judy; Pickett, Cecil; Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Dr Raymond R; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer D.A.; Sackler, Theresa
Sent: Thu Jul 01 13:41:33 2010
Subject: Norspan

Please circulate to the interested Board members a package of presentations that describe:

1. The marketing program
2. The sales program
3. The phase 4 research program
4. The 2nd gen patch program
5. The pro forma for the product though 2015

Please try and get this out before the weekend.



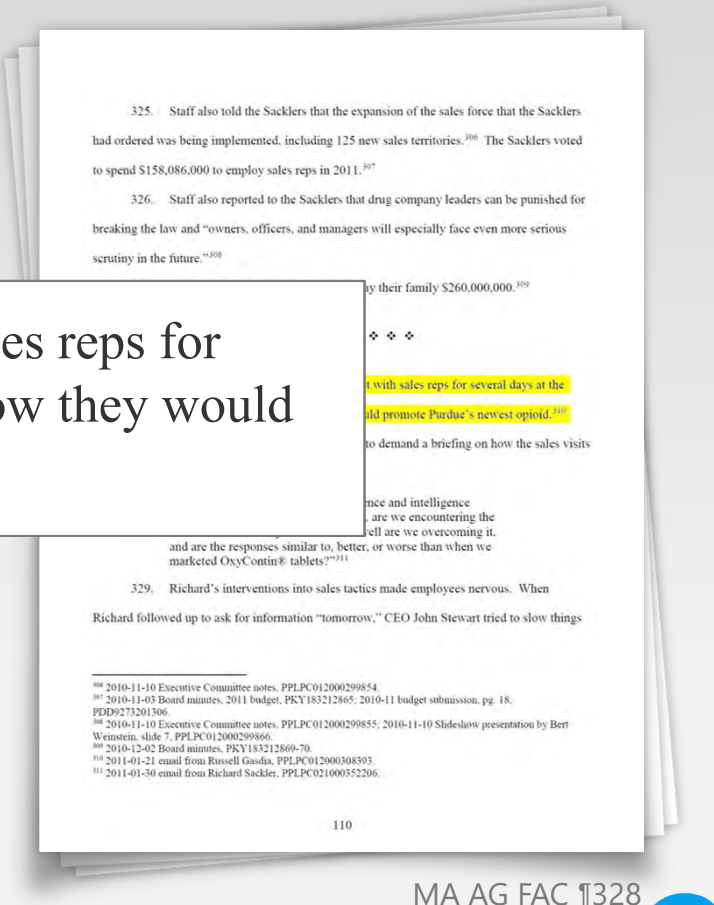
- Butrans, not OxyContin
- OIG confirmed compliance for 2010

7/1/10 Email from R. Sackler (PPLPC012000277480)

Allegation: 2011 Meeting With Sales Reps At Butrans Launch

Massachusetts AG FAC ¶328:

328. In January 2011, Richard Sackler met with sales reps for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid.



325. Staff also told the Sacklers that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories.[306] The Sacklers voted to spend $158,086,000 to employ sales reps in 2011.[307]

326. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and "owners, officers, and managers will especially face even more serious scrutiny in the future."[308]

...y their family $260,000,000.[309]

❖ ❖ ❖

...t with sales reps for several days at the

...ld promote Purdue's newest opioid.[310]

...to demand a briefing on how the sales visits

...nce and intelligence
..., are we encountering the
...ell are we overcoming it.
and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?"[311]

329. Richard's interventions into sales tactics made employees nervous. When Richard followed up to ask for information "tomorrow," CEO John Stewart tried to slow things

[306] 2010-11-10 Executive Committee notes, PPLPC012000299854.
[307] 2010-11-03 Board minutes, 2011 budget, PKY183212865; 2010-11 budget submission, pg. 18, PDD9273201306.
[308] 2010-11-10 Executive Committee notes, PPLPC012000299855; 2010-11-10 Slideshow presentation by Bert Weinstein, slide 7, PPLPC012000299866.
[309] 2010-12-02 Board minutes, PKY183212869-70.
[310] 2011-01-21 email from Russell Gasdia, PPLPC012000308393.
[311] 2011-01-30 email from Richard Sackler, PPLPC021000352206.

110

MA AG FAC ¶328

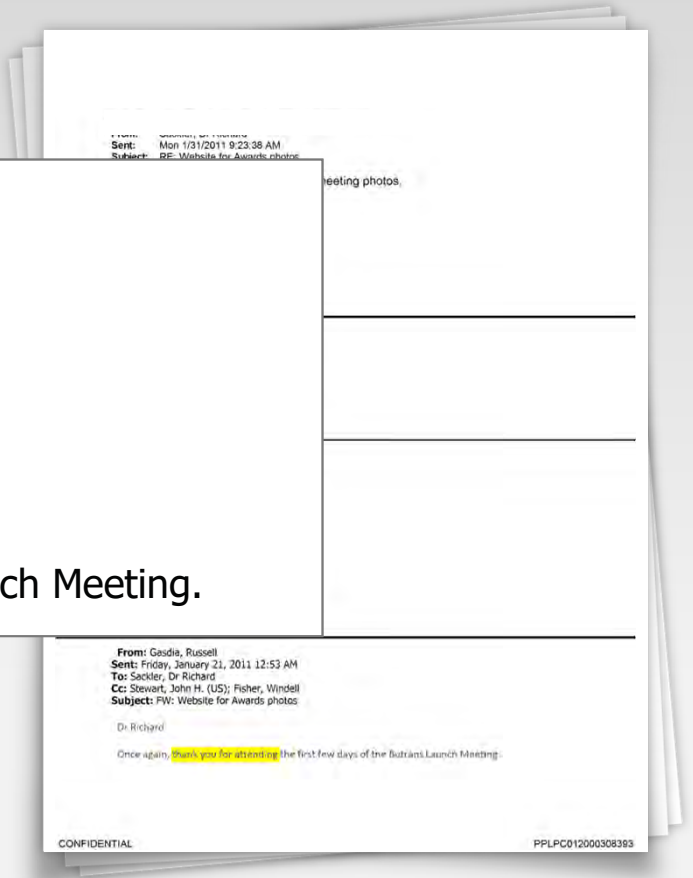
2011 Email Contains No Suggestion of Improper Marketing

- True but irrelevant

From: Gasdia, Russell
Sent: Friday, January 21, 201112:53 AM
To: Sackler, Dr Richard
Cc: Stewart, John H. (US); Fisher, Windell
Subject: FW: Website for Awards photos

Dr Richard

Once again, thank you for attending the first few days of the Butrans Launch Meeting.



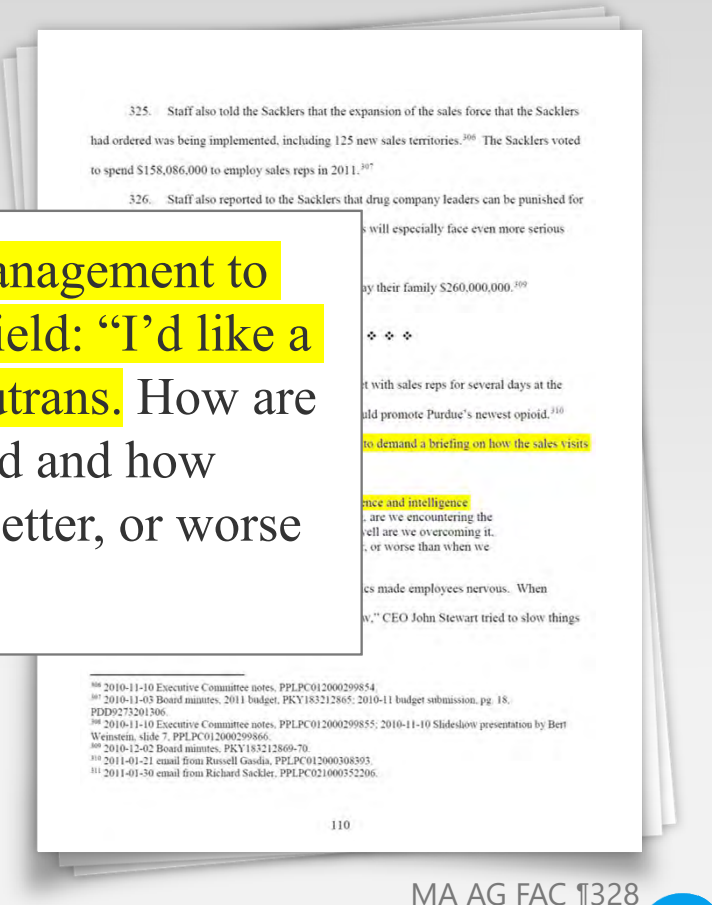
- Butrans, not OxyContin
- OIG confirmed compliance for 2011

1/21/11 Email from R. Gasdia (PPLPC012000308393)

Allegation: Request For Information About Butrans Sales

Massachusetts AG FAC ¶328:

328. …. Richard quickly followed up with sales management to demand a briefing on how the sales visits were going in the field: "I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?"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[306] 2010-11-10 Executive Committee notes, PPLPC012000299854.
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[308] 2010-11-10 Executive Committee notes, PPLPC012000299855; 2010-11-10 Slideshow presentation by Bert Weinstein, slide 7, PPLPC012000299866.
[309] 2010-12-02 Board minutes, PKY183212869-70.
[310] 2011-01-21 email from Russell Gasdia, PPLPC012000308393.
[311] 2011-01-30 email from Richard Sackler, PPLPC012000352206.

110

MA AG FAC ¶328

- True but irrelevant

2011 Email Requests Info About HCP Reactions To Butrans

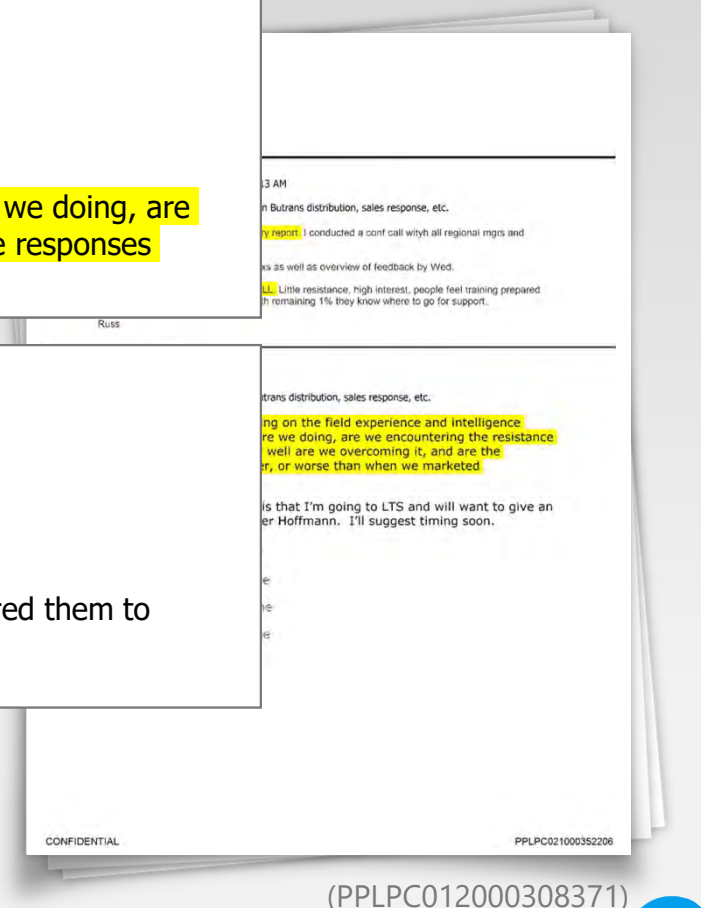
From: Sackler, Dr Richard
To: JHS (US); Gasdia, Russell
Sent: Sun Jan 30 09:48:18 2011
Subject: Going to LTS briefing on Butrans distribution, sales response, etc.

Next week, I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?

From: Gasdia, Russell
Sent: Sunday, January 30, 201111:13 AM
To: Sackler, Dr Richard; JHS (US)
Subject: Re: Going to LTS briefing on Butrans distribution, sales response, etc.

We are developing an exec summary report. …

Top line - things are going VERY WELL. Little resistance, high interest, people feel training prepared them to handle 99% of questions with remaining 1 % they know where to go for support.



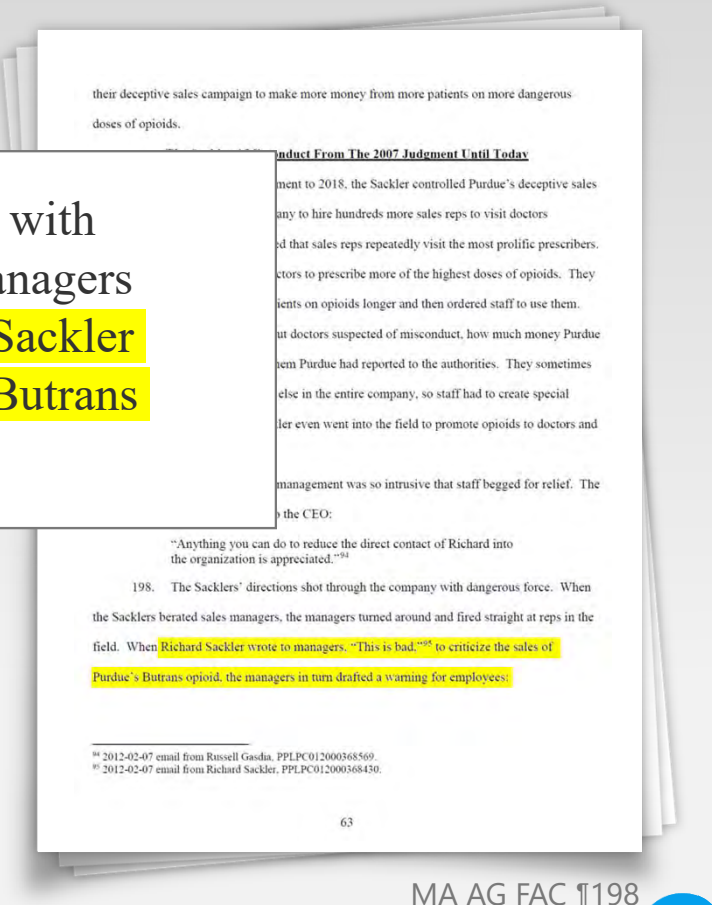
- **Butrans, not OxyContin**
- **OIG confirmed compliance for 2011**

(PPLPC012000308371)

Allegation: "This Is Bad"

Massachusetts AG FAC ¶198:

198. The Sacklers' directions shot through the company with dangerous force. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field. When Richard Sackler wrote to managers, "This is bad," to criticize the sales of Purdue's Butrans opioid, the managers in turn drafted a warning for employees: …


their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

nduct From The 2007 Judgment Until Today

ment to 2018, the Sackler controlled Purdue's deceptive sales
any to hire hundreds more sales reps to visit doctors
d that sales reps repeatedly visit the most prolific prescribers.
ctors to prescribe more of the highest doses of opioids. They
ients on opioids longer and then ordered staff to use them.
ut doctors suspected of misconduct, how much money Purdue
em Purdue had reported to the authorities. They sometimes
else in the entire company, so staff had to create special
ler even went into the field to promote opioids to doctors and

management was so intrusive that staff begged for relief. The
the CEO:

"Anything you can do to reduce the direct contact of Richard into the organization is appreciated."[94]

198. The Sacklers' directions shot through the company with dangerous force. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field. When Richard Sackler wrote to managers, "This is bad,"[95] to criticize the sales of Purdue's Butrans opioid, the managers in turn drafted a warning for employees:

[94] 2012-02-07 email from Russell Gasdia, PPLPC012000368569.
[95] 2012-02-07 email from Richard Sackler, PPLPC012000368430.

63

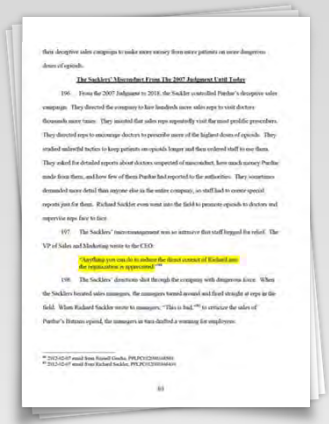
MA AG FAC ¶198

- **Butrans, not OxyContin**
- **2012 email concerning sales, not marketing**
- **OIG confirmed compliance for this period**

Allegation: Alleged "Micromanagement"

Massachusetts AG FAC ¶197:

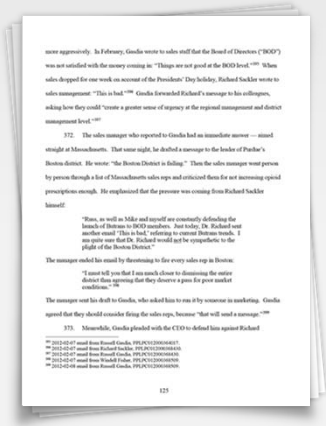
197. The Sacklers' micromanagement was so intrusive that staff begged for relief. The VP of Sales and Marketing wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated."



MA AG FAC ¶197

Massachusetts AG FAC ¶373:

373. Meanwhile, Gasdia pleaded with the CEO to defend him against Richard Sackler's micromanagement of sales: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." A week later, Richard wrote to sales management again to criticize them for U.S. sales being "among the worst" in the world.

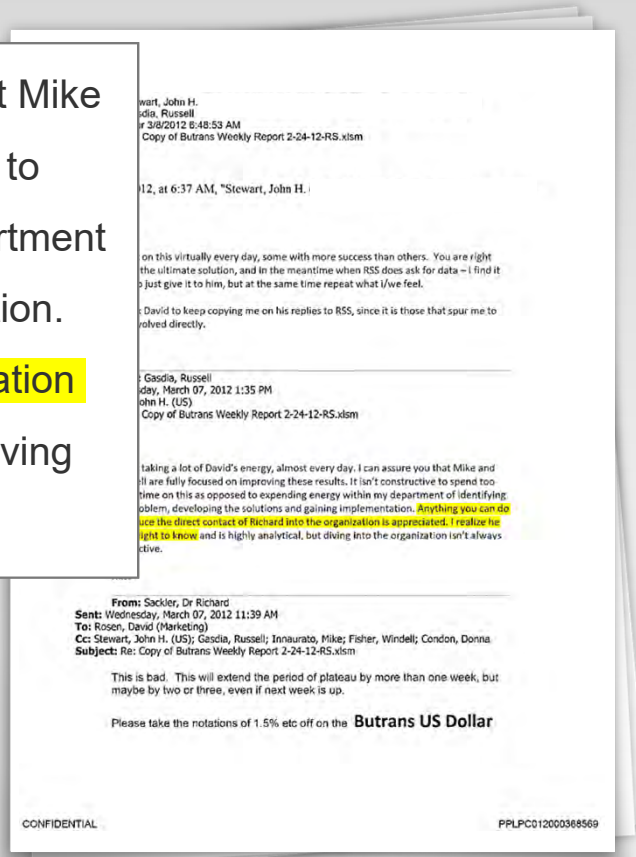


MA AG FAC ¶373

First 2012 Email: Richard Irked Management With Information Requests

March 7, 2012 email from R. Gasdia to J. Stewart

This is taking a lot of David's energy, almost every day. I can assure you that Mike and Windell are fully focused on improving these results. It isn't constructive to spend too much time on this as opposed to expending energy with my department of identifying the problem, developing the solutions and gaining implementation. Anything you can do to reduce the direct contact of Richard into the organization is appreciated. I realize he has a right to know and is highly analytical, but diving into the organization isn't always productive.



wart, John H.
dia, Russell
r 3/8/2012 6:48:53 AM
Copy of Butrans Weekly Report 2-24-12-RS.xlsm

12, at 6:37 AM, "Stewart, John H.

on this virtually every day, some with more success than others. You are right the ultimate solution, and in the meantime when RSS does ask for data – I find it just give it to him, but at the same time repeat what I/we feel.

David to keep copying me on his replies to RSS, since it is those that spur me to olved directly.

Gasdia, Russell
day, March 07, 2012 1:35 PM
ohn H. (US)
Copy of Butrans Weekly Report 2-24-12-RS.xlsm

taking a lot of David's energy, almost every day. I can assure you that Mike and ll are fully focused on improving these results. It isn't constructive to spend too time on this as opposed to expending energy within my department of identifying oblem, developing the solutions and gaining implementation. Anything you can do uce the direct contact of Richard into the organization is appreciated. I realize he ight to know and is highly analytical, but diving into the organization isn't always ctive.

From: Sackler, Dr Richard
Sent: Wednesday, March 07, 2012 11:39 AM
To: Rosen, David (Marketing)
Cc: Stewart, John H. (US); Gasdia, Russell; Innaurato, Mike; Fisher, Windell; Condon, Donna
Subject: Re: Copy of Butrans Weekly Report 2-24-12-RS.xlsm

This is bad. This will extend the period of plateau by more than one week, but maybe by two or three, even if next week is up.

Please take the notations of 1.5% etc off on the **Butrans US Dollar**

CONFIDENTIAL PPLPC012000368569

3/7/12 Email from R. Gasdia (PPLPC012000368569)

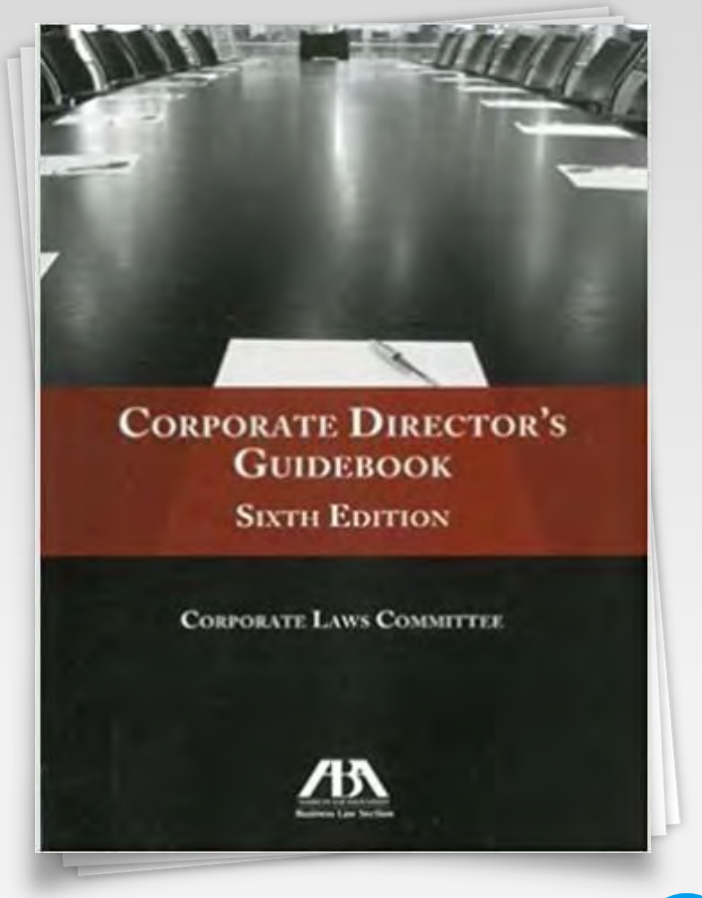
- **Butrans, not OxyContin**
- **Sales, not marketing**
- **OIG confirmed compliance for this period**

Information Requests From Directors Are Important To Good Corporate Governance

ABA Bus L. Sec., Corporate Director's Guidebook at 17 (6th ed. 2011):

"[A]ll directors have both legal and customary rights of access to the information and resources needed to do the job. Among the most important are the rights:

- to inspect books and records;
- to request additional information reasonably necessary to exercise informed oversight and make careful decisions...."



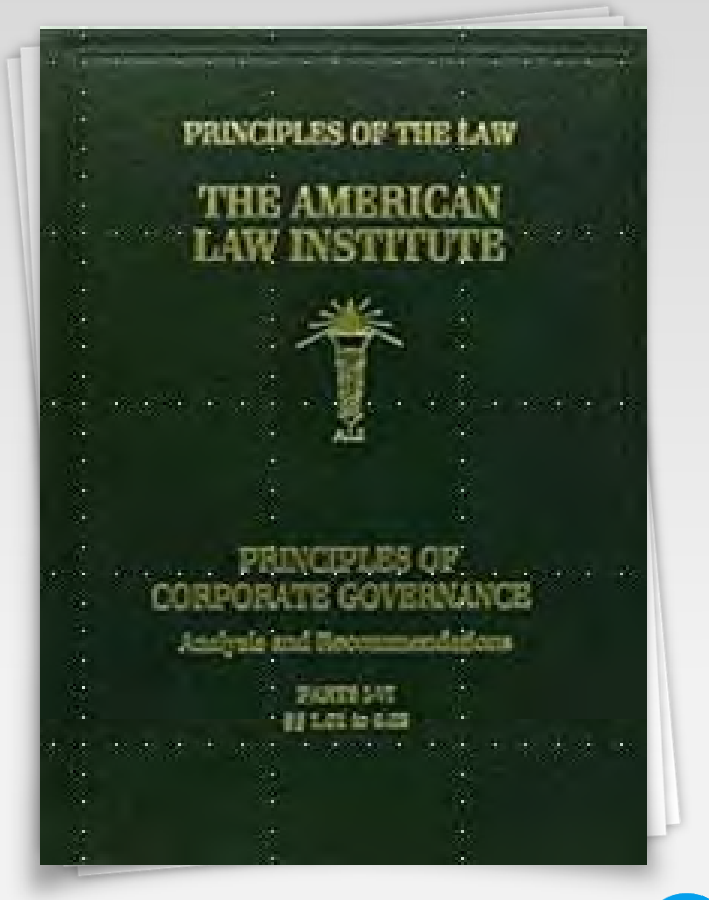
Information Requests From Directors Are Important To Good Corporate Governance

ALI Principles of Corporate Governance:

§ 3.02(a): "The board of directors of a publicly held corporation should perform the following functions: ***

> "(2) Oversee the conduct of the corporation's business to evaluate whether the business is being properly managed"

§ 3.03: "Every director has the right ... to inspect and copy all books, records, and documents of every kind ... of the corporation and of its subsidiaries"



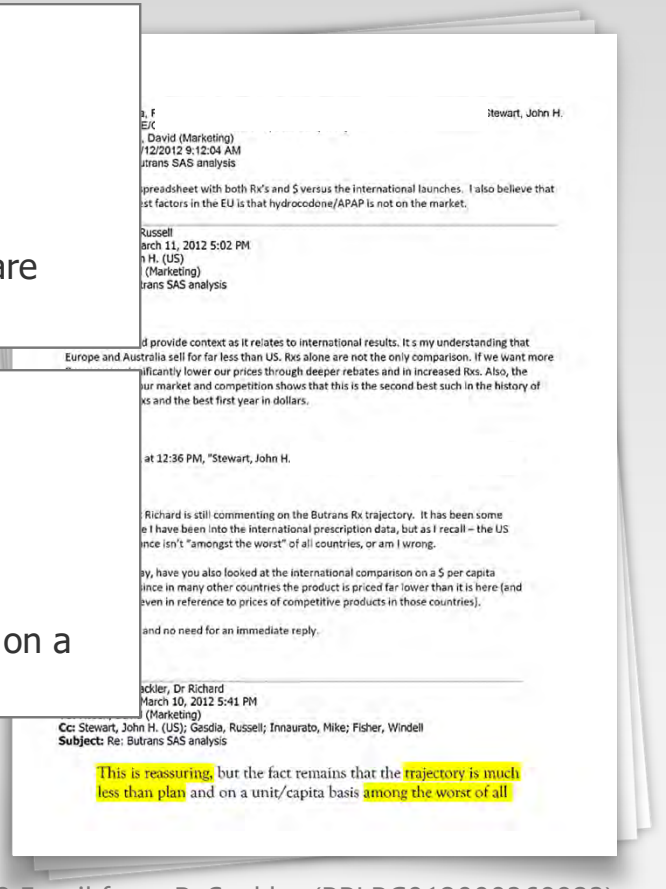
Second 2012 Email: Concern About Butrans Sales Trajectory

From: "Rosen, David (Marketing)"
Date: Fri, 9 Mar 2012 10:16:48 -0500
To: "Richard S. Sackler"
Cc: John Stewart, "Gasdia, Russell", "Innaurato, Mike","Fisher, Windell"
Subject: Butrans SAS analysis

Hi, Dr. Richard. Based on your request, here is a summary our SAS analysis of the share data trends.

From: Sackler, Dr Richard
Sent: Saturday, March 10, 2012 5:41 PM
To: Rosen, David (Marketing)
Cc: Stewart, John H. (US); Gasdia, Russell; Innaurato, Mike; Fisher, Windell
Subject: Re: Butrans SAS analysis

This is reassuring, but the fact remains that the trajectory is much less than plan and on a unit/capita basis among the worst of all the Butrans launches.



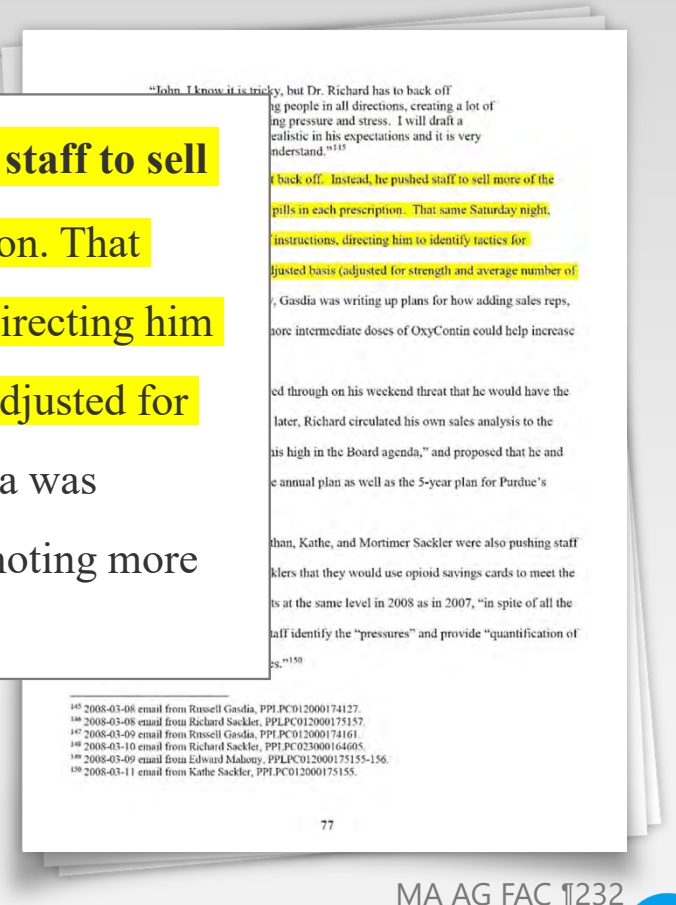
- **Butrans, not OxyContin**
- **OIG <u>confirmed compliance</u> for this period**

3/10/12 Email from R. Sackler (PPLPC012000368823)

Allegation: Richard Pushed To Sell Highest Doses

Massachusetts AG FAC ¶232:

232. **Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids** and get more pills in each prescription. That same Saturday night, Richard sent Gasdia yet another set of instructions, directing him to identify tactics for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)." The very next day, Gasdia was writing up plans for how adding sales reps, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.


"John, I know it is tricky, but Dr. Richard has to back off
ng people in all directions, creating a lot of
ng pressure and stress. I will draft a
ealistic in his expectations and it is very
nderstand."[145]

back off. Instead, he pushed staff to sell more of the

pills in each prescription. That same Saturday night,

instructions, directing him to identify tactics for

djusted basis (adjusted for strength and average number of

, Gasdia was writing up plans for how adding sales reps,

nore intermediate doses of OxyContin could help increase

ed through on his weekend threat that he would have the

later, Richard circulated his own sales analysis to the

his high in the Board agenda," and proposed that he and

e annual plan as well as the 5-year plan for Purdue's

than, Kathe, and Mortimer Sackler were also pushing staff

klers that they would use opioid savings cards to meet the

ts at the same level in 2008 as in 2007, "in spite of all the

taff identify the "pressures" and provide "quantification of

es."[150]

[145] 2008-03-08 email from Russell Gasdia, PPLPC012000174127.
[146] 2008-03-08 email from Richard Sackler, PPLPC012000175157.
[147] 2008-03-09 email from Russell Gasdia, PPLPC012000174161.
[148] 2008-03-10 email from Richard Sackler, PPLPC023000164605.
[149] 2008-03-09 email from Edward Mahony, PPLPC012000175155-156.
[150] 2008-03-11 email from Kathe Sackler, PPLPC012000175155.

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MA AG FAC ¶232

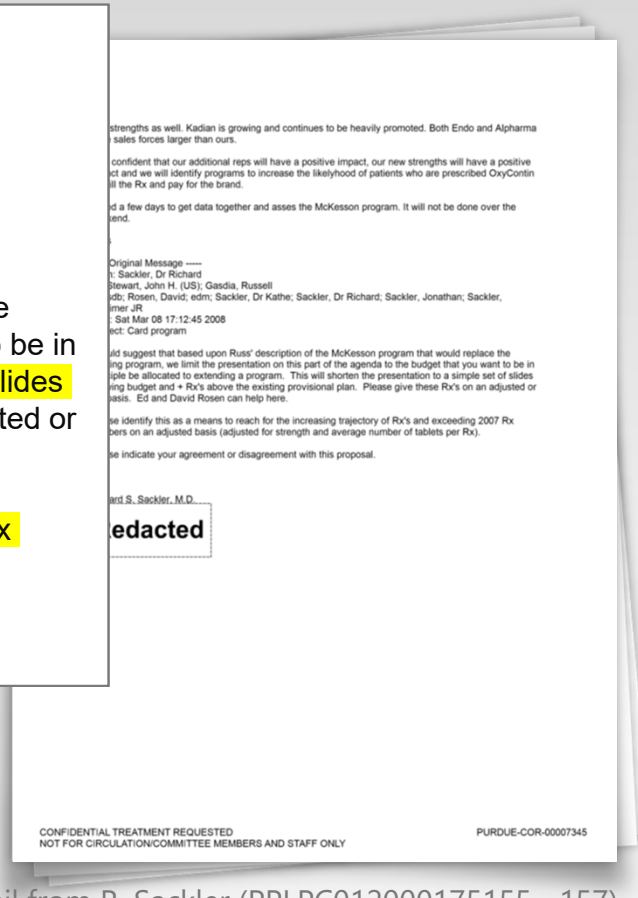
2008 Email Concerns Higher Sales, Not Higher Doses

From: Sackler, Dr Richard
To: Stewart, John H. (US); Gasdia, Russell
Cc: sdb; Rosen, David; edm; Sackler, Dr Kathe; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer JR
Sent: Sat Mar 08 17:12:45 2008
Subject: Card program

I would suggest that based upon Russ' description of the McKesson program that would replace the existing program, we limit the presentation on this part of the agenda to the budget that you want to be in principle be allocated to extending a program. This will shorten the presentation to a simple set of slides showing budget and + Rx's above the existing provisional plan. Please give these Rx's on an adjusted or KG basis. Ed and David Rosen can help here.

Please identify this as a means to reach for the increasing trajectory of Rx's and exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx).

Please indicate your agreement or disagreement with this proposal.



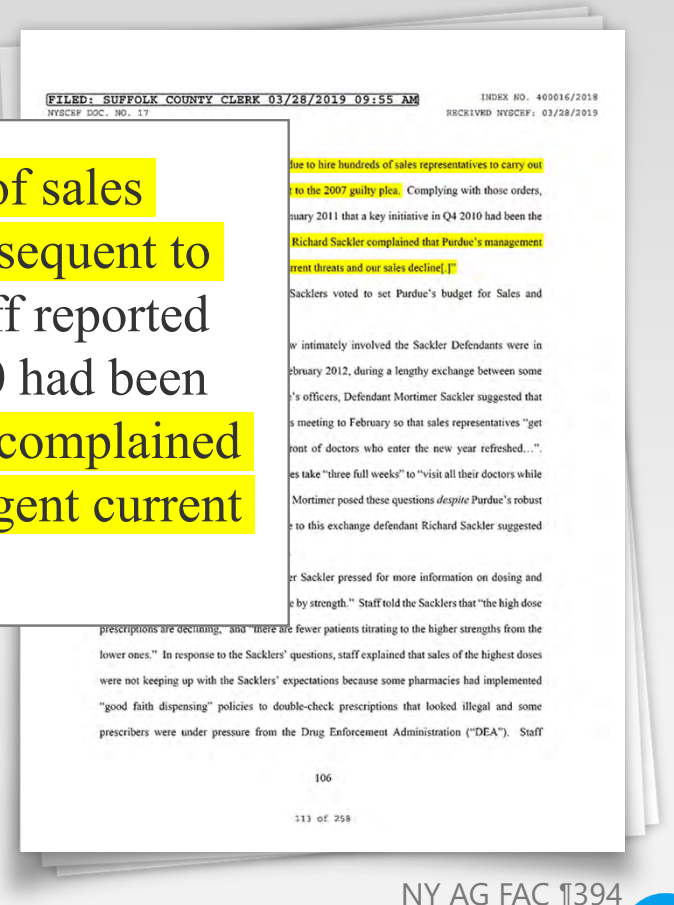
- **2008 email urges higher sales, not higher doses**
- **OIG confirmed compliance for 2008**

3/8/08 Email from R. Sackler (PPLPC012000175155, -157)

Allegation: Board Directed Sales Force Hike; Richard Concerned About Sales

New York AG FAC ¶394:

394. The Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign subsequent to the 2007 guilty plea. Complying with those orders, Purdue staff reported to the Sacklers in January 2011 that a key initiative in Q4 2010 had been the expansion of the sales force. But in 2012, Richard Sackler complained that Purdue's management was not sufficiently focused on "urgent current threats and our sales decline[.]"


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

...due to hire hundreds of sales representatives to carry out ...t to the 2007 guilty plea. Complying with those orders, ...nuary 2011 that a key initiative in Q4 2010 had been the ... Richard Sackler complained that Purdue's management ...rrent threats and our sales decline[.]"

Sacklers voted to set Purdue's budget for Sales and ...

...w intimately involved the Sackler Defendants were in ...ebruary 2012, during a lengthy exchange between some ...'s officers, Defendant Mortimer Sackler suggested that ...s meeting to February so that sales representatives "get ...ront of doctors who enter the new year refreshed...". ...es take "three full weeks" to "visit all their doctors while ... Mortimer posed these questions *despite* Purdue's robust ...e to this exchange defendant Richard Sackler suggested ...

...er Sackler pressed for more information on dosing and ...e by strength." Staff told the Sacklers that "the high dose prescriptions are declining, and there are fewer patients titrating to the higher strengths from the lower ones." In response to the Sacklers' questions, staff explained that sales of the highest doses were not keeping up with the Sacklers' expectations because some pharmacies had implemented "good faith dispensing" policies to double-check prescriptions that looked illegal and some prescribers were under pressure from the Drug Enforcement Administration ("DEA"). Staff

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113 of 258

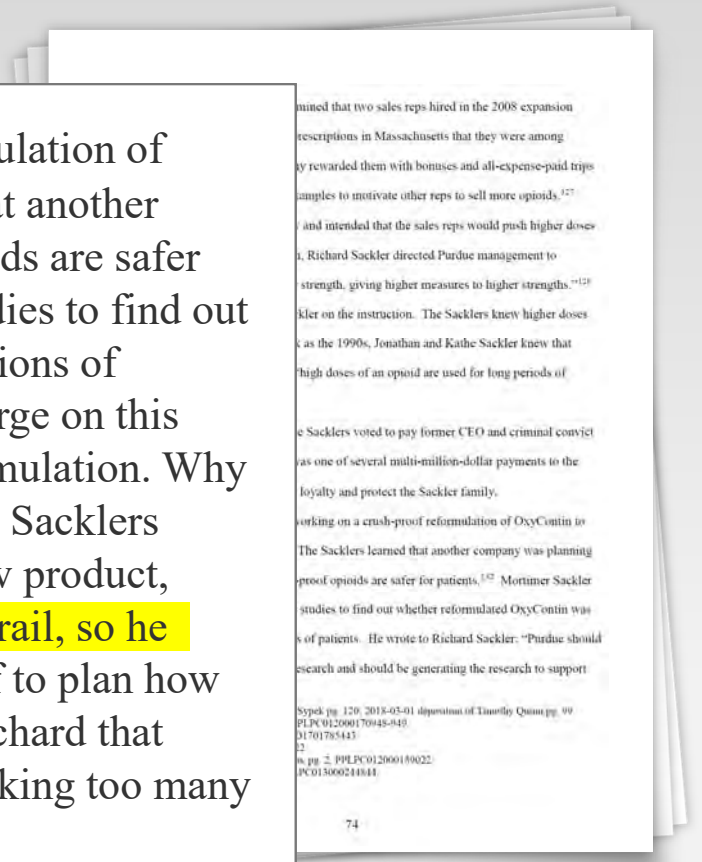
NY AG FAC ¶394

- **OIG confirmed compliance for this period**

Allegation: No "Paper Trail"

Massachusetts AG FAC ¶228:

228. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids are safer for patients. Mortimer Sackler suggested that Purdue conduct similar studies to find out whether reformulated OxyContin was really safer before selling it to millions of patients. He wrote to Richard Sackler: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up …? Shouldn't we have studies like this …?" The Sacklers decided not to do the research because they wanted the profits from a new product, regardless of whether the deaths continued. Richard didn't want a paper trail, so he instructed Mortimer to call him, and CEO John Stewart met with his staff to plan how to phrase a carefully worded reply. Later that month, Stewart wrote to Richard that reformulating OxyContin "will not stop patients from the simple act of taking too many pills."



MA AG FAC ¶228

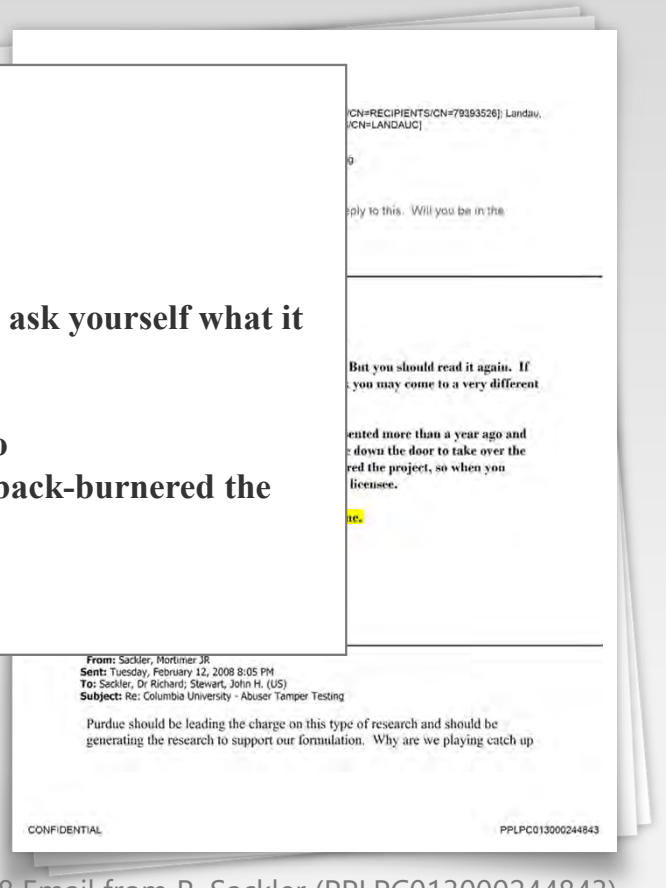
2008 Email Requests A Phone Call To Discuss A Study

From: Sackler, Dr Richard
Sent: Tuesday, February 12, 2008 8:26 PM
To: Sackler, Mortimer JR
Cc: Stewart, John H. (US)
Subject: RE: Columbia University - Abuser Tamper Testing

My sentiments exactly the first time I read it. But you should read it again. If you do and ask yourself what it means, I think you may come to a very different conclusion, as I now have.

The reason I sent it to you was that it was presented more than a year ago and perhaps to surprise, no one broke down the door to take over the product. We know that they have back-burnered the project, so when you reread it, ask yourself why it didn't generate a licensee.

We should talk about it. Give me a call at home.



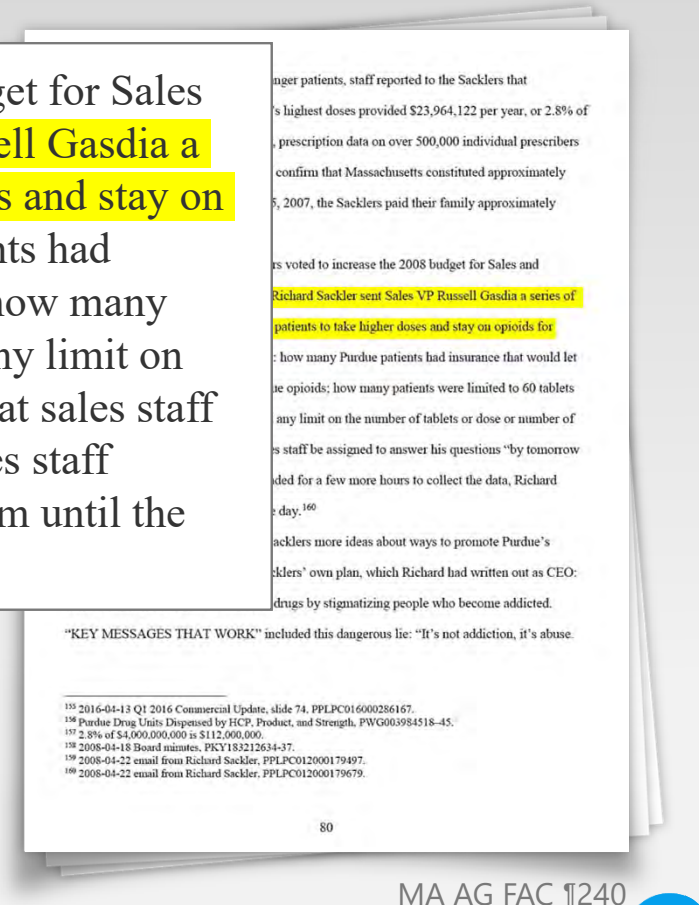
- Innocuous email about a Columbia University study
- OIG confirmed compliance for 2008

2/12/08 Email from R. Sackler (PPLPC013000244843)

Allegation: Demands To Get Patients On Higher Doses, For Longer Times

Massachusetts AG FAC ¶240:

240. On April 18, the Sacklers voted to increase the 2008 budget for Sales and Promotion to $155,802,000. Then, Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard wanted to know: how many Purdue patients had insurance that would let them take unlimited quantities of Purdue opioids; how many patients were limited to 60 tablets per month; and how many patients had any limit on the number of tablets or dose or number of tablets per day. He demanded that sales staff be assigned to answer his questions "by tomorrow morning." When the sales staff pleaded for a few more hours to collect the data, Richard agreed to give them until the end of the day.


nger patients, staff reported to the Sacklers that
's highest doses provided $23,964,122 per year, or 2.8% of
, prescription data on over 500,000 individual prescribers
confirm that Massachusetts constituted approximately
5, 2007, the Sacklers paid their family approximately

rs voted to increase the 2008 budget for Sales and
Richard Sackler sent Sales VP Russell Gasdia a series of
patients to take higher doses and stay on opioids for
: how many Purdue patients had insurance that would let
ie opioids; how many patients were limited to 60 tablets
any limit on the number of tablets or dose or number of
s staff be assigned to answer his questions "by tomorrow
ded for a few more hours to collect the data, Richard
day.[160]

acklers more ideas about ways to promote Purdue's
klers' own plan, which Richard had written out as CEO:
drugs by stigmatizing people who become addicted.

"KEY MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse.

[155] 2016-04-13 Q1 2016 Commercial Update, slide 74, PPLPC016000286167.
[156] Purdue Drug Units Dispensed by HCP, Product, and Strength, PWG003984518-45.
[157] 2.8% of $4,000,000,000 is $112,000,000.
[158] 2008-04-18 Board minutes, PKY183212634-37.
[159] 2008-04-22 email from Richard Sackler, PPLPC012000179497.
[160] 2008-04-22 email from Richard Sackler, PPLPC012000179679.

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MA AG FAC ¶240

2008 Email: Insurance Questions

From: Sackler, Dr Richard
Sent: Tuesday, April 22, 2008 11:51 AM
To: Gasdia, Russell; Innaurato, Mike
Subject: Covered lives
Importance: High

What is the status of covered lives now with OxyContin?

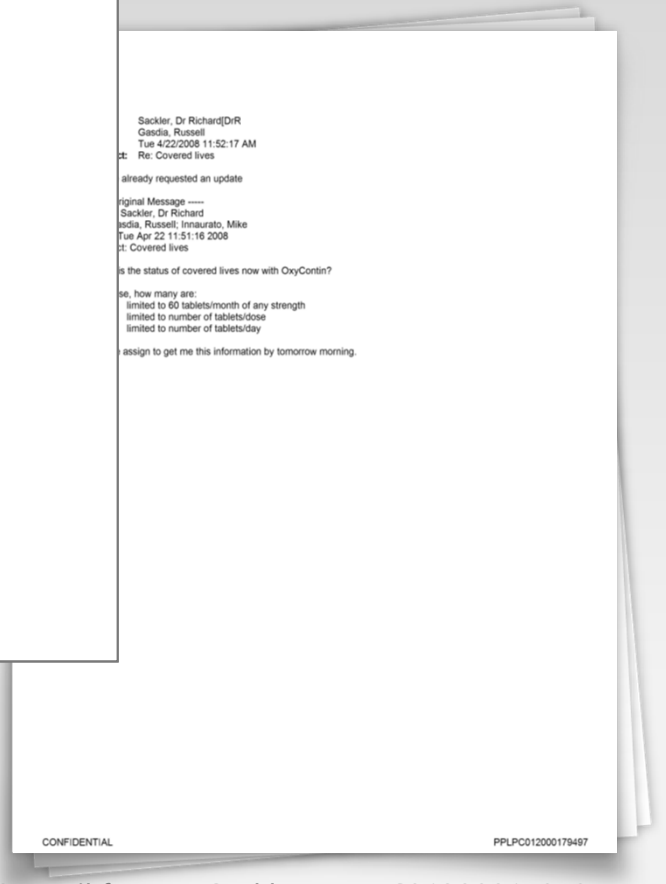
Of these, how many are:

1. limited to 60 tablets/month of any strength

2. limited to number of tablets/dose

3. limited to number of tablets/day

please assign to get me this information by tomorrow morning.



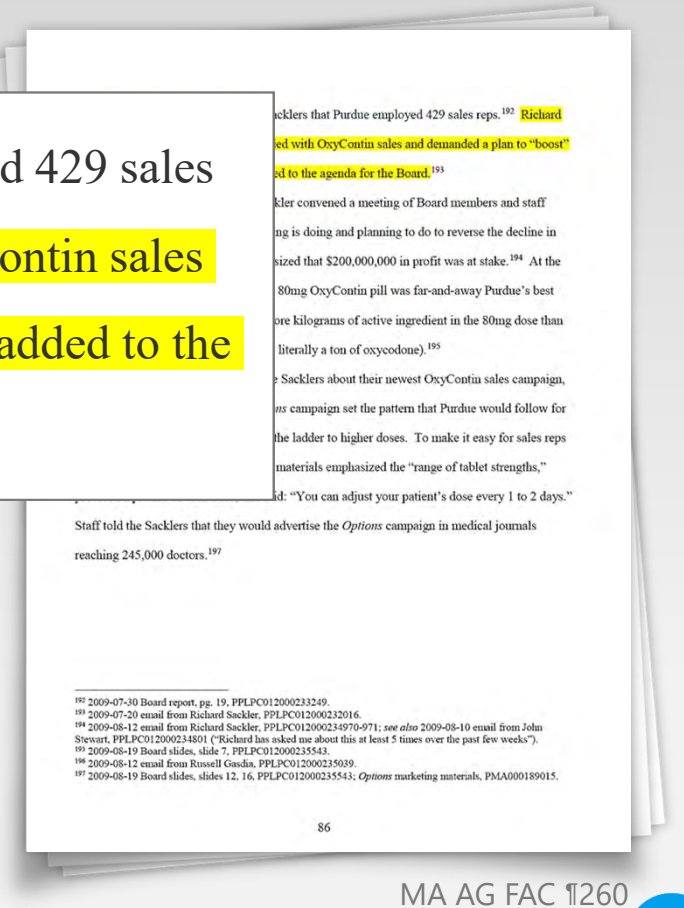
- No promotion of higher doses
- Email asks about insurance limitations on the number of tablets per month covered
- OIG confirmed compliance for 2008

4/22/08 Email from R. Sackler (PPLPC012000179497)

Allegation: Demands To "Boost" Sales

Massachusetts AG FAC ¶260:

260. In July, staff told the Sacklers that Purdue employed 429 sales reps. Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to "boost" them. He asked for the topic to be added to the agenda for the Board.


acklers that Purdue employed 429 sales reps.[192] Richard
ed with OxyContin sales and demanded a plan to "boost"
d to the agenda for the Board.[193]
kler convened a meeting of Board members and staff
ng is doing and planning to do to reverse the decline in
sized that $200,000,000 in profit was at stake.[194] At the
80mg OxyContin pill was far-and-away Purdue's best
ore kilograms of active ingredient in the 80mg dose than
literally a ton of oxycodone).[195]
Sacklers about their newest OxyContin sales campaign,
ns campaign set the pattern that Purdue would follow for
he ladder to higher doses. To make it easy for sales reps
materials emphasized the "range of tablet strengths,"
d: "You can adjust your patient's dose every 1 to 2 days."
Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.[197]

[192] 2009-07-30 Board report, pg. 19, PPLPC012000233249.
[193] 2009-07-20 email from Richard Sackler, PPLPC012000232016.
[194] 2009-08-12 email from Richard Sackler, PPLPC012000234970-971; *see also* 2009-08-10 email from John Stewart, PPLPC012000234801 ("Richard has asked me about this at least 5 times over the past few weeks").
[195] 2009-08-19 Board slides, slide 7, PPLPC012000235543.
[196] 2009-08-12 email from Russell Gasdia, PPLPC012000235039.
[197] 2009-08-19 Board slides, slides 12, 16, PPLPC012000235543; *Options* marketing materials, PMA00189015.

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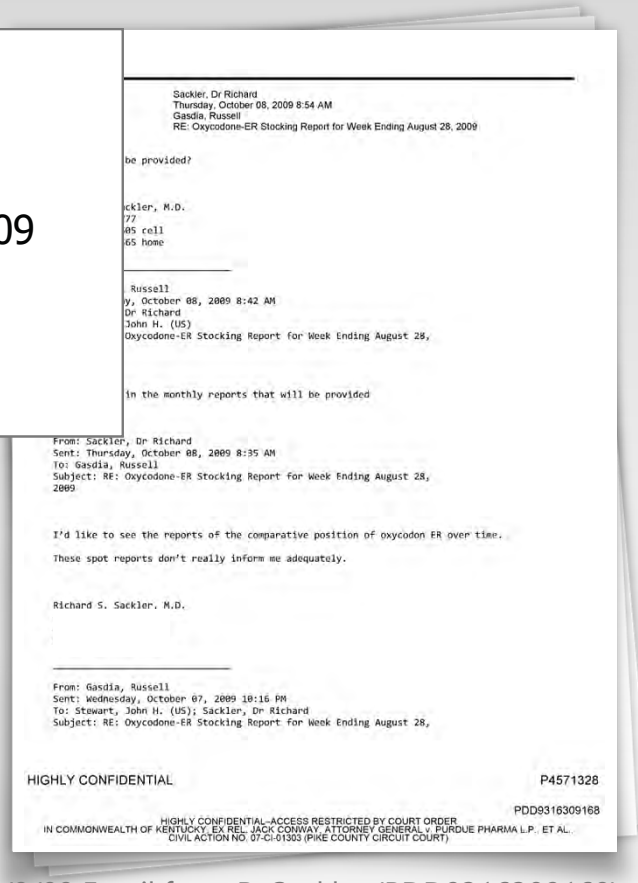
MA AG FAC ¶260

2009 Emails: No Demands To "Boost" Sales

From: Sackler, Dr Richard
Sent: Wednesday, October 07, 2009 8:21 AM
To: Stewart, John H. (US)
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

John,

Are we continuing to make progress with OER and OxyContin® tablets?



Sackler, Dr Richard
Thursday, October 08, 2009 8:54 AM
Gasdia, Russell
RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

be provided?

ckler, M.D.
77
05 cell
65 home

Russell
y, October 08, 2009 8:42 AM
Dr Richard
John H. (US)
Oxycodone-ER Stocking Report for Week Ending August 28,

in the monthly reports that will be provided

From: Sackler, Dr Richard
Sent: Thursday, October 08, 2009 8:35 AM
To: Gasdia, Russell
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

I'd like to see the reports of the comparative position of oxycodon ER over time.

These spot reports don't really inform me adequately.

Richard S. Sackler. M.D.

From: Gasdia, Russell
Sent: Wednesday, October 07, 2009 10:16 PM
To: Stewart, John H. (US); Sackler, Dr Richard
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28,

HIGHLY CONFIDENTIAL P4571328

PDD9316309168

HIGHLY CONFIDENTIAL–ACCESS RESTRICTED BY COURT ORDER
IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL.
CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

10/8/09 Email from R. Sackler (PDD9316309168)

- Email asks about progress with sales
- No reference to boosting sales
- OIG confirmed compliance for 2009

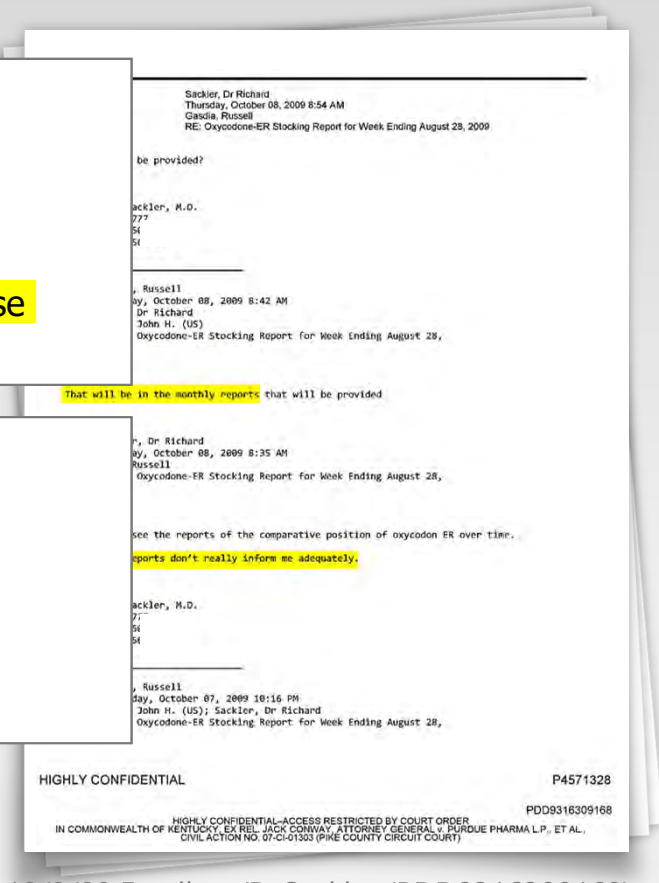
2009 Emails: No Demands To "Boost" Sales

From: Sackler, Dr Richard
Sent: Thursday, October 08, 2009 8:35 AM
To: Gasdia, Russell
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

I'd like to see the reports of the comparative position of oxycodon ER over time. These spot reports don't really inform me adequately.

From: Gasdia, Russell
Sent: Thursday, October 08, 2009 8:42 AM
To: Sackler, Dr Richard
Cc: Stewart, John H. (US)
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

That will be in the monthly reports that will be provided



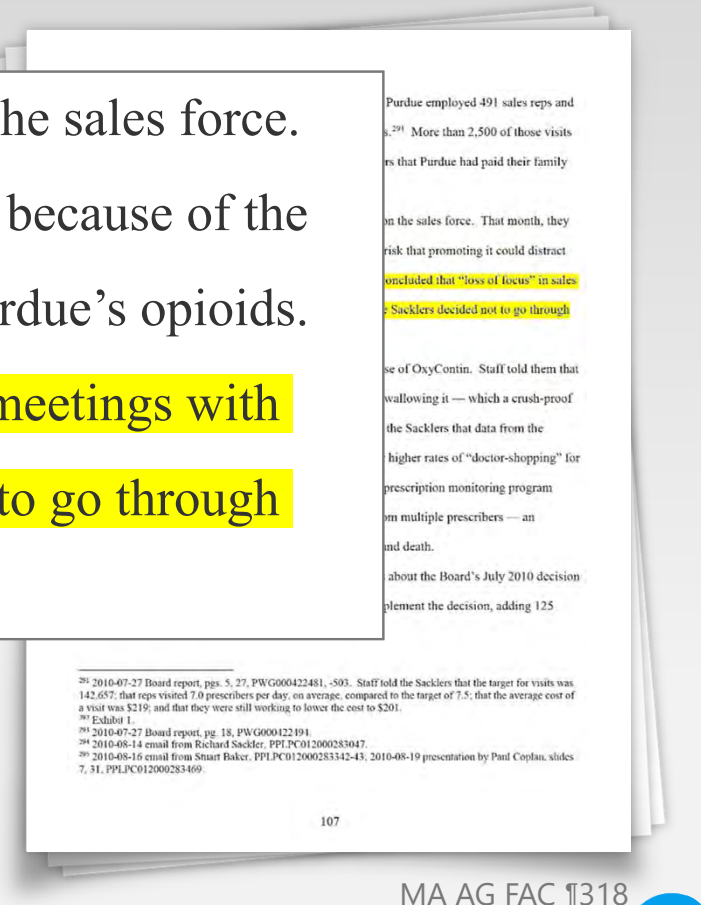
- Appropriate request for adequate information
- OIG confirmed compliance for 2009

10/8/09 Emails w/R. Sackler (PDD9316309168)

Allegation: Decision Not To Acquire Insomnia Drug

Massachusetts AG FAC ¶318:

318. In August, the Sacklers continued to focus on the sales force. That month, they decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales reps from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales reps' meetings with prescribers was too great a risk, and the Sacklers decided not to go through with the deal.

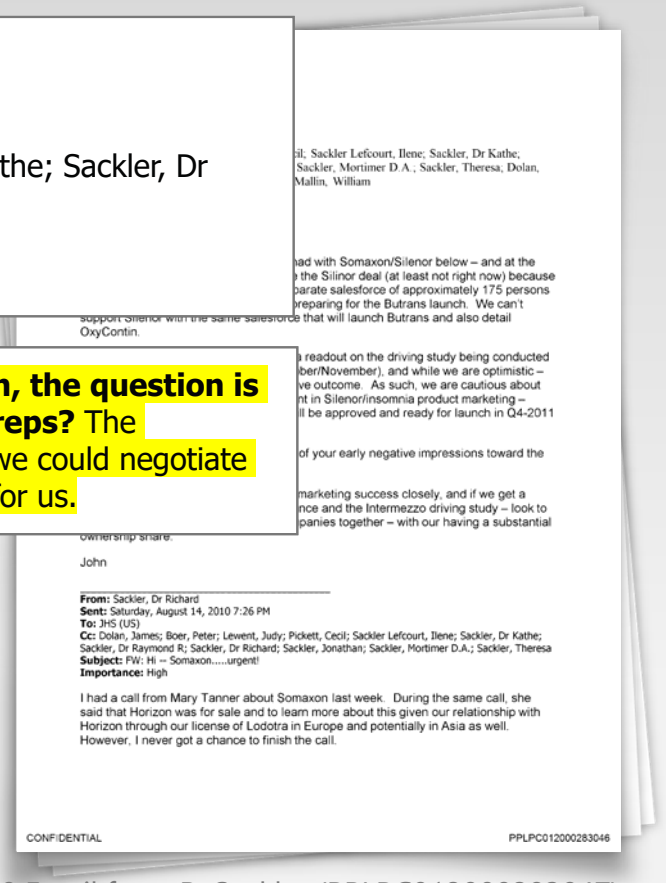

Purdue employed 491 sales reps and
s.[291] More than 2,500 of those visits
rs that Purdue had paid their family
on the sales force. That month, they
risk that promoting it could distract
oncluded that "loss of focus" in sales
Sacklers decided not to go through
se of OxyContin. Staff told them that
wallowing it — which a crush-proof
the Sacklers that data from the
higher rates of "doctor-shopping" for
prescription monitoring program
om multiple prescribers — an
nd death.
about the Board's July 2010 decision
plement the decision, adding 125
[291] 2010-07-27 Board report, pgs. 5, 27, PWG000422481, -503. Staff told the Sacklers that the target for visits was 142,657; that reps visited 7.0 prescribers per day, on average, compared to the target of 7.5; that the average cost of a visit was $219; and that they were still working to lower the cost to $201.
[292] Exhibit 1.
[293] 2010-07-27 Board report, pg. 18, PWG000122191.
[294] 2010-08-14 email from Richard Sackler, PPLPC012000283047.
[295] 2010-08-16 email from Stuart Baker, PPLPC012000283342-43; 2010-08-19 presentation by Paul Coplan, slides 7, 31, PPLPC012000283469.
107

MA AG FAC ¶318

2010 Email: Concern About Launching Two Products Simultaneously

From: Sackler, Dr Richard
Sent: Saturday, August 14, 2010 7:26 PM
To: JHS (US)
Cc: Dolan, James; Boer, Peter; Lewent, Judy; Pickett, Cecil; Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Dr Raymond R; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer D.A.; Sackler, Theresa
Subject: FW: Hi -- Somaxon ..... urgent!
Importance: High

... **I'm not sure when Silenor will launch, but assuming it is close to the Butrans launch, the question is raised how can we successfully launch two products at the same time with the same reps?** The complexities of loss of focus on the calls seems great. But if **there were a way to do it**, and if we could negotiate a deal that would give us options to commit only after we saw success, it would be a sweet deal for us.



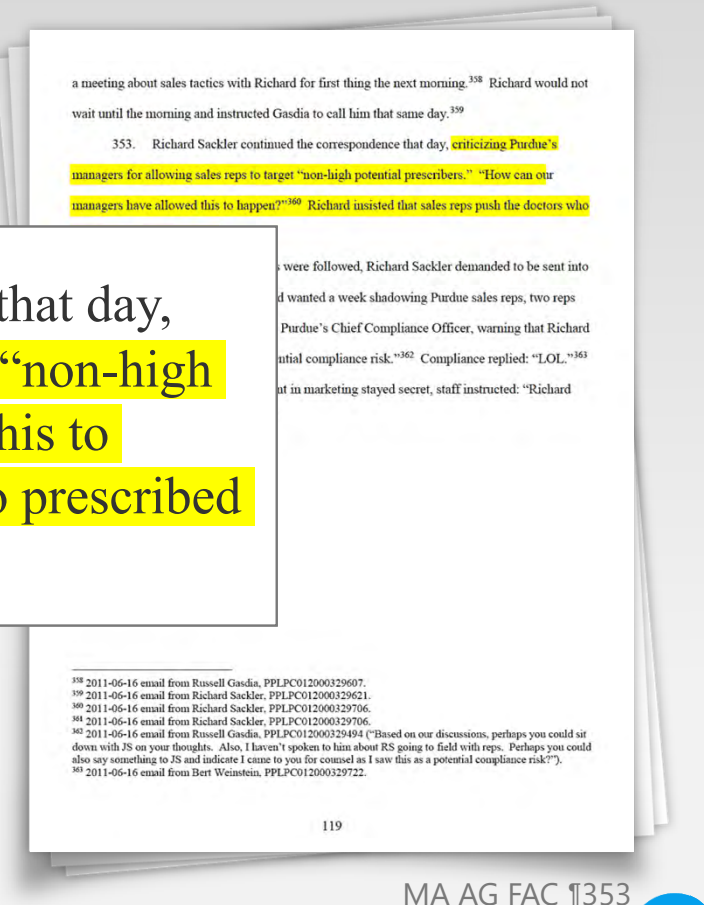
- Email questions launching two products at once
- OIG confirmed compliance for 2010

8/14/10 Email from R. Sackler (PPLPC012000283047)

Allegation: Criticism For Not Targeting High Potential Prescribers

Massachusetts AG FAC ¶353:

353. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales reps to target "non-high potential prescribers." "How can our managers have allowed this to happen?" Richard insisted that sales reps push the doctors who prescribed the most drugs.



a meeting about sales tactics with Richard for first thing the next morning.[358] Richard would not wait until the morning and instructed Gasdia to call him that same day.[359]

353. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales reps to target "non-high potential prescribers." "How can our managers have allowed this to happen?"[360] Richard insisted that sales reps push the doctors who

were followed, Richard Sackler demanded to be sent into
d wanted a week shadowing Purdue sales reps, two reps
Purdue's Chief Compliance Officer, warning that Richard
ntial compliance risk."[362] Compliance replied: "LOL."[363]
nt in marketing stayed secret, staff instructed: "Richard

[358] 2011-06-16 email from Russell Gasdia, PPLPC012000329607.
[359] 2011-06-16 email from Richard Sackler, PPLPC012000329621.
[360] 2011-06-16 email from Richard Sackler, PPLPC012000329706.
[361] 2011-06-16 email from Richard Sackler, PPLPC012000329706.
[362] 2011-06-16 email from Russell Gasdia, PPLPC012000329494 ("Based on our discussions, perhaps you could sit down with JS on your thoughts. Also, I haven't spoken to him about RS going to field with reps. Perhaps you could also say something to JS and indicate I came to you for counsel as I saw this as a potential compliance risk?").
[363] 2011-06-16 email from Bert Weinstein, PPLPC012000329722.

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MA AG FAC ¶353

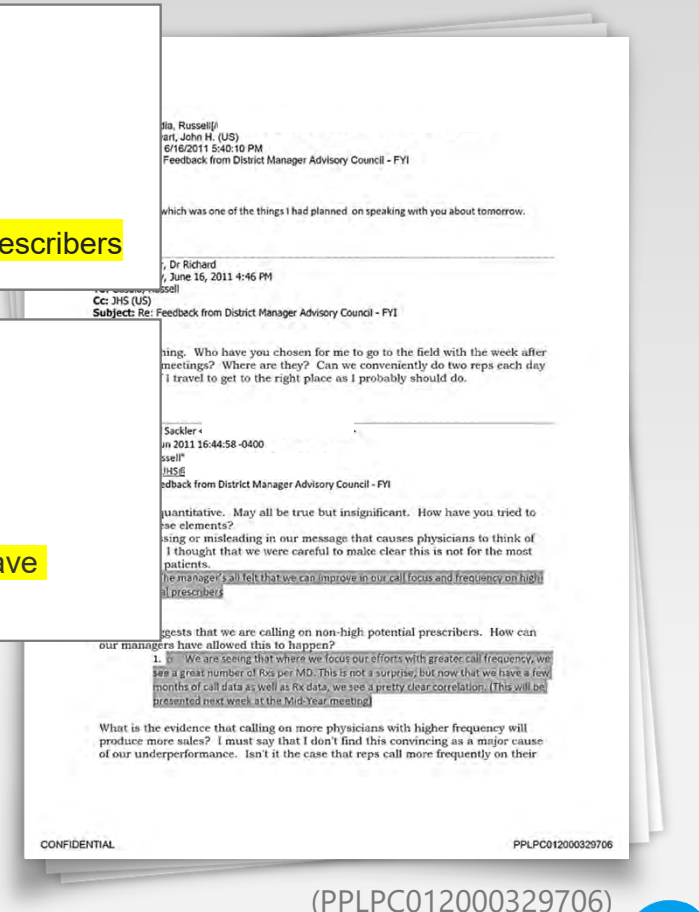
2011 Email: Sales Call Focus, Not Marketing

From: Gasdia, Russell
Sent: Thursday, June 16, 2011 9:24 AM
To: Sackler, Dr Richard
Subject: Feedback from District Manager Advisory Council – FYI
…

- The manager's all felt that we can improve in our call focus and frequency on high-potential prescribers

From: Richard Sackler
Date: Thu, 16 Jun 201116:44:58 -0400
To: "Gasdia, Russell"
Cc: "JHS (US)"
Subject: RE: Feedback from District Manager Advisory Council – FYI

1 Above suggests that we are calling on non-high potential prescribers. How can our managers have allowed this to happen? …



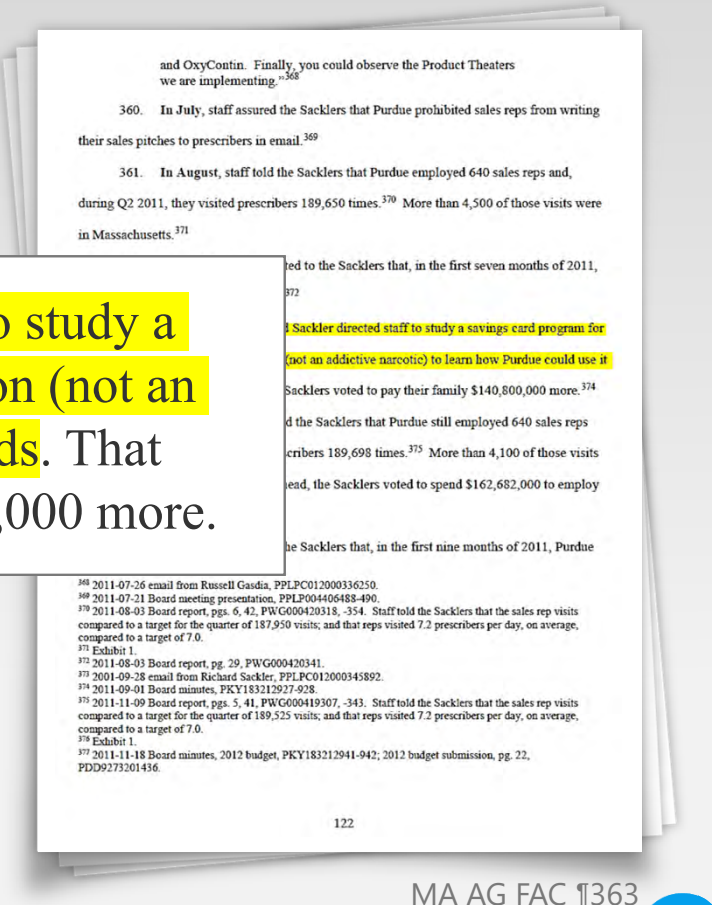
- Appropriate inquiry about sales call focus
- OIG confirmed compliance for 2011

(PPLPC012000329706)

Allegation: Study Of Savings Card For Cholesterol Drug

Massachusetts AG FAC ¶363:

363. In September, Richard Sackler directed staff to study a savings card program for a widely-used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids. That same month, the Sacklers voted to pay their family $140,800,000 more.



and OxyContin. Finally, you could observe the Product Theaters we are implementing."[368]

360. In July, staff assured the Sacklers that Purdue prohibited sales reps from writing their sales pitches to prescribers in email.[369]

361. In August, staff told the Sacklers that Purdue employed 640 sales reps and, during Q2 2011, they visited prescribers 189,650 times.[370] More than 4,500 of those visits were in Massachusetts.[371]

ed to the Sacklers that, in the first seven months of 2011,

372

Sackler directed staff to study a savings card program for

(not an addictive narcotic) to learn how Purdue could use it

Sacklers voted to pay their family $140,800,000 more.[374]

d the Sacklers that Purdue still employed 640 sales reps

cribers 189,698 times.[375] More than 4,100 of those visits

ead, the Sacklers voted to spend $162,682,000 to employ

he Sacklers that, in the first nine months of 2011, Purdue

[368] 2011-07-26 email from Russell Gasdia, PPLPC012000336250.
[369] 2011-07-21 Board meeting presentation, PPLP004406488-490.
[370] 2011-08-03 Board report, pgs. 6, 42, PWG000420318, -354. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 187,950 visits; and that reps visited 7.2 prescribers per day, on average, compared to a target of 7.0.
[371] Exhibit 1.
[372] 2011-08-03 Board report, pg. 29, PWG000420341.
[373] 2001-09-28 email from Richard Sackler, PPLPC012000345892.
[374] 2011-09-01 Board minutes, PKY183212927-928.
[375] 2011-11-09 Board report, pgs. 5, 41, PWG000419307, -343. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 189,525 visits; and that reps visited 7.2 prescribers per day, on average, compared to a target of 7.0.
[376] Exhibit 1.
[377] 2011-11-18 Board minutes, 2012 budget, PKY183212941-942; 2012 budget submission, pg. 22, PDD9273201436.

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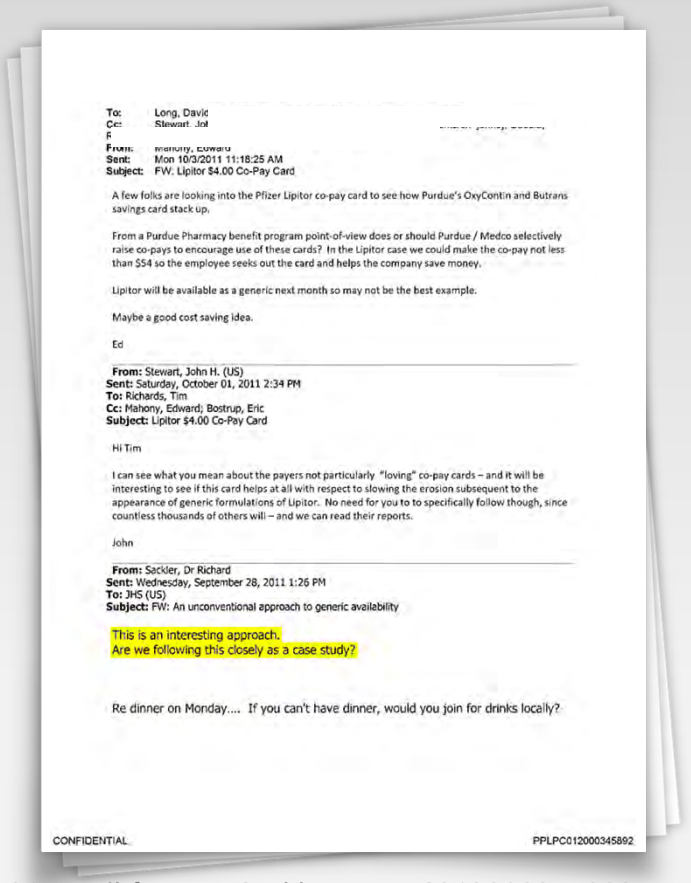
MA AG FAC ¶363

2011 Email Forwards Article About Lipitor Savings Card

From: Sackler, Dr Richard
Date: Wednesday, September 28, 2011 1:26 PM
To: JHS (US)
Subject: FW: An unconventional approach to generic availability

This is an interesting approach.
Are we following this closely as a case study?

- Email forwards article about Lipitor savings card
- OIG confirmed compliance for 2011



To: Long, David
Cc: Stewart, Joi
F
From: Mahony, Edward
Sent: Mon 10/3/2011 11:18:25 AM
Subject: FW: Lipitor $4.00 Co-Pay Card

A few folks are looking into the Pfizer Lipitor co-pay card to see how Purdue's OxyContin and Butrans savings card stack up.

From a Purdue Pharmacy benefit program point-of-view does or should Purdue / Medco selectively raise co-pays to encourage use of these cards? In the Lipitor case we could make the co-pay not less than $54 so the employee seeks out the card and helps the company save money.

Lipitor will be available as a generic next month so may not be the best example.

Maybe a good cost saving idea.

Ed

From: Stewart, John H. (US)
Sent: Saturday, October 01, 2011 2:34 PM
To: Richards, Tim
Cc: Mahony, Edward; Bostrup, Eric
Subject: Lipitor $4.00 Co-Pay Card

Hi Tim

I can see what you mean about the payers not particularly "loving" co-pay cards – and it will be interesting to see if this card helps at all with respect to slowing the erosion subsequent to the appearance of generic formulations of Lipitor. No need for you to to specifically follow though, since countless thousands of others will – and we can read their reports.

John

From: Sackler, Dr Richard
Sent: Wednesday, September 28, 2011 1:26 PM
To: JHS (US)
Subject: FW: An unconventional approach to generic availability

This is an interesting approach.
Are we following this closely as a case study?

Re dinner on Monday.... If you can't have dinner, would you join for drinks locally?

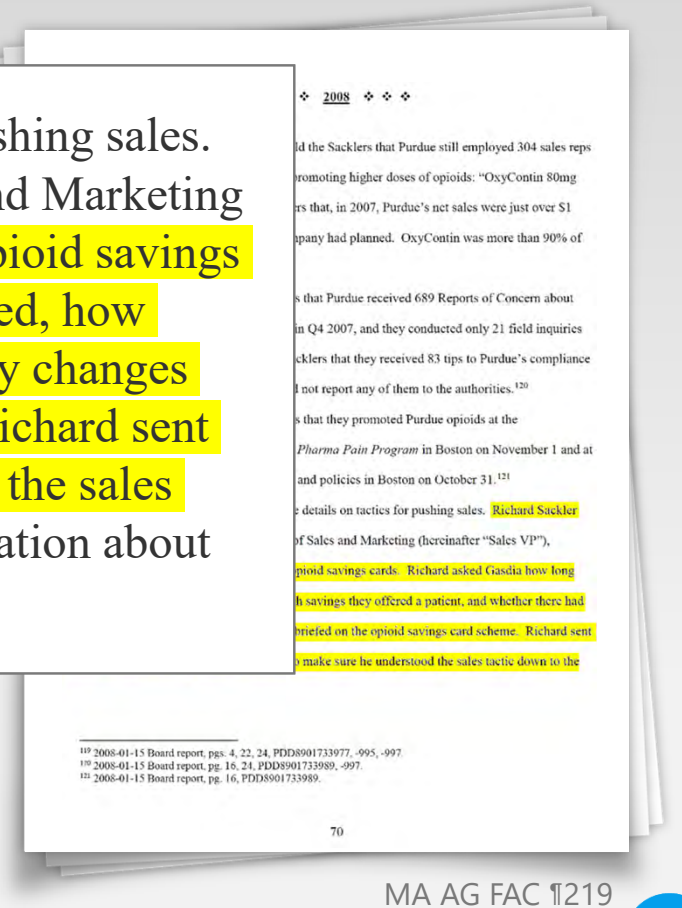
CONFIDENTIAL PPLPC012000345892

9/28/01 Email from R. Sackler (PPLPC012000345892)

Allegation: Request For Savings Card Details

Massachusetts AG FAC ¶219:

219. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter "Sales VP"), demanding information about Purdue's opioid savings cards. Richard asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings card scheme. Richard sent Gasdia a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.



MA AG FAC ¶219

2008 Email Seeks Clarification Due To Typo

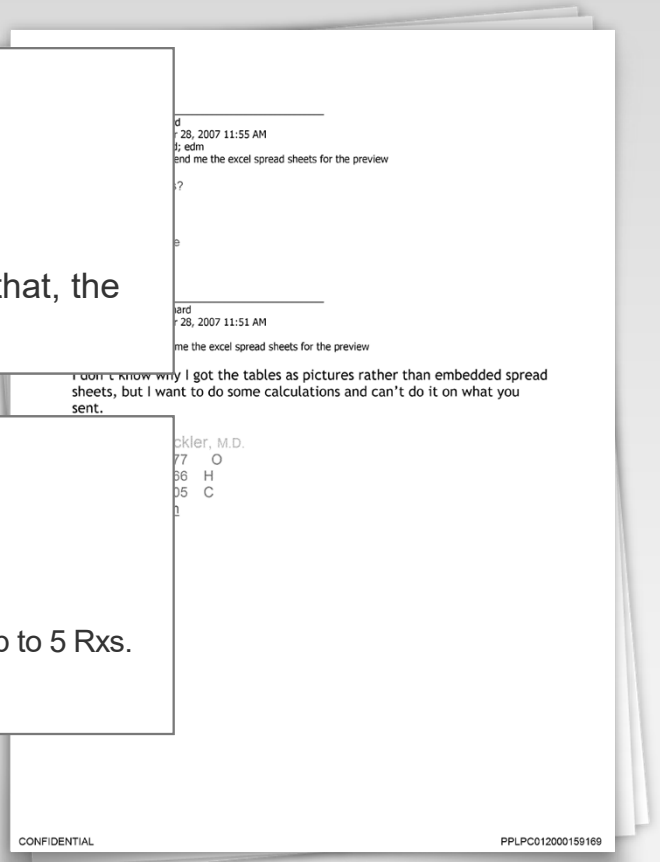
From: Sackler, Dr Richard
To: Gasdia, Russell
Sent: Wed Jan 30 18:25:10 2008
Subject: RE: Teva looks to be done

… I don't get the $500? If the Rx is $1000 and the patient is obligated to pay 30% of that, the card handles 30% of 1000 or $300-$10? That seems to be a very serious obligation.

To: Sackler, Dr Richard
From: Gasdia, Russell
Sent: Thur 1/31/2008 8:28:39 AM
Subject: Re: Teva looks to be done

My fault. It was a typo. It is 50 not 500. You have it right at 50 above the first 10. They are good for up to 5 Rxs.

Sorry for the confusion



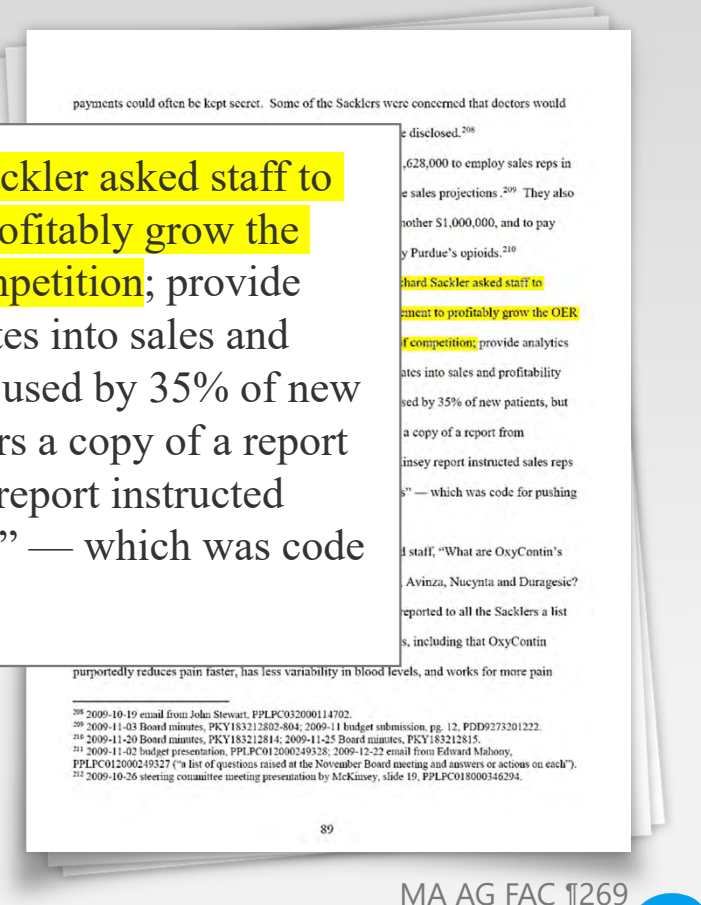
- Email seeks clarification of typo in prior email
- OIG confirmed compliance for 2008

1/30/08 Emails from R. Sackler (PPLPC012000168321)

Allegation: Questions About Sales And Marketing

Massachusetts AG FAC ¶269:

269. At the Board meeting that month, Kathe and Richard Sackler asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;" and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales.[211] The McKinsey report instructed sales reps to maximize profits by "emphasizing [the] broad range of doses" — which was code for pushing the doses that were highest and most profitable.


payments could often be kept secret. Some of the Sacklers were concerned that doctors would

e disclosed.[208]

,628,000 to employ sales reps in

e sales projections.[209] They also

nother $1,000,000, and to pay

y Purdue's opioids.[210]

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purportedly reduces pain faster, has less variability in blood levels, and works for more pain

[208] 2009-10-19 email from John Stewart, PPLPC032000114702.
[209] 2009-11-03 Board minutes, PKY183212802-804; 2009-11 budget submission, pg. 12, PDD9273201222.
[210] 2009-11-20 Board minutes, PKY183212814; 2009-11-25 Board minutes, PKY183212815.
[211] 2009-11-02 budget presentation, PPLPC012000249328; 2009-12-22 email from Edward Mahony, PPLPC012000249327 ("a list of questions raised at the November Board meeting and answers or actions on each").
[212] 2009-10-26 steering committee meeting presentation by McKinsey, slide 19, PPLPC018000346294.

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MA AG FAC ¶269

2009 Document: Director Questions About Sales, Marketing Programs

Q: Dr. Richard and Dr. Kathy asked for:

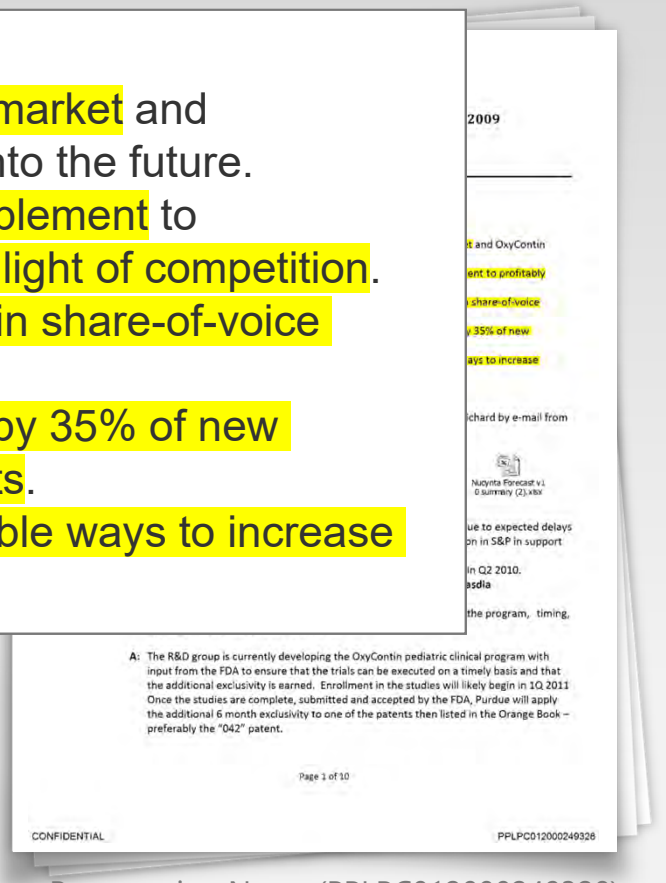
i. a detailed review of the long acting SEO market, the OER market and OxyContin growth rate for purposes of projecting into the future.

ii. identify specific programs that Sales and Marketing will implement to profitably grow the OER market and OxyContin in light of competition.

iii. provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth.

iv. clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients.

v. provide a copy of the OxyContin McKinsey report on possible ways to increase OxyContin sales and market share.


2009

A: The R&D group is currently developing the OxyContin pediatric clinical program with input from the FDA to ensure that the trials can be executed on a timely basis and that the additional exclusivity is earned. Enrollment in the studies will likely begin in 1Q 2011 Once the studies are complete, submitted and accepted by the FDA, Purdue will apply the additional 6 month exclusivity to one of the patents then listed in the Orange Book – preferably the "042" patent.

Page 1 of 10

CONFIDENTIAL

PPLPC012000249328

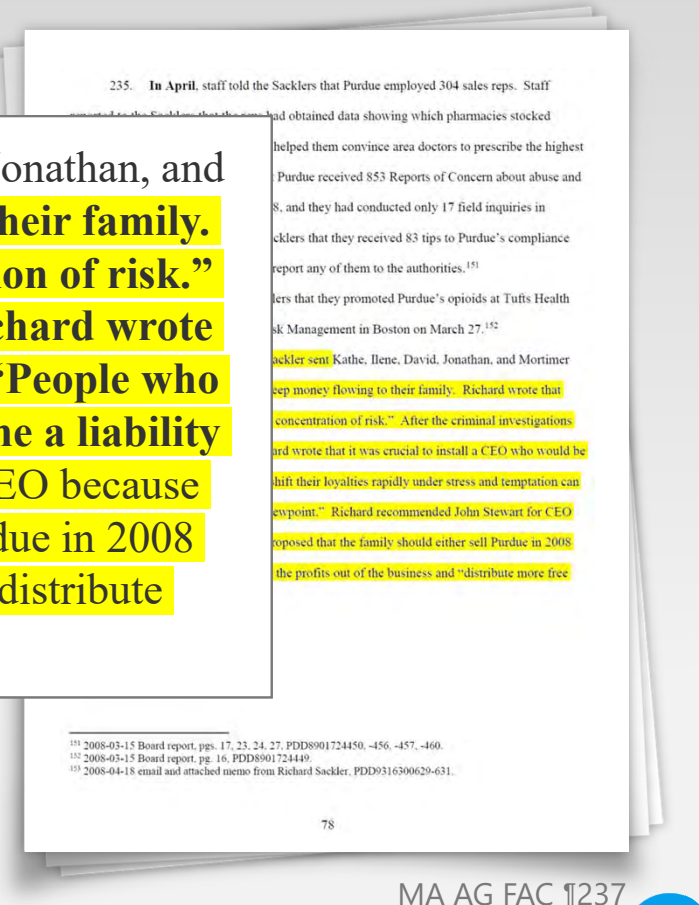
- Appropriate inquiries from directors
- OIG confirmed compliance for 2009

11/2-3/09 Budget Presentation Notes (PPLPC012000249328)

Allegation: Secret Memo To Keep Money Flowing To Family

Massachusetts AG FAC ¶237:

237. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler **a secret memo about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint."** Richard recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.


235. **In April**, staff told the Sacklers that Purdue employed 304 sales reps. Staff

ad obtained data showing which pharmacies stocked

helped them convince area doctors to prescribe the highest

Purdue received 853 Reports of Concern about abuse and

8, and they had conducted only 17 field inquiries in

cklers that they received 83 tips to Purdue's compliance

report any of them to the authorities.[151]

lers that they promoted Purdue's opioids at Tufts Health

sk Management in Boston on March 27.[152]

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[151] 2008-03-15 Board report, pgs. 17, 23, 24, 27, PDD8901724450, -456, -457, -460.
[152] 2008-03-15 Board report, pg. 16, PDD8901724449.
[153] 2008-04-18 email and attached memo from Richard Sackler, PDD9316300629-631.

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MA AG FAC ¶237

Cited Document: Confidential Memo About CEO Hiring

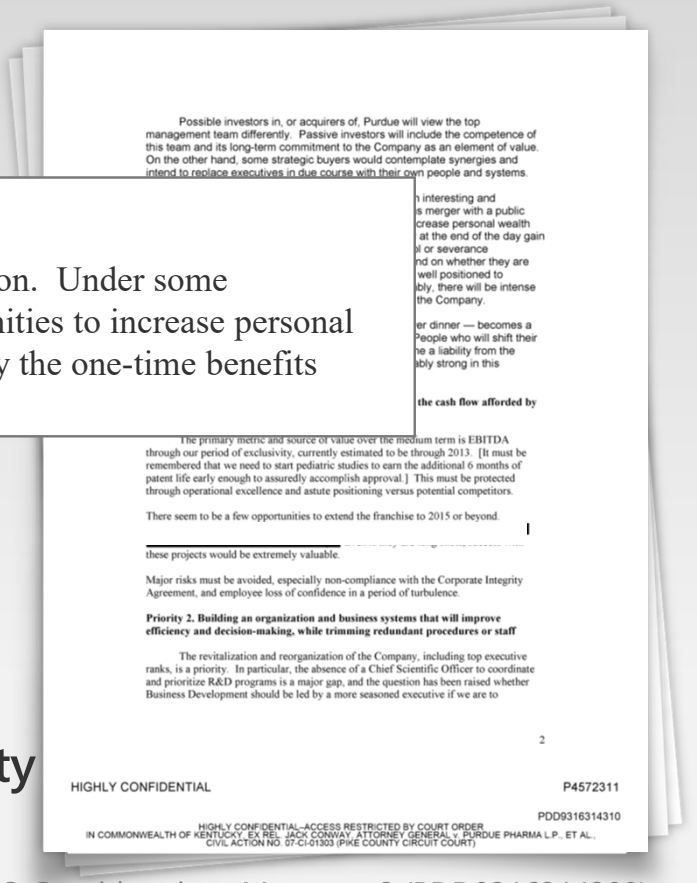
- CEO loyalty in context of sale of business or recap
- No reference to prior criminal investigation

Re: CEO Considerations

***

The Purdue CEO and his top team are thus in an interesting and potentially conflicted position. Under some circumstances, such as a merger with a public company, they may gain exceptional opportunities to increase personal wealth through equity packages. On the other hand, they may at the end of the day gain only the one-time benefits specified in change-of-control or severance agreements.

- "Concentration of risk" — wealth in single company dependent on single product with 2013 patent cliff
- "Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement...."
- The only litigation risk discussed concerns patent exclusivity for OxyContin


Possible investors in, or acquirers of, Purdue will view the top management team differently. Passive investors will include the competence of this team and its long-term commitment to the Company as an element of value. On the other hand, some strategic buyers would contemplate synergies and intend to replace executives in due course with their own people and systems.

...interesting and ...s merger with a public ...crease personal wealth ...at the end of the day gain ...or severance ...nd on whether they are ...well positioned to ...bly, there will be intense ...the Company.

...er dinner — becomes a ...People who will shift their ...he a liability from the ...bly strong in this

...the cash flow afforded by

The primary metric and source of value over the medium term is EBITDA through our period of exclusivity, currently estimated to be through 2013. [It must be remembered that we need to start pediatric studies to earn the additional 6 months of patent life early enough to assuredly accomplish approval.] This must be protected through operational excellence and astute positioning versus potential competitors.

There seem to be a few opportunities to extend the franchise to 2015 or beyond.

these projects would be extremely valuable.

Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement, and employee loss of confidence in a period of turbulence.

Priority 2. Building an organization and business systems that will improve efficiency and decision-making, while trimming redundant procedures or staff

The revitalization and reorganization of the Company, including top executive ranks, is a priority. In particular, the absence of a Chief Scientific Officer to coordinate and prioritize R&D programs is a major gap, and the question has been raised whether Business Development should be led by a more seasoned executive if we are to

2

HIGHLY CONFIDENTIAL P4572311

PDD9316314310

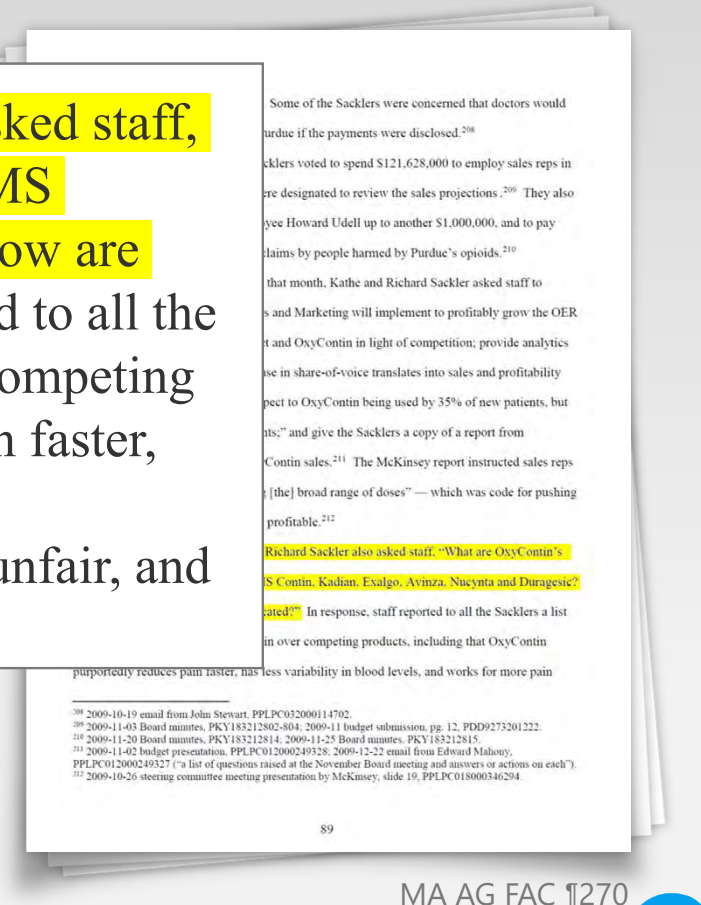
HIGHLY CONFIDENTIAL--ACCESS RESTRICTED BY COURT ORDER
IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL.,
CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

4/08 CEO Considerations Memo, p. 2 (PDD9316314309)

Allegation: Question About OxyContin's Clinical Advantages

Massachusetts AG FAC ¶270:

270. At the same meeting, Richard Sackler also asked staff, "What are OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?" In response, staff reported to all the Sacklers a list of purported advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. These were all improper, unfair, and deceptive claims that Purdue had admitted were prohibited.


Some of the Sacklers were concerned that doctors would
urdue if the payments were disclosed.[208]
cklers voted to spend $121,628,000 to employ sales reps in
re designated to review the sales projections.[209] They also
yee Howard Udell up to another $1,000,000, and to pay
laims by people harmed by Purdue's opioids.[210]
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t and OxyContin in light of competition; provide analytics
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Richard Sackler also asked staff, "What are OxyContin's
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[208] 2009-10-19 email from John Stewart, PPLPC032000114702.
[209] 2009-11-03 Board minutes, PKY183212802-804; 2009-11 budget submission, pg. 12, PDD9273201222.
[210] 2009-11-20 Board minutes, PKY183212814; 2009-11-25 Board minutes, PKY183212815.
[211] 2009-11-02 budget presentation, PPLPC012000249328; 2009-12-22 email from Edward Mahony, PPLPC012000249327 ("a list of questions raised at the November Board meeting and answers or actions on each").
[212] 2009-10-26 steering committee meeting presentation by McKinsey, slide 19, PPLPC018000346294.
89

MA AG FAC ¶270

- Appropriate questions about competitive products

2009 Document: Request For Information, Not Direction, About Marketing

Q: What are OxyContin's clinical advantages vs. Opana ER, MS Cantin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?

A: OxyContin has the following advantages vs. the other above products:

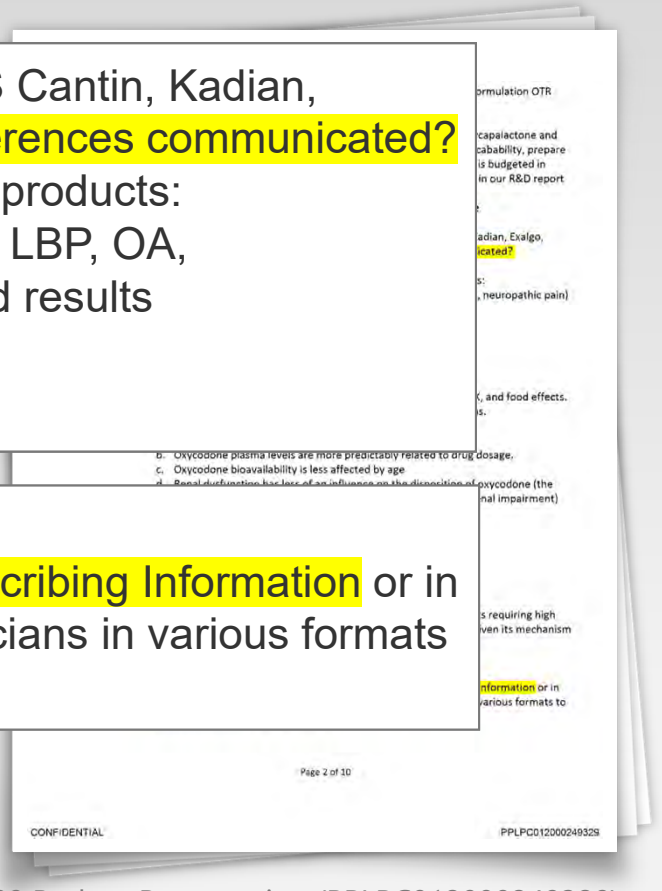
i. OxyContin has been studied in more pain syndromes (e.g., LBP, OA, neuropathic pain) with demonstrated efficacy and published results

ii. Prompt onset of analgesia

iii. Less variability in blood levels

… Methods of communication

i. Most of the differences above are published in the Full Prescribing Information or in the medical literature and, as such, can be provided to clinicians in various formats to provide clinicians with the information.



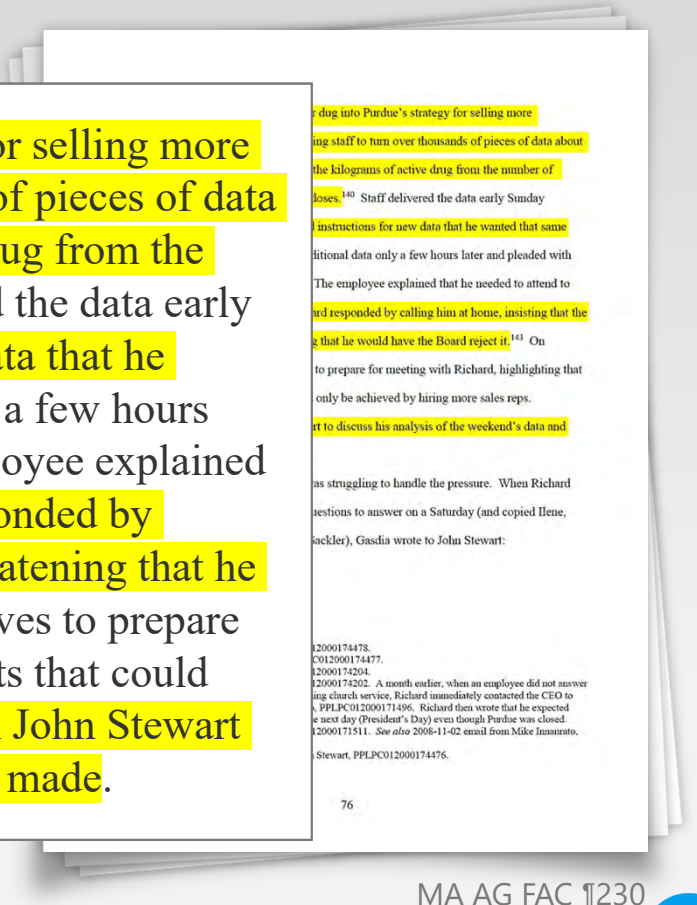
- "Full Prescribing Information" is FDA-approved label
- OIG confirmed compliance for 2009

11/2/09 Budget Presentation (PPLPC012000249329)

Allegation: Demands For Sales Trends

Massachusetts AG FAC ¶230:

230. In March, Richard Sackler dug into Purdue's strategy for selling more OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early Sunday morning; Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later and pleaded with Richard: "I have done as much as I can." The employee explained that he needed to attend to family visiting from out of town. Richard responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales reps. Meanwhile, Richard met with John Stewart to discuss his analysis of the weekend's data and new graphs Richard had made.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loses.[140] Staff delivered the data early Sunday
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The employee explained that he needed to attend to
rd responded by calling him at home, insisting that the
g that he would have the Board reject it.[143] On
to prepare for meeting with Richard, highlighting that
only be achieved by hiring more sales reps.
rt to discuss his analysis of the weekend's data and
as struggling to handle the pressure. When Richard
uestions to answer on a Saturday (and copied Ilene,
ackler), Gasdia wrote to John Stewart:
12000174478.
C012000174477.
12000174204.
12000174202. A month earlier, when an employee did not answer
ing church service, Richard immediately contacted the CEO to
, PPLPC012000171496. Richard then wrote that he expected
e next day (President's Day) even though Purdue was closed.
12000171511. *See also* 2008-11-02 email from Mike Innaurato,
Stewart, PPLPC012000174476.
76

MA AG FAC ¶230

2008 Email Requests Information About Sales Forecast

From: Sackler, Dr Richard
Sent: Sunday, March 09, 2008 12:13 PM
To: Rosen, David
Cc: Innaurato, Mike; Gasdia, Russell; Mahony, Edward; Gadski, Kimberly
Subject: RE: OxyContin Rx data with Kg graphs
Importance: High

Thanks for the quick turn around. This looks very different and much more encouraging, doesn't it? I'm really excited to dig into the data

I assume you've validated and spreadsheet and have checked the equations, but I wonder if you could touch it up a bit.

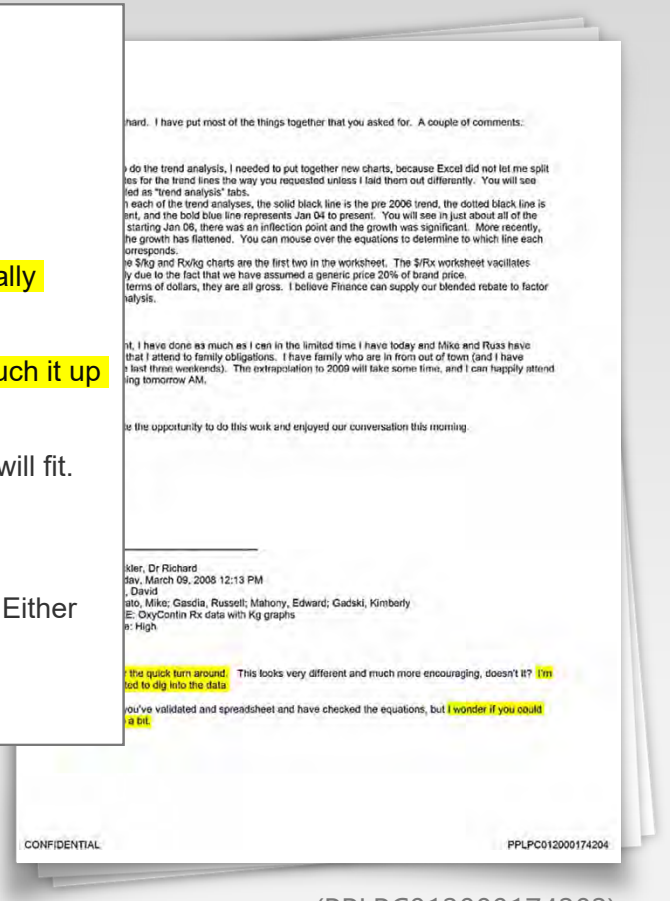
1. Change the scale on the charts from all strengths to fill the charts as we did in my office so everything will fit.

…

5. Anything else you think is worthy of considering in setting out a forecast.

I trust that the $'s you show are net, but if this isn't feasible don't mix and match them unless you have to. Either gross or net (net preferred since our rebates are rising).

Can you conveniently do this this morning?


hard. I have put most of the things together that you asked for. A couple of comments:

do the trend analysis, I needed to put together new charts, because Excel did not let me split
les for the trend lines the way you requested unless I laid them out differently. You will see
led as "trend analysis" tabs.
each of the trend analyses, the solid black line is the pre 2006 trend, the dotted black line is
ent, and the bold blue line represents Jan 04 to present. You will see in just about all of the
starting Jan 06, there was an inflection point and the growth was significant. More recently,
he growth has flattened. You can mouse over the equations to determine to which line each
orresponds.
e $/kg and Rx/kg charts are the first two in the worksheet. The $/Rx worksheet vacillates
y due to the fact that we have assumed a generic price 20% of brand price.
terms of dollars, they are all gross. I believe Finance can supply our blended rebate to factor
alysis.

t, I have done as much as I can in the limited time I have today and Mike and Russ have
that I attend to family obligations. I have family who are in from out of town (and I have
last three weekends). The extrapolation to 2009 will take some time, and I can happily attend
ing tomorrow AM.

e the opportunity to do this work and enjoyed our conversation this morning

kler, Dr Richard
day, March 09, 2008 12:13 PM
, David
ato, Mike; Gasdia, Russell; Mahony, Edward; Gadski, Kimberly
E: OxyContin Rx data with Kg graphs
e: High

the quick turn around. This looks very different and much more encouraging, doesn't it? I'm
ted to dig into the data

ou've validated and spreadsheet and have checked the equations, but I wonder if you could
a bit.

CONFIDENTIAL PPLPC012000174204

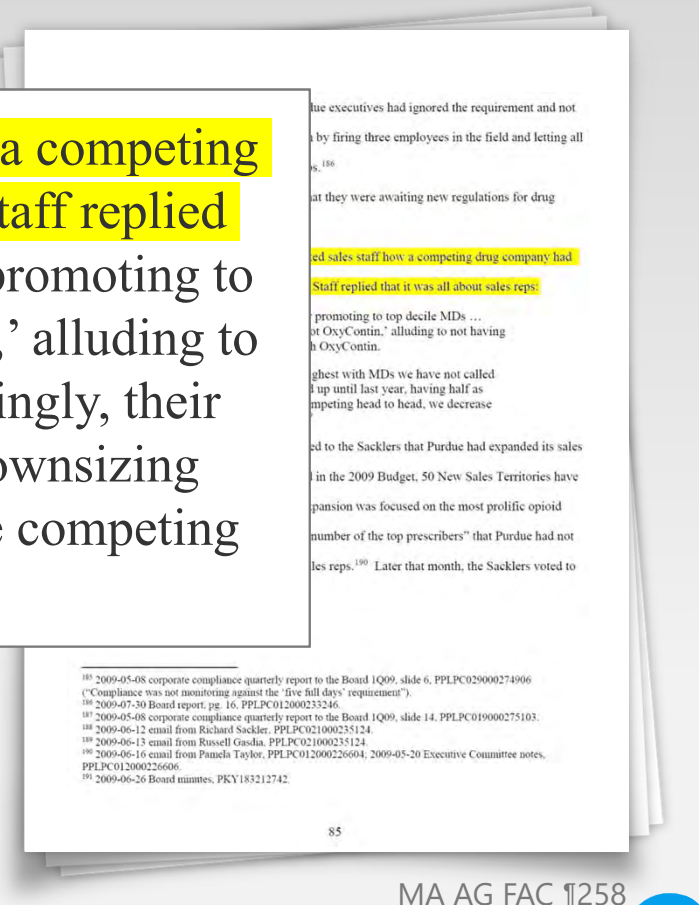
(PPLPC012000174202)

- Sales, not marketing
- OIG confirmed compliance for 2008

Allegation: "What Is Happening???"

Massachusetts AG FAC ¶258:

258. In June, Richard Sackler asked sales staff how a competing drug company had increased sales: "What is happening???" Staff replied that it was all about sales reps: "They have 500 reps actively promoting to top decile MDs … Their messaging is 'we are not OxyContin,' alluding to not having the 'baggage' that comes with OxyContin. Interestingly, their share is highest with MDs we have not called on due to our downsizing and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%."


lue executives had ignored the requirement and not
by firing three employees in the field and letting all
s.[186]
at they were awaiting new regulations for drug
ed sales staff how a competing drug company had
Staff replied that it was all about sales reps:
promoting to top decile MDs …
ot OxyContin,' alluding to not having
h OxyContin.
ghest with MDs we have not called
l up until last year, having half as
mpeting head to head, we decrease
ed to the Sacklers that Purdue had expanded its sales
in the 2009 Budget, 50 New Sales Territories have
pansion was focused on the most prolific opioid
number of the top prescribers" that Purdue had not
les reps.[190] Later that month, the Sacklers voted to
[185] 2009-05-08 corporate compliance quarterly report to the Board 1Q09, slide 6, PPLPC029000274906 ("Compliance was not monitoring against the 'five full days' requirement").
[186] 2009-07-30 Board report, pg. 16, PPLPC012000233246.
[187] 2009-05-08 corporate compliance quarterly report to the Board 1Q09, slide 14, PPLPC019000275103.
[188] 2009-06-12 email from Richard Sackler, PPLPC021000235124.
[189] 2009-06-13 email from Russell Gasdia, PPLPC021000235124.
[190] 2009-06-16 email from Pamela Taylor, PPLPC012000226604; 2009-05-20 Executive Committee notes, PPLPC012000226606.
[191] 2009-06-26 Board minutes, PKY183212742.
85

MA AG FAC ¶258

Irrelevant 2009 Email Requests Information About Competitor's Sales

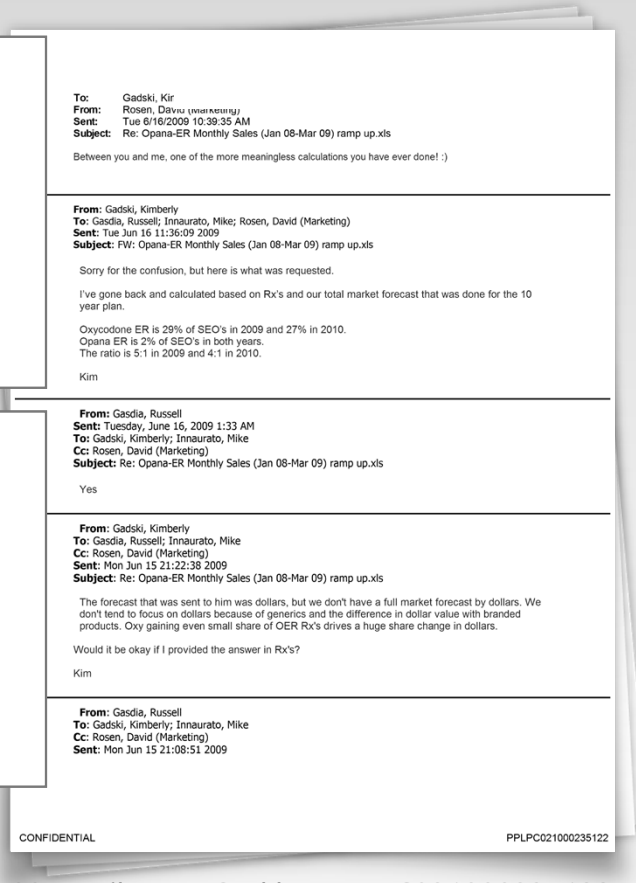
From: Sackler, Dr Richard
To: Stewart, John H. (US); Gasdia, Russell
Sent: Fri Jun 12 14:40:31 2009
Subject: FW: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xis

Huge increase in Opana sales, it appears.

What is happening???

From: Sackler, Dr Richard
To: Gasdia, Russell; Stewart, John H. (US)
Cc: Innaurato, Mike
Sent: Sun Jun 14 20:46:06 2009
Subject: RE: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xis

Thank you.
What is your planned market share ratio OxyContin® tablets : Opana for 2009 and 201 O? Please calculate and advise if you haven't developed this metric.



To: Gadski, Kir
From: Rosen, David (Marketing)
Sent: Tue 6/16/2009 10:39:35 AM
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Between you and me, one of the more meaningless calculations you have ever done! :)

From: Gadski, Kimberly
To: Gasdia, Russell; Innaurato, Mike; Rosen, David (Marketing)
Sent: Tue Jun 16 11:36:09 2009
Subject: FW: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Sorry for the confusion, but here is what was requested.

I've gone back and calculated based on Rx's and our total market forecast that was done for the 10 year plan.

Oxycodone ER is 29% of SEO's in 2009 and 27% in 2010.
Opana ER is 2% of SEO's in both years.
The ratio is 5:1 in 2009 and 4:1 in 2010.

Kim

From: Gasdia, Russell
Sent: Tuesday, June 16, 2009 1:33 AM
To: Gadski, Kimberly; Innaurato, Mike
Cc: Rosen, David (Marketing)
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Yes

From: Gadski, Kimberly
To: Gasdia, Russell; Innaurato, Mike
Cc: Rosen, David (Marketing)
Sent: Mon Jun 15 21:22:38 2009
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

The forecast that was sent to him was dollars, but we don't have a full market forecast by dollars. We don't tend to focus on dollars because of generics and the difference in dollar value with branded products. Oxy gaining even small share of OER Rx's drives a huge share change in dollars.

Would it be okay if I provided the answer in Rx's?

Kim

From: Gasdia, Russell
To: Gadski, Kimberly; Innaurato, Mike
Cc: Rosen, David (Marketing)
Sent: Mon Jun 15 21:08:51 2009

CONFIDENTIAL PPLPC021000235122

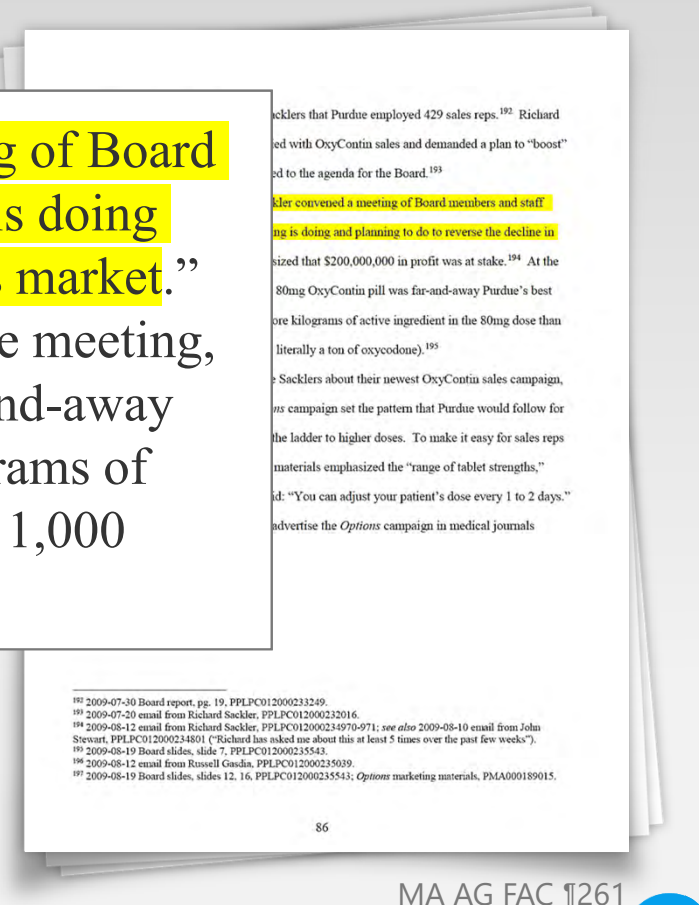
- **OIG <u>confirmed compliance</u> for 2009**

6/14/09 Emails w/R. Sackler (PPLPC021000235122)

Allegation: Richard Convened Board Meeting About Sales

Massachusetts AG FAC ¶261:

261. In August, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that $200,000,000 in profit was at stake. At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (about 1,000 kilograms: literally a ton of oxycodone).



acklers that Purdue employed 429 sales reps.[192] Richard
ed with OxyContin sales and demanded a plan to "boost"
ed to the agenda for the Board.[193]
kler convened a meeting of Board members and staff
ng is doing and planning to do to reverse the decline in
sized that $200,000,000 in profit was at stake.[194] At the
80mg OxyContin pill was far-and-away Purdue's best
ore kilograms of active ingredient in the 80mg dose than
literally a ton of oxycodone).[195]
Sacklers about their newest OxyContin sales campaign,
ns campaign set the pattern that Purdue would follow for
he ladder to higher doses. To make it easy for sales reps
materials emphasized the "range of tablet strengths,"
id: "You can adjust your patient's dose every 1 to 2 days."
advertise the *Options* campaign in medical journals

[192] 2009-07-30 Board report, pg. 19, PPLPC012000233249.
[193] 2009-07-20 email from Richard Sackler, PPLPC012000232016.
[194] 2009-08-12 email from Richard Sackler, PPLPC012000234970-971; *see also* 2009-08-10 email from John Stewart, PPLPC012000234801 ("Richard has asked me about this at least 5 times over the past few weeks").
[195] 2009-08-19 Board slides, slide 7, PPLPC012000235543.
[196] 2009-08-12 email from Russell Gasdia, PPLPC012000235039.
[197] 2009-08-19 Board slides, slides 12, 16, PPLPC012000235543; *Options* marketing materials, PMA000189015.

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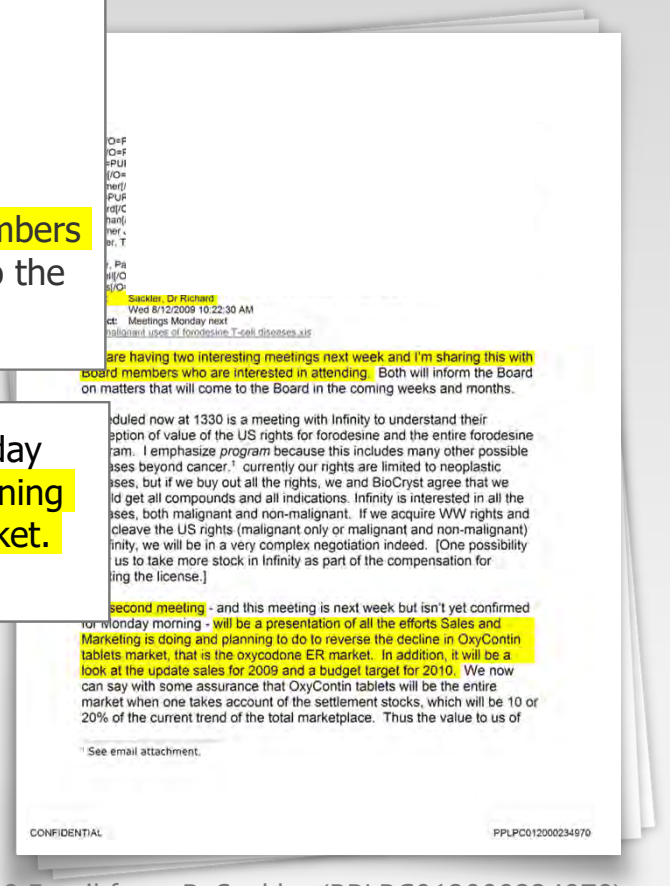
MA AG FAC ¶261

2009 Email: Invitation To Informational Board Meetings

From: Sackler, Dr Richard
Sent: Wed 8/12/2009 10:22:30 AM
Subject: Meetings Monday next
Non-malignant uses of forodesine T-cell diseases.xls

We are having two interesting meetings next week and I'm sharing this with Board members who are interested in attending. Both will inform the Board on matters that will come to the Board in the coming weeks and months.

… The second meeting - and this meeting is next week but isn't yet confirmed for Monday morning - will be a presentation of all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market, that is the oxycodone ER market. In addition, it will be a look at the update sales for 2009 and a budget target for 2010.


Sackler, Dr Richard
Wed 8/12/2009 10:22:30 AM
Meetings Monday next
Non-malignant uses of forodesine T-cell diseases.xls

are having two interesting meetings next week and I'm sharing this with Board members who are interested in attending. Both will inform the Board on matters that will come to the Board in the coming weeks and months.

CONFIDENTIAL
PPLPC012000234970

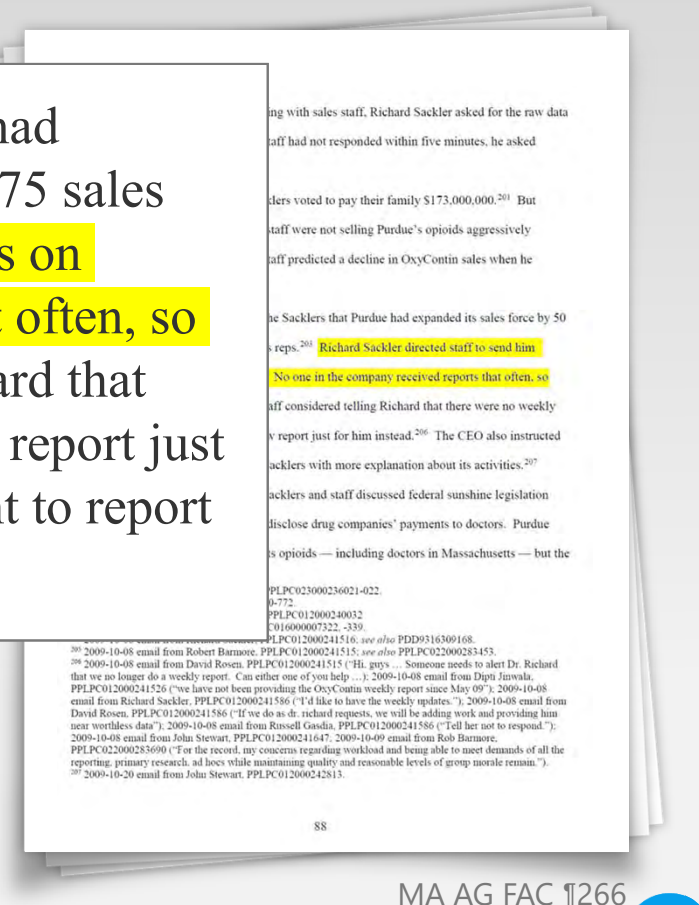
- Appropriate information-gathering by directors
- OIG confirmed compliance for 2009

8/12/09 Email from R. Sackler (PPLPC012000234970)

Allegation: Direction To Send Weekly Sales Reports

Massachusetts AG FAC ¶266:

266. In October, staff told the Sacklers that Purdue had expanded its sales force by 50 territories and now employed 475 sales reps. Richard Sackler directed staff to send him weekly reports on OxyContin sales. No one in the company received reports that often, so staff were not sure how to reply. Staff considered telling Richard that there were no weekly reports, but they decided to make a new report just for him instead. The CEO also instructed the Sales Department to report to the Sacklers with more explanation about its activities.



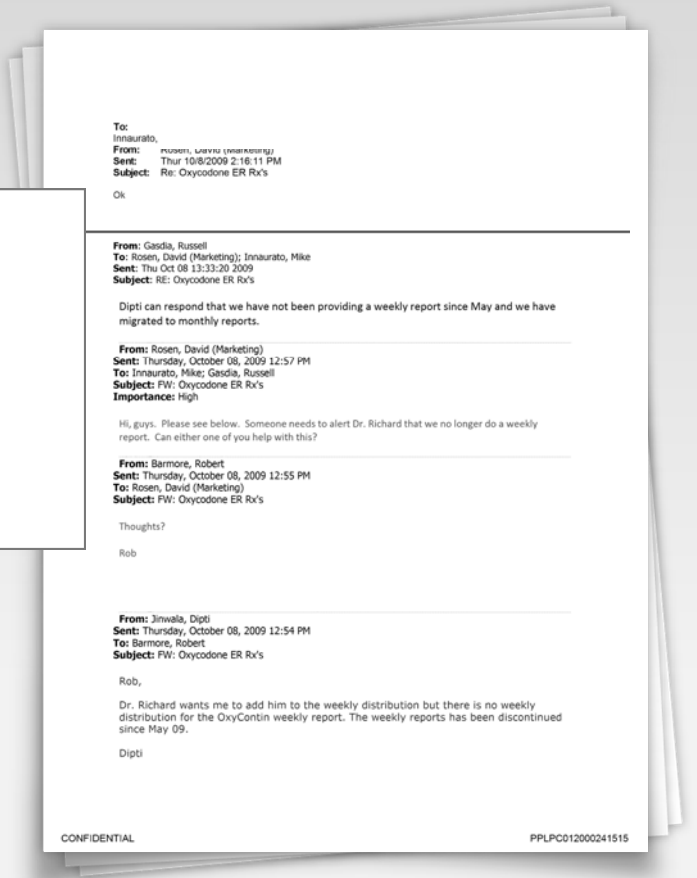
MA AG FAC ¶266

2009 Email: Request To Be Added To Weekly Circulation

From: Sackler, Dr Richard
Sent: Thursday, October 08, 2009 12:08 PM
To: Jinwala, Dipti
Subject: RE: Oxycodone ER Rx's

Please add me to the weekly circulation.

- Irrelevant 2009 email asks for weekly sales reports
- OIG confirmed compliance for 2009



To:
Innaurato,
From: [redacted]
Sent: Thur 10/8/2009 2:16:11 PM
Subject: Re: Oxycodone ER Rx's

Ok

From: Gasdia, Russell
To: Rosen, David (Marketing); Innaurato, Mike
Sent: Thu Oct 08 13:33:20 2009
Subject: RE: Oxycodone ER Rx's

Dipti can respond that we have not been providing a weekly report since May and we have migrated to monthly reports.

From: Rosen, David (Marketing)
Sent: Thursday, October 08, 2009 12:57 PM
To: Innaurato, Mike; Gasdia, Russell
Subject: FW: Oxycodone ER Rx's
Importance: High

Hi, guys. Please see below. Someone needs to alert Dr. Richard that we no longer do a weekly report. Can either one of you help with this?

From: Barmore, Robert
Sent: Thursday, October 08, 2009 12:55 PM
To: Rosen, David (Marketing)
Subject: FW: Oxycodone ER Rx's

Thoughts?

Rob

From: Jinwala, Dipti
Sent: Thursday, October 08, 2009 12:54 PM
To: Barmore, Robert
Subject: FW: Oxycodone ER Rx's

Rob,

Dr. Richard wants me to add him to the weekly distribution but there is no weekly distribution for the OxyContin weekly report. The weekly reports has been discontinued since May 09.

Dipti

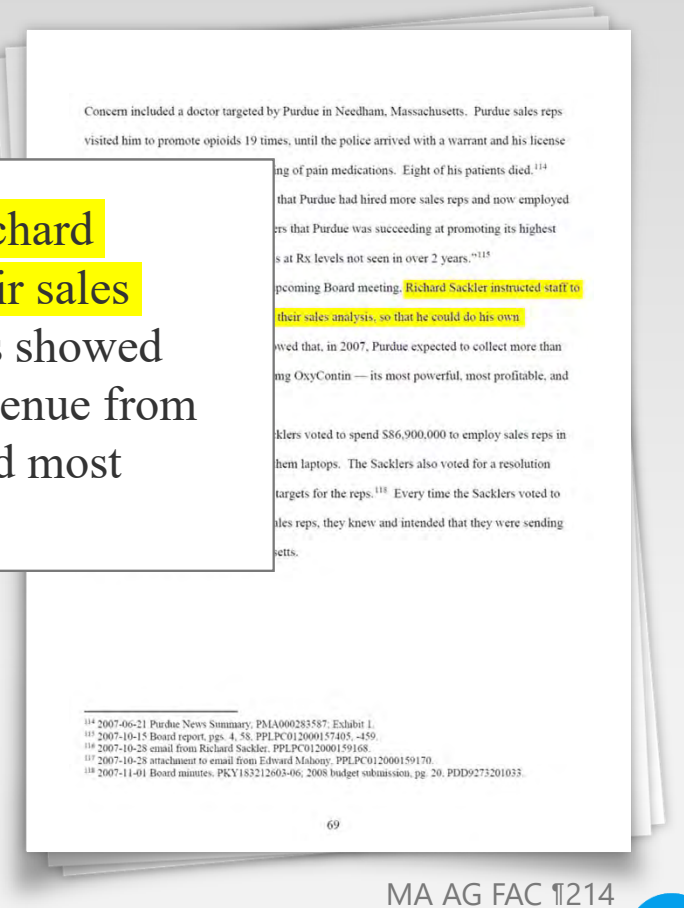
CONFIDENTIAL PPLPC012000241515

10/8/09 Email from R. Sackler (PPLPC012000241515)

Allegation: Request For Spreadsheets Underlying Sales Analysis

Massachusetts AG FAC ¶214:

214. In preparation for an upcoming Board meeting, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin — its most powerful, most profitable, and most dangerous pill.



Concern included a doctor targeted by Purdue in Needham, Massachusetts. Purdue sales reps visited him to promote opioids 19 times, until the police arrived with a warrant and his license ng of pain medications. Eight of his patients died.[114] that Purdue had hired more sales reps and now employed rs that Purdue was succeeding at promoting its highest s at Rx levels not seen in over 2 years."[115] pcoming Board meeting, Richard Sackler instructed staff to their sales analysis, so that he could do his own wed that, in 2007, Purdue expected to collect more than mg OxyContin — its most powerful, most profitable, and klers voted to spend $86,900,000 to employ sales reps in hem laptops. The Sacklers also voted for a resolution targets for the reps.[118] Every time the Sacklers voted to les reps, they knew and intended that they were sending setts.

[114] 2007-06-21 Purdue News Summary, PMA000283587; Exhibit 1.
[115] 2007-10-15 Board report, pgs. 4, 58, PPLPC012000157405, -459.
[116] 2007-10-28 email from Richard Sackler, PPLPC012000159168.
[117] 2007-10-28 attachment to email from Edward Mahony, PPLPC012000159170.
[118] 2007-11-01 Board minutes, PKY183212603-06; 2008 budget submission, pg. 20, PDD9273201033.

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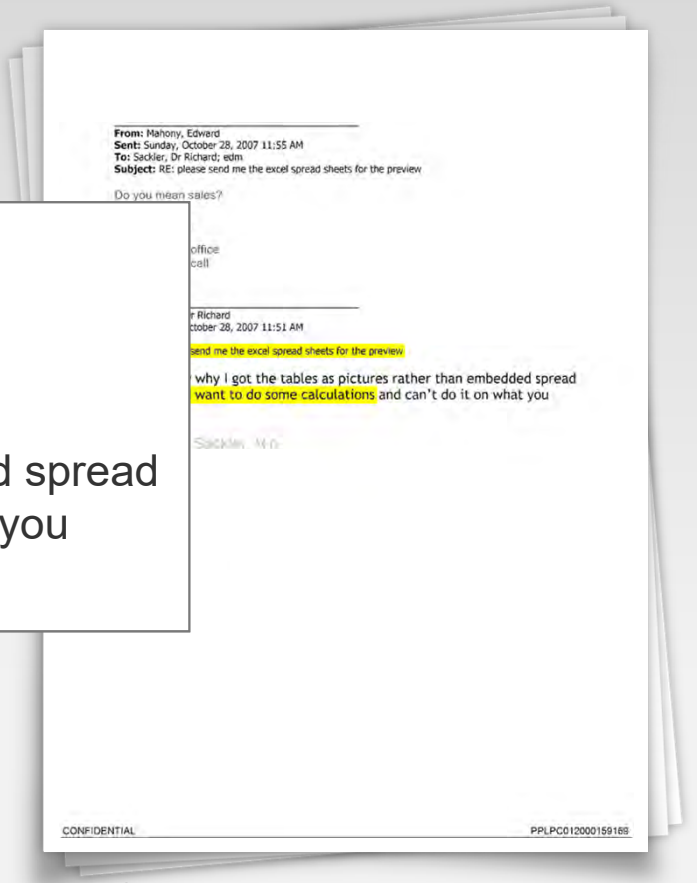
MA AG FAC ¶214

Irrelevant 2007 Request For Underlying Sales Data

From: Sackler, Dr Richard
Sent: Sunday, October 28, 2007 11:51 AM
To: edm
Subject: please send me the excel spread sheets for the preview

I don't know why I got the tables as pictures rather than embedded spread sheets, but I want to do some calculations and can't do it on what you sent.



- OIG confirmed compliance for this period

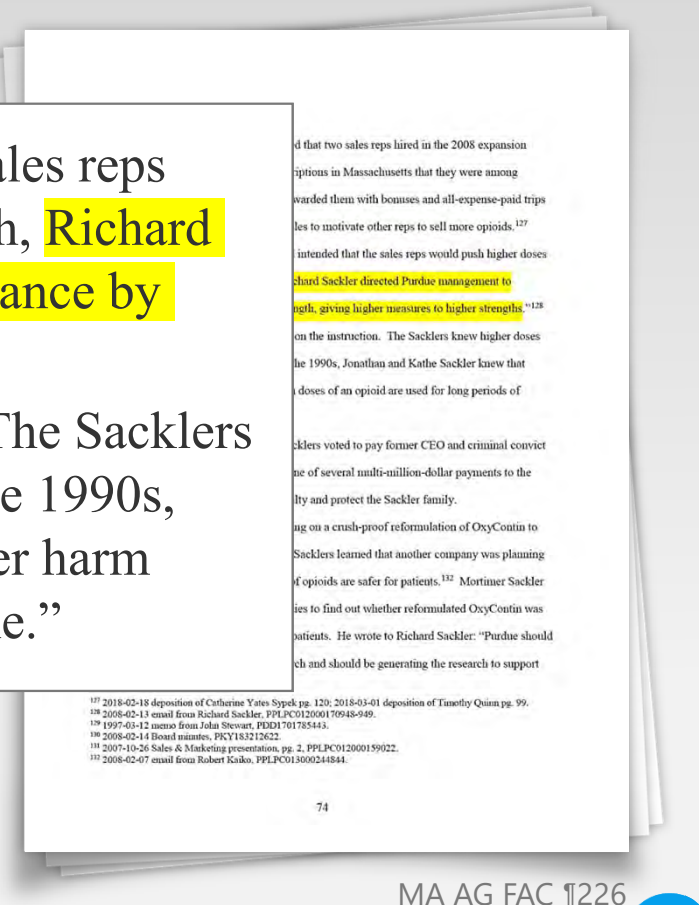
10/28/07 Email from R. Sackler (PPLPC012000159168)

Allegation: Direction To Management Re Measuring Sales

Massachusetts AG FAC ¶226:

226. The Sacklers also knew and intended that the sales reps would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths."

He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when "high doses of an opioid are used for long periods of time."



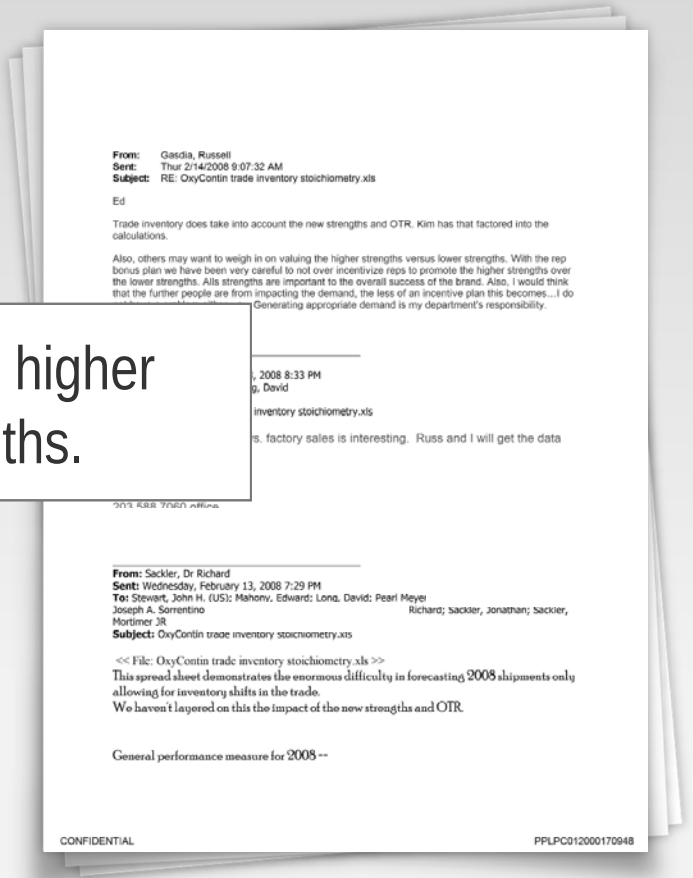
MA AG FAC ¶226

Irrelevant 2008 Email Suggests Sales Performance Metric

February 13, 2008 email from Richard to J. Stewart and others

Let's measure our performance by Rx's by strength, giving higher measures to higher strengths an especially the new strengths.

- OIG confirmed compliance for 2008



From: Gasdia, Russell
Sent: Thur 2/14/2008 9:07:32 AM
Subject: RE: OxyContin trade inventory stoichiometry.xls

Ed

Trade inventory does take into account the new strengths and OTR. Kim has that factored into the calculations.

Also, others may want to weigh in on valuing the higher strengths versus lower strengths. With the rep bonus plan we have been very careful to not over incentivize reps to promote the higher strengths over the lower strengths. Alls strengths are important to the overall success of the brand. Also, I would think that the further people are from impacting the demand, the less of an incentive plan this becomes...I do

Generating appropriate demand is my department's responsibility.

2008 8:33 PM
David

inventory stoichiometry.xls

factory sales is interesting. Russ and I will get the data

From: Sackler, Dr Richard
Sent: Wednesday, February 13, 2008 7:29 PM
To: Stewart, John H. (US); Mahony, Edward; Long, David; Pearl Meyer
Joseph A. Sorrentino Richard; Sackler, Jonathan; Sackler, Mortimer JR
Subject: OxyContin trade inventory stoichiometry.xls

<< File: OxyContin trade inventory stoichiometry.xls >>
This spread sheet demonstrates the enormous difficulty in forecasting 2008 shipments only allowing for inventory shifts in the trade.
We haven't layered on this the impact of the new strengths and OTR.

General performance measure for 2008 --

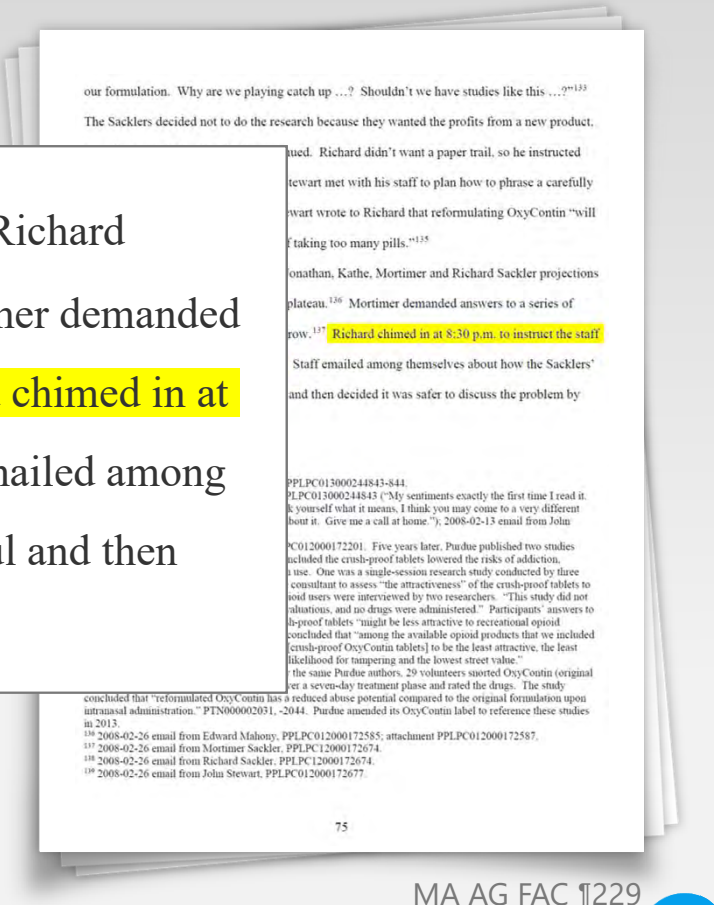
CONFIDENTIAL PPLPC012000170948

2/13/08 Email from R. Sackler (PPLPC012000170948)

Allegation: Instruction To Find Answers "Before Tomorrow"

Massachusetts AG FAC ¶229:

229. Meanwhile, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau. Mortimer demanded answers to a series of questions about why sales would not grow. Richard chimed in at 8:30 p.m. to instruct the staff to find answers "before tomorrow." Staff emailed among themselves about how the Sacklers' demands were unrealistic and harmful and then decided it was safer to discuss the problem by phone.


our formulation. Why are we playing catch up …? Shouldn't we have studies like this …?"[133]

The Sacklers decided not to do the research because they wanted the profits from a new product,

tued. Richard didn't want a paper trail, so he instructed

tewart met with his staff to plan how to phrase a carefully

wart wrote to Richard that reformulating OxyContin "will

f taking too many pills."[135]

onathan, Kathe, Mortimer and Richard Sackler projections

plateau.[136] Mortimer demanded answers to a series of

row.[137] Richard chimed in at 8:30 p.m. to instruct the staff

Staff emailed among themselves about how the Sacklers'

and then decided it was safer to discuss the problem by

PPLPC013000244843-844.
PLPC013000244843 ("My sentiments exactly the first time I read it.
k yourself what it means, I think you may come to a very different
bout it. Give me a call at home."); 2008-02-13 email from John

PC012000172201. Five years later, Purdue published two studies
ncluded the crush-proof tablets lowered the risks of addiction.
use. One was a single-session research study conducted by three
consultant to assess "the attractiveness" of the crush-proof tablets to
noid users were interviewed by two researchers. "This study did not
alutatious, and no drugs were administered." Participants' answers to
h-proof tablets "might be less attractive to recreational opioid
concluded that "among the available opioid products that we included
[crush-proof OxyContin tablets] to be the least attractive, the least
likelihood for tampering and the lowest street value."
the same Purdue authors, 29 volunteers snorted OxyContin (original
ver a seven-day treatment phase and rated the drugs. The study
concluded that "reformulated OxyContin has a reduced abuse potential compared to the original formulation upon
intranasal administration." PTN000002031, -2044. Purdue amended its OxyContin label to reference these studies
in 2013.
[136] 2008-02-26 email from Edward Mahony, PPLPC012000172585; attachment PPLPC012000172587.
[137] 2008-02-26 email from Mortimer Sackler, PPLPC012000172674.
[138] 2008-02-26 email from Richard Sackler, PPLPC012000172674.
[139] 2008-02-26 email from John Stewart, PPLPC012000172677.

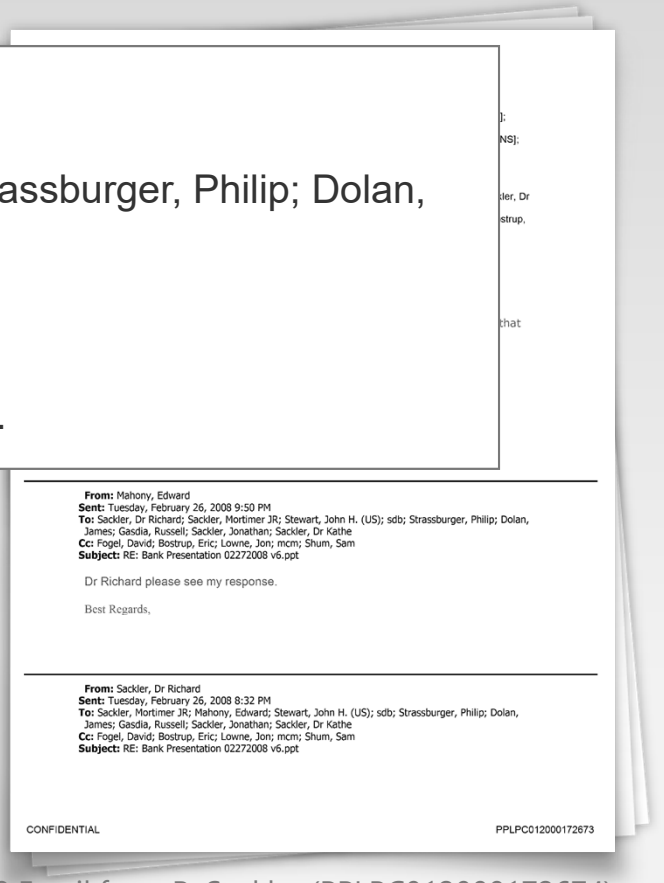
75

MA AG FAC ¶229

Irrelevant 2008 Email Requests Information About Sales, Not Marketing

From: Sackler, Dr Richard
Sent: Tuesday, February 26, 2008 8:32 PM
To: Sackler, Mortimer JR; Mahony, Edward; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe
Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam
Subject: RE: Bank Presentation 02272008 v6.ppt

Ed, if you can repair this before tomorrow, it would be very welcome.



From: Mahony, Edward
Sent: Tuesday, February 26, 2008 9:50 PM
To: Sackler, Dr Richard; Sackler, Mortimer JR; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe
Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam
Subject: RE: Bank Presentation 02272008 v6.ppt

Dr Richard please see my response.

Best Regards,

From: Sackler, Dr Richard
Sent: Tuesday, February 26, 2008 8:32 PM
To: Sackler, Mortimer JR; Mahony, Edward; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe
Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam
Subject: RE: Bank Presentation 02272008 v6.ppt

CONFIDENTIAL PPLPC012000172673

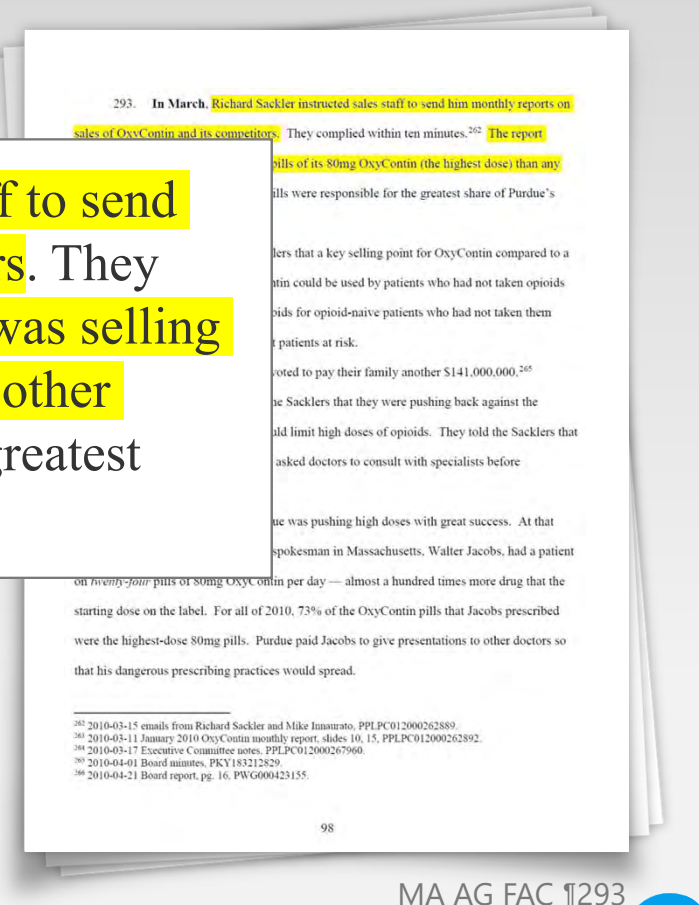
2/26/08 Email from R. Sackler (PPLPC012000172674)

- OIG confirmed compliance for 2008

Allegation: Request For Monthly Sales Reports

Massachusetts AG FAC ¶293:

293. In March, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes. The report showed that Purdue was selling more pills of its 80mg OxyContin (the highest dose) than any other dose, and that the highest dose pills were responsible for the greatest share of Purdue's revenue by far.


293. **In March**, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes.[262] The report

ills of its 80mg OxyContin (the highest dose) than any

ills were responsible for the greatest share of Purdue's

lers that a key selling point for OxyContin compared to a

ntin could be used by patients who had not taken opioids

oids for opioid-naive patients who had not taken them

patients at risk.

oted to pay their family another $141,000,000.[265]

he Sacklers that they were pushing back against the

ld limit high doses of opioids. They told the Sacklers that

asked doctors to consult with specialists before

ue was pushing high doses with great success. At that

spokesman in Massachusetts, Walter Jacobs, had a patient

on *twenty-four* pills of 80mg OxyContin per day — almost a hundred times more drug that the starting dose on the label. For all of 2010, 73% of the OxyContin pills that Jacobs prescribed were the highest-dose 80mg pills. Purdue paid Jacobs to give presentations to other doctors so that his dangerous prescribing practices would spread.

[262] 2010-03-15 emails from Richard Sackler and Mike Innaurato, PPLPC012000262889.
[263] 2010-03-11 January 2010 OxyContin monthly report, slides 10, 15, PPLPC012000262892.
[264] 2010-03-17 Executive Committee notes, PPLPC012000267960.
[265] 2010-04-01 Board minutes, PKY183212829.
[266] 2010-04-21 Board report, pg. 16, PWG000423155.

98

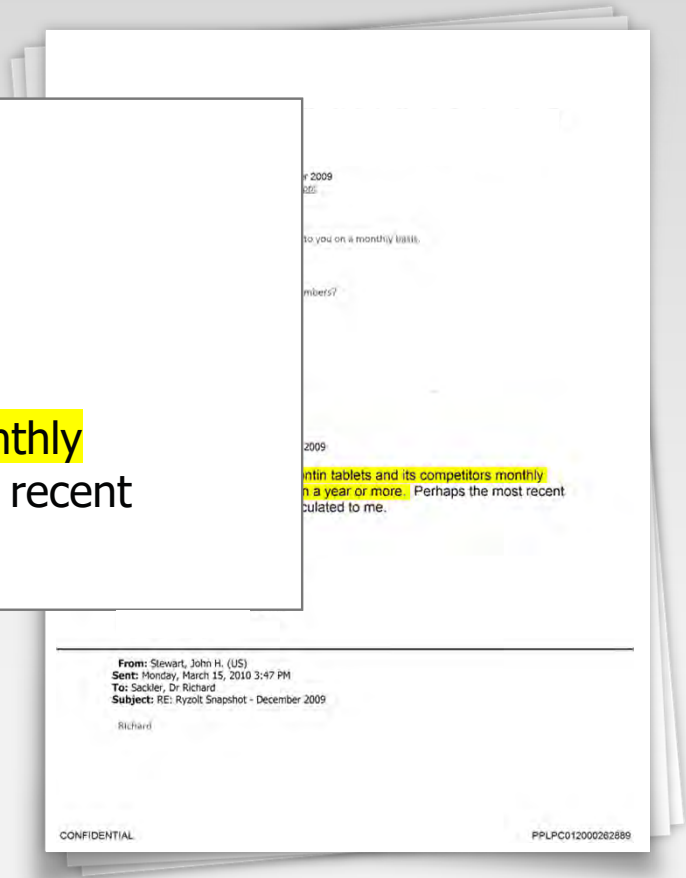
MA AG FAC ¶293

Irrelevant 2010 Email Requests Monthly Information Not Seen In A Year

From: Sackler, Dr Richard
Sent: Monday, March 15, 2010 4:39 PM
To: Stewart, John H. (US)
Cc: Gasdia, Russell; Innaurato, Mike
Subject: RE: Ryzolt Snapshot - December 2009

Can we continue to get OxyContin tablets and its competitors monthly information. I haven't seen it in a year or more. Perhaps the most recent edictions of these could be circulated to me.

- OIG confirmed compliance for 2010

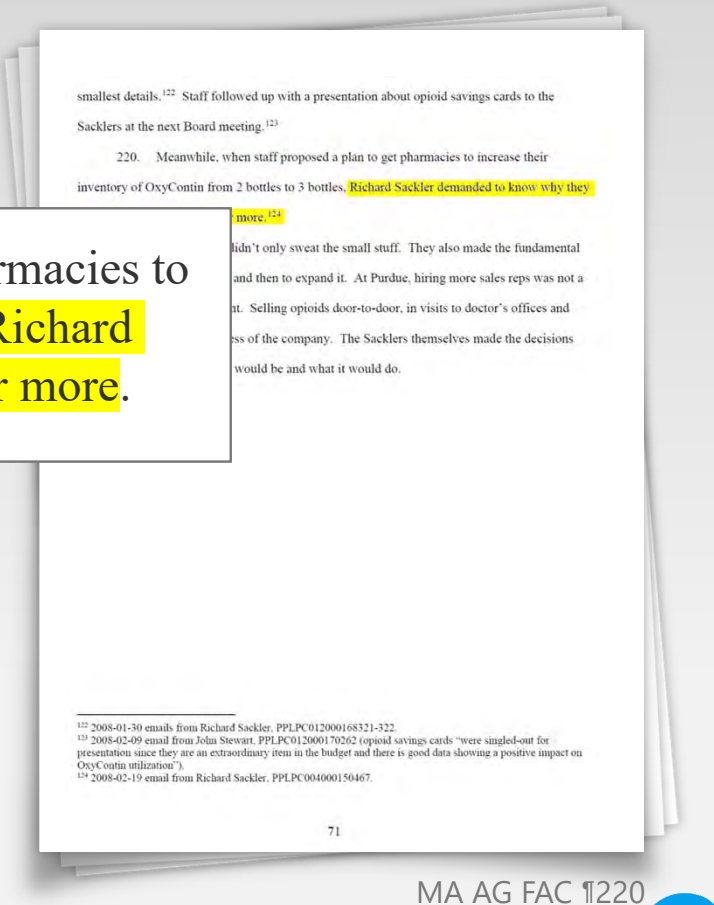


3/15/10 Email from R. Sackler (PPLPC012000262889)

Allegation: Question About Pharmacy Stocking Increase Plan

Massachusetts AG FAC ¶220:

220. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they couldn't get up to 4 bottles or more.



smallest details.[122] Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.[123]

220. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they

more.[124]

lidn't only sweat the small stuff. They also made the fundamental

and then to expand it. At Purdue, hiring more sales reps was not a

it. Selling opioids door-to-door, in visits to doctor's offices and

ss of the company. The Sacklers themselves made the decisions

would be and what it would do.

[122] 2008-01-30 emails from Richard Sackler, PPLPC012000168321-322.
[123] 2008-02-09 email from John Stewart, PPLPC012000170262 (opioid savings cards "were singled-out for presentation since they are an extraordinary item in the budget and there is good data showing a positive impact on OxyContin utilization").
[124] 2008-02-19 email from Richard Sackler, PPLPC004000150467.

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MA AG FAC ¶220

Irrelevant 2008 Questions About Pharmacy Stocking Calculations

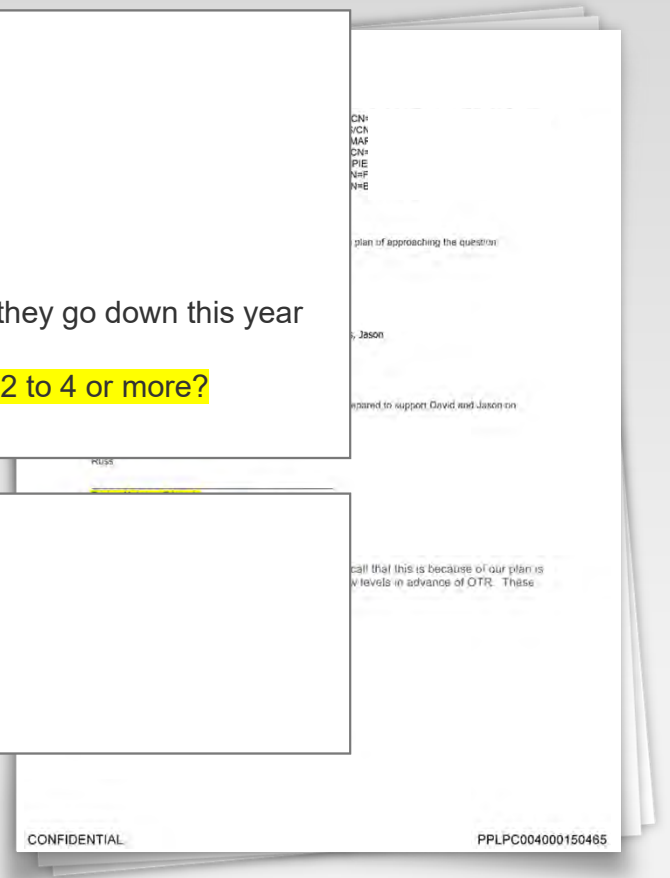
From: Sackler, Dr Richard
Sent: Tuesday, February 19, 2008 7:24 PM
To: Mahony, Edward; Stewart, John H. (US); Gasdia, Russell; Fogel, David
Subject: RE:

Questions:

1. Wholesalers
   a. Turns were about 17/year (assuming 21 days of stock)
   b. Why will turns increase if we increase SKU's from 4 to 7 and then to 14**?** Shouldn't they go down this year
2. Pharmacies
   a. I see that average pharmacy stock goes from 2 to 3, but why wouldn't it go up from 2 to 4 or more?
   b. On average more than double the SKU's (4-7-14-7)

From: Mahony, Edward
Sent: Wednesday, February 20, 2008 7:20 AM
To: Stewart, John H. (US); Gasdia, Russell
Cc: Barnes, Jason; Fogel, David; Long, David
Subject: RE:

Dr Richard is right that the number looks low.



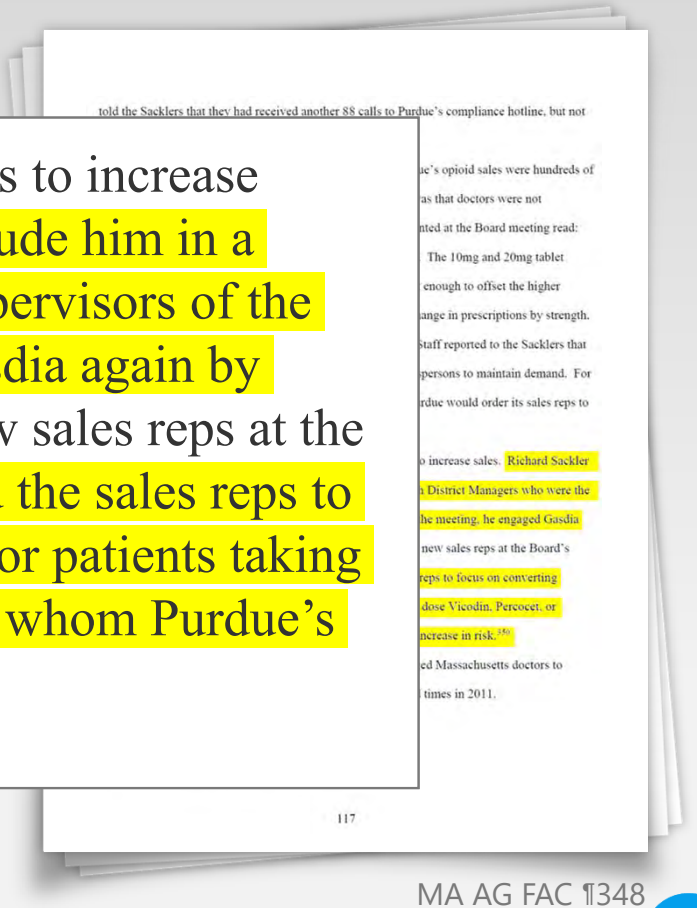
- OIG confirmed compliance for 2008

2/19/08 Email from R. Sackler (PPLPC004000150467)

Allegation: Request To Attend District Manager Meeting

Massachusetts AG FAC ¶348:

348. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the day-to-day supervisors of the sales reps. Then, having missed the meeting, he engaged Gasdia again by email. . . . Gasdia told Richard that Purdue had hired 147 new sales reps at the Board's direction. Gasdia told Richard that Purdue instructed the sales reps to focus on converting patients who had never been on opioids or patients taking "low dose Vicodin, Percocet, or tramadol" — all patients for whom Purdue's opioids posed an increase in risk.


told the Sacklers that they had received another 88 calls to Purdue's compliance hotline, but not

ue's opioid sales were hundreds of
as that doctors were not
nted at the Board meeting read:
The 10mg and 20mg tablet
enough to offset the higher
ange in prescriptions by strength.
staff reported to the Sacklers that
persons to maintain demand. For
rdue would order its sales reps to

o increase sales. Richard Sackler
District Managers who were the
he meeting, he engaged Gasdia
new sales reps at the Board's
reps to focus on converting
dose Vicodin, Percocet, or
ncrease in risk.[350]
ed Massachusetts doctors to
times in 2011.

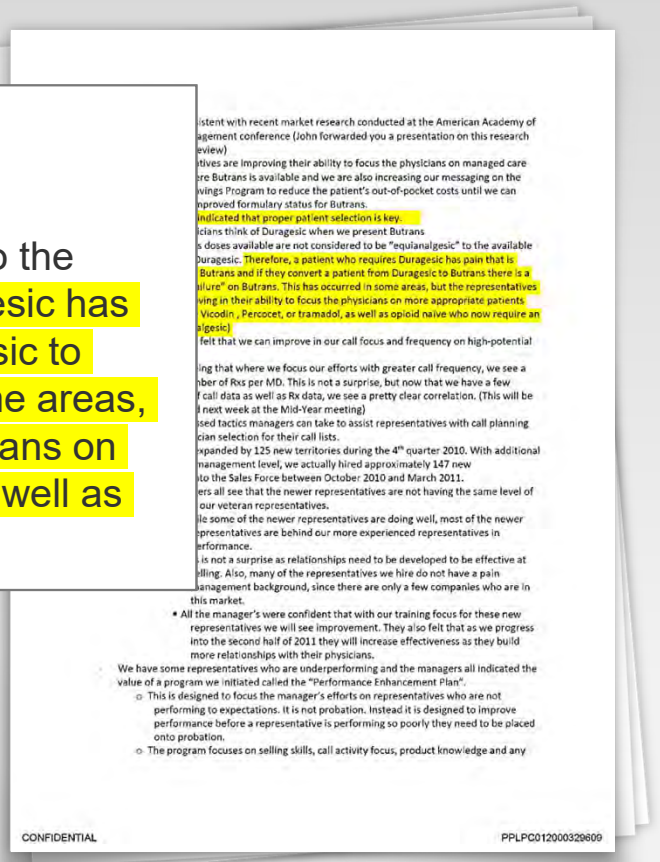
117

MA AG FAC ¶348

2011 Email: Managers Focused On Proper Patient Selection

The managers all indicated that proper patient selection is key.

- o Some physicians think of Duragesic when we present Butrans
- o The Butrans doses available are not considered to be "equianalgesic" to the available doses of Duragesic. Therefore, a patient who requires Duragesic has pain that is "beyond" Butrans and if they convert a patient from Duragesic to Butrans there is a risk on "failure" on Butrans. This has occurred in some areas, but the representatives are improving in their ability to focus the physicians on more appropriate patients (low dose Vicodin, Percocet, or tramadol, as well as opioid naive who now require an opioid analgesic)



istent with recent market research conducted at the American Academy of agement conference (John forwarded you a presentation on this research eview)
tives are improving their ability to focus the physicians on managed care re Butrans is available and we are also increasing our messaging on the vings Program to reduce the patient's out-of-pocket costs until we can nproved formulary status for Butrans.
ndicated that proper patient selection is key.
icians think of Duragesic when we present Butrans
s doses available are not considered to be "equianalgesic" to the available uragesic. Therefore, a patient who requires Duragesic has pain that is Butrans and if they convert a patient from Duragesic to Butrans there is a ilure" on Butrans. This has occurred in some areas, but the representatives ving in their ability to focus the physicians on more appropriate patients Vicodin , Percocet, or tramadol, as well as opioid naive who now require an lgesic)
felt that we can improve in our call focus and frequency on high-potential

ng that where we focus our efforts with greater call frequency, we see a ber of Rxs per MD. This is not a surprise, but now that we have a few call data as well as Rx data, we see a pretty clear correlation. (This will be next week at the Mid-Year meeting)
sed tactics managers can take to assist representatives with call planning cian selection for their call lists.
xpanded by 125 new territories during the 4th quarter 2010. With additional nanagement level, we actually hired approximately 147 new to the Sales Force between October 2010 and March 2011.
ers all see that the newer representatives are not having the same level of our veteran representatives.
le some of the newer representatives are doing well, most of the newer epresentatives are behind our more experienced representatives in erformance.
is not a surprise as relationships need to be developed to be effective at lling. Also, many of the representatives we hire do not have a pain anagement background, since there are only a few companies who are in this market.
- All the manager's were confident that with our training focus for these new representatives we will see improvement. They also felt that as we progress into the second half of 2011 they will increase effectiveness as they build more relationships with their physicians.

We have some representatives who are underperforming and the managers all indicated the value of a program we initiated called the "Performance Enhancement Plan".
- o This is designed to focus the manager's efforts on representatives who are not performing to expectations. It is not probation. Instead it is designed to improve performance before a representative is performing so poorly they need to be placed onto probation.
- o The program focuses on selling skills, call activity focus, product knowledge and any

CONFIDENTIAL PPLPC012000329609

- Butrans, not OxyContin
- OIG confirmed compliance for 2011

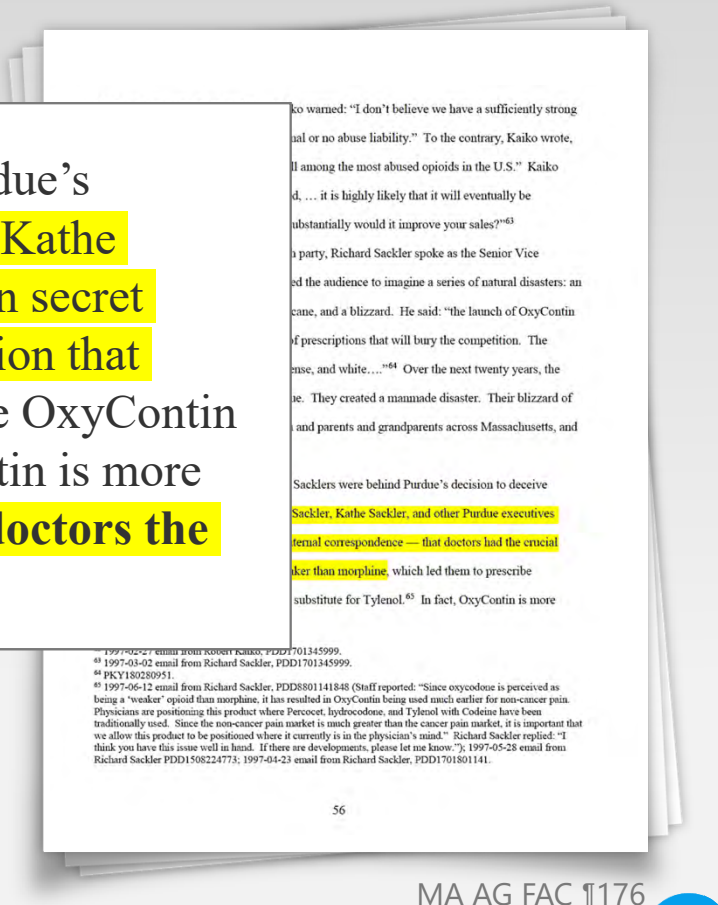
6/16/11 Email from R. Gasdia (PPLPC012000329609)

Pre-2007 Released Marketing Allegations About Richard Sackler

Allegation: Misperceptions Of OxyContin

Massachusetts AG FAC ¶176:

176. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined — and recorded in secret internal correspondence — that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. In fact, OxyContin is more potent than morphine. **Richard directed Purdue staff not to tell doctors the truth, because the truth could reduce OxyContin sales**.

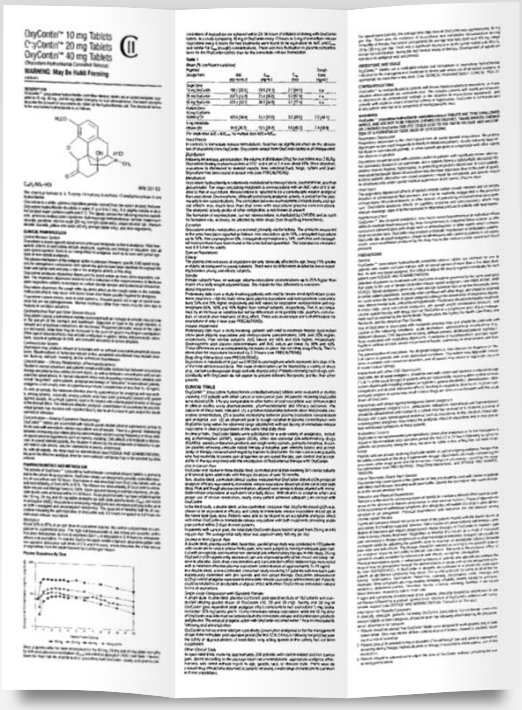


- There is no such "direct[ion]" in the cited document
- Doctors knew from the label that this was not true

MA AG FAC ¶176

Label Has Always Equated the Abuse Potential of OxyContin & Morphine

- "OxyContin is a mu-agonist opioid **with an abuse liability similar to morphine** and is a Schedule II controlled substance" (Original 1995 Label)
- "OxyContin is an opioid agonist and a Schedule II controlled substance **with an abuse liability similar to morphine**" (2001, 2005, 2007 Labels)
- "OxyContin contains oxycodone, a Schedule II controlled substance with a **high potential for abuse similar to other opioids including … morphine**" (2015 Label)
- "OxyContin contains oxycodone, a substance with a **high potential for abuse similar to other opioids including … morphine**" (2018 Label)



Label Showed OxyContin Is Twice As Strong As Morphine

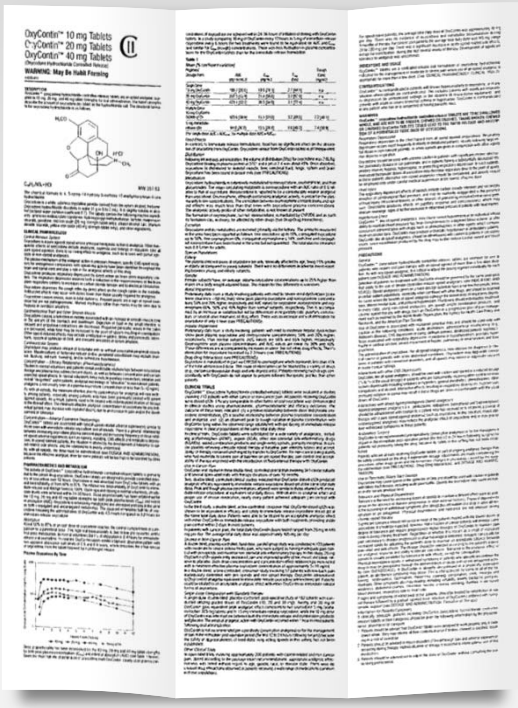
Table 3

*Multiplication Factors for Converting the Daily Dose of Prior Opioids to the Daily Dose of Oral Oxycodone**

(Mg/Day Prior Opioid x Factor=Mg/Day Oral Oxycodone)

	Oral Prior Opioid	Parenteral Prior Opioid
Oxycodone	1	–
Codeine	0.15	–
Fentanyl TTS	SEE BELOW	SEE BELOW
Hydrocodone	0.9	–
Hydromorphone	4	20
Levorphanol	7.5	15
Meperidine	0.1	0.4
Methadone	1.5	3
Morphine	0.5	3

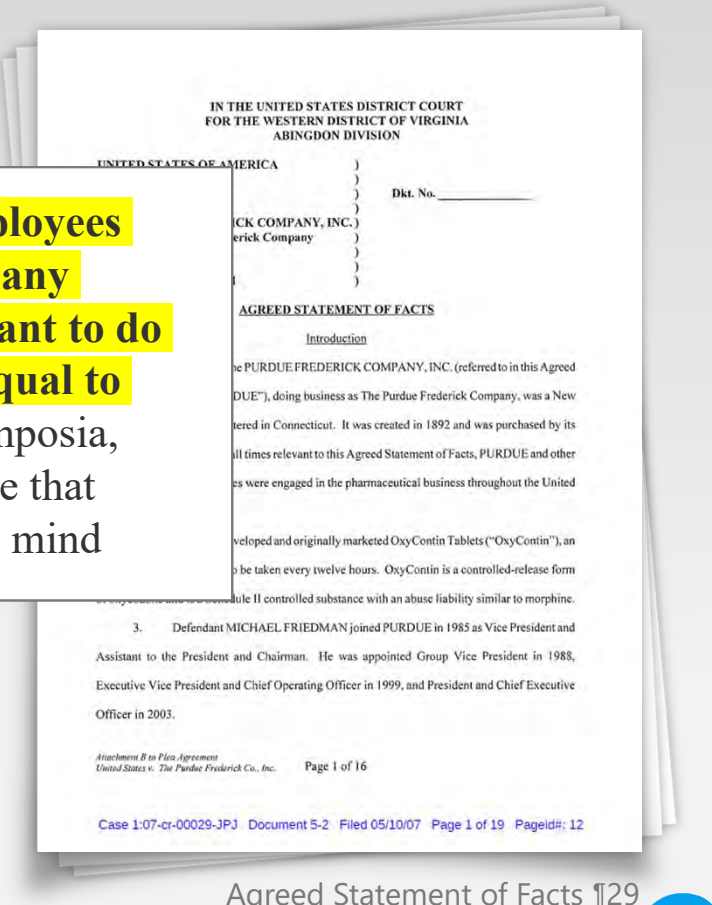
*To be used only for conversion to oral oxycodone. For patients receiving high-dose parenteral opioids, a more conservative conversion is warranted. For example, for high-dose parenteral morphine, use 1.5 instead of 3 as a multiplication factor In all cases, supplemental analgesia (see below) should be made available in the form of immediate-release oral oxycodone or another suitable shod acting analgesic.



1995 OxyContin Label (PDD150170001)

Employees' Misstatements Admitted, Settled and Released In 2007

29. **In or about May 1997, certain PURDUE supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger or equal to morphine"** or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians mind *(sic)*."



IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
) Dkt. No. _____
)
(CK COMPANY, INC.)
erick Company)
)
)
)

AGREED STATEMENT OF FACTS

Introduction

he PURDUE FREDERICK COMPANY, INC. (referred to in this Agreed
DUE"), doing business as The Purdue Frederick Company, was a New
tered in Connecticut. It was created in 1892 and was purchased by its
ll times relevant to this Agreed Statement of Facts, PURDUE and other
es were engaged in the pharmaceutical business throughout the United

veloped and originally marketed OxyContin Tablets ("OxyContin"), an
be taken every twelve hours. OxyContin is a controlled-release form
dule II controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive Officer in 2003.

Attachment B to Plea Agreement
United States v. The Purdue Frederick Co., Inc. Page 1 of 16

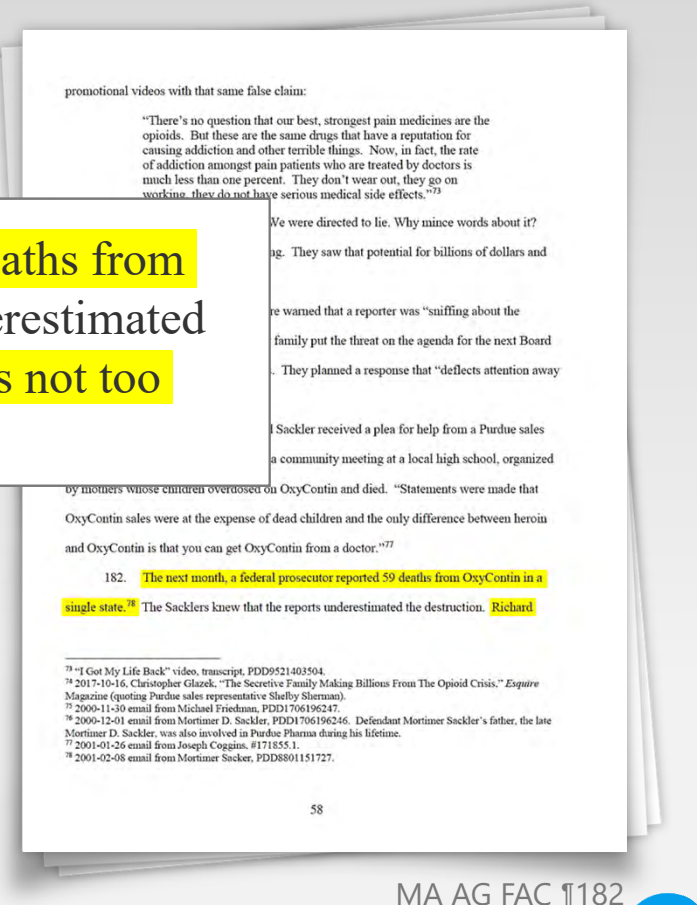
Case 1:07-cr-00029-JPJ Document 5-2 Filed 05/10/07 Page 1 of 19 PageId#: 12

Agreed Statement of Facts ¶29

Allegation: February 2001 Reaction To Reports of Death

Massachusetts AG FAC ¶182:

182. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state. The Sacklers knew that the reports underestimated the destruction. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."



promotional videos with that same false claim:

"There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects."[73]

We were directed to lie. Why mince words about it?

ng. They saw that potential for billions of dollars and

re warned that a reporter was "sniffing about the

family put the threat on the agenda for the next Board

. They planned a response that "deflects attention away

l Sackler received a plea for help from a Purdue sales

a community meeting at a local high school, organized

by mothers whose children overdosed on OxyContin and died. "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."[77]

182. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state.[78] The Sacklers knew that the reports underestimated the destruction. Richard

[73] "I Got My Life Back" video, transcript, PDD9521403504.
[74] 2017-10-16, Christopher Glazek, "The Secretive Family Making Billions From The Opioid Crisis," *Esquire* Magazine (quoting Purdue sales representative Shelby Sherman).
[75] 2000-11-30 email from Michael Friedman, PDD1706196247.
[76] 2000-12-01 email from Mortimer D. Sackler, PDD1706196246. Defendant Mortimer Sackler's father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.
[77] 2001-01-26 email from Joseph Coggins, #171855.1.
[78] 2001-02-08 email from Mortimer Sacker, PDD8801151727.

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MA AG FAC ¶182

Cited Email Reacts To Lengthy *New York Times* Article

- The allegation distorts the email
- Negative *New York Times* article expected
- Not as negative as expected
- It included the response of Purdue's medical director

2/8/01 Email from R. Sackler
(PPLPC045000004037)

From: Sackler, Dr Richard
Sent: Thursday, February 08, 2001 9:59 PM
To: Hogen, Robin; Haddox, Dr. J. David; mxf; hru
Cc: pdg; eda; edm
Subject: FW: NYTimes.com Article: Cancer Painkillers Are Being Abused

This is not too bad. It could have been far worse.
Thanks for all the support.

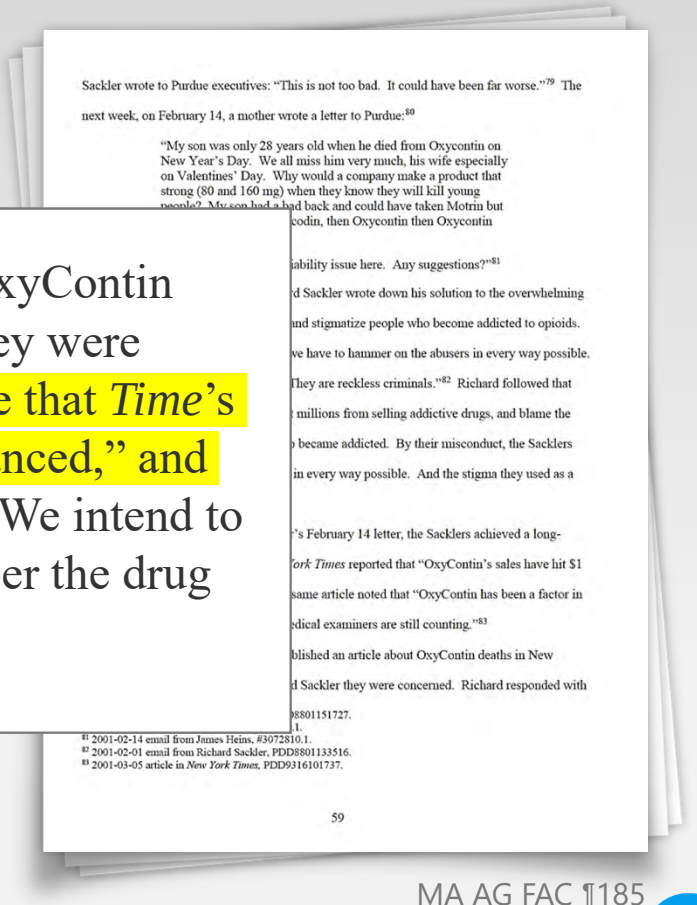
Richard S. Sackler, M.D.
President, Purdue Pharma, L.P.
Laptop 2000 machine
One Stamford Forum
Stamford, CT 06901
Telephone
Internet
Intranet Located in Connecticut

----Original Message-----
From: msackler@me.net

Allegation: January 2001 Time Magazine Article

Massachusetts AG FAC ¶185:

185. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain – who far outnumber the drug addicts abusing our product."


Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."[79] The

next week, on February 14, a mother wrote a letter to Purdue:[80]

"My son was only 28 years old when he died from Oxycontin on New Year's Day. We all miss him very much, his wife especially on Valentines' Day. Why would a company make a product that strong (80 and 160 mg) when they know they will kill young people? My son had a bad back and could have taken Motrin but codin, then Oxycontin then Oxycontin

iability issue here. Any suggestions?"[81]

d Sackler wrote down his solution to the overwhelming

nd stigmatize people who become addicted to opioids.

ve have to hammer on the abusers in every way possible.

They are reckless criminals."[82] Richard followed that

millions from selling addictive drugs, and blame the

became addicted. By their misconduct, the Sacklers

in every way possible. And the stigma they used as a

's February 14 letter, the Sacklers achieved a long-

ork Times reported that "OxyContin's sales have hit $1

same article noted that "OxyContin has been a factor in

edical examiners are still counting."[83]

blished an article about OxyContin deaths in New

d Sackler they were concerned. Richard responded with

8801151727.

[81] 2001-02-14 email from James Heins, #3072810.1.
[82] 2001-02-01 email from Richard Sackler, PDD8801133516.
[83] 2001-03-05 article in *New York Times*, PDD9316101737.

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MA AG FAC ¶185

One-Page Memo Discussing January 2001 Time Magazine Article

Dear Colleagues,

Some of you have expressed concern about an article in this week's *Time* magazine, "The Potent Perils of a Miracle Drug," which unfortunately emphasizes the abuse and diversion rather than the therapeutic qualities of our leading product, OxyContin®.

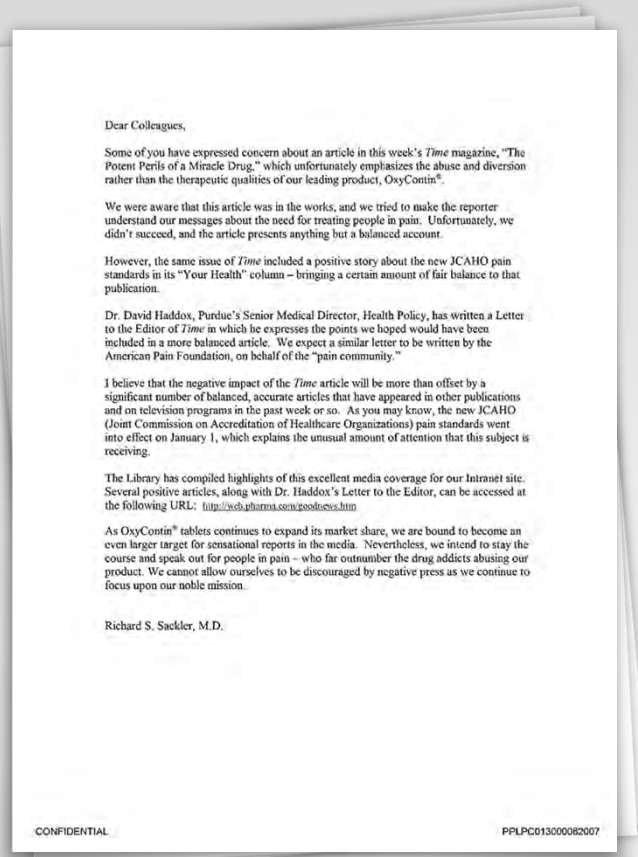
We were aware that this article was in the works, and we tried to make the reporter understand our messages about the need for treating people in pain. Unfortunately, we didn't succeed, and the article presents anything but a balanced account.

However, the same issue of Time included a positive story about the new JCAHO pain standards in its "Your Health" column - bringing a certain amount of fair balance to that publication. …

As OxyContin® tablets continues to expand its market share, we are bound to become an even larger target for sensational reports in the media. Nevertheless, we intend to stay the course and speak out for people in pain - who far outnumber the drug addicts abusing our product. We cannot allow ourselves to be discouraged by negative press as we continue to focus upon our noble mission.

Richard S. Sackler, M.D.

- No suggestion "deaths were the fault of 'the drug addicts'"


Dear Colleagues,

Some of you have expressed concern about an article in this week's *Time* magazine, "The Potent Perils of a Miracle Drug," which unfortunately emphasizes the abuse and diversion rather than the therapeutic qualities of our leading product, OxyContin®.

We were aware that this article was in the works, and we tried to make the reporter understand our messages about the need for treating people in pain. Unfortunately, we didn't succeed, and the article presents anything but a balanced account.

However, the same issue of *Time* included a positive story about the new JCAHO pain standards in its "Your Health" column – bringing a certain amount of fair balance to that publication.

Dr. David Haddox, Purdue's Senior Medical Director, Health Policy, has written a Letter to the Editor of *Time* in which he expresses the points we hoped would have been included in a more balanced article. We expect a similar letter to be written by the American Pain Foundation, on behalf of the "pain community."

I believe that the negative impact of the *Time* article will be more than offset by a significant number of balanced, accurate articles that have appeared in other publications and on television programs in the past week or so. As you may know, the new JCAHO (Joint Commission on Accreditation of Healthcare Organizations) pain standards went into effect on January 1, which explains the unusual amount of attention that this subject is receiving.

The Library has compiled highlights of this excellent media coverage for our Intranet site. Several positive articles, along with Dr. Haddox's Letter to the Editor, can be accessed at the following URL: http://web.pharma.com/goodnews.htm

As OxyContin® tablets continues to expand its market share, we are bound to become an even larger target for sensational reports in the media. Nevertheless, we intend to stay the course and speak out for people in pain – who far outnumber the drug addicts abusing our product. We cannot allow ourselves to be discouraged by negative press as we continue to focus upon our noble mission.

Richard S. Sackler, M.D.

CONFIDENTIAL

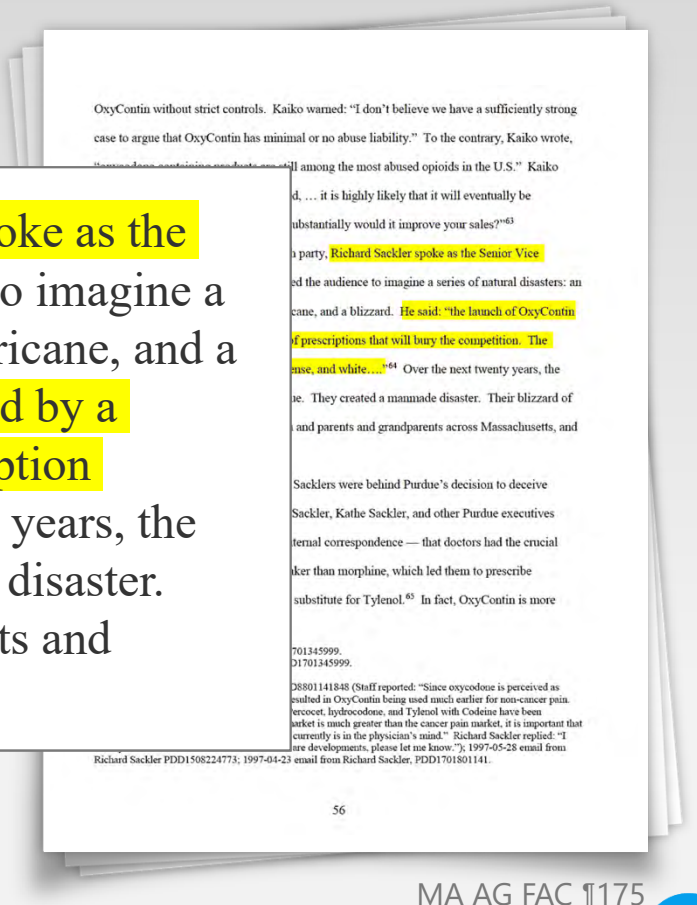
PPLPC013000062007

1/9/01 Letter from R. Sackler (PPLPC013000062006)

Allegation: The Blizzard Of 1996

Massachusetts AG FAC ¶175:

175. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white…." Over the next twenty years, the Sacklers made Richard's boast come true. They created a manmade disaster. Their blizzard of dangerous prescriptions buried children and parents and grandparents across Massachusetts, and the burials continue.


OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, ll among the most abused opioids in the U.S." Kaiko d, … it is highly likely that it will eventually be ubstantially would it improve your sales?"[63] a party, Richard Sackler spoke as the Senior Vice ed the audience to imagine a series of natural disasters: an cane, and a blizzard. He said: "the launch of OxyContin f prescriptions that will bury the competition. The nse, and white…."[64] Over the next twenty years, the e. They created a manmade disaster. Their blizzard of and parents and grandparents across Massachusetts, and Sacklers were behind Purdue's decision to deceive Sackler, Kathe Sackler, and other Purdue executives ternal correspondence — that doctors had the crucial ker than morphine, which led them to prescribe substitute for Tylenol.[65] In fact, OxyContin is more 701345999. D1701345999. D8801141848 (Staff reported: "Since oxycodone is perceived as esulted in OxyContin being used much earlier for non-cancer pain. ercocet, hydrocodone, and Tylenol with Codeine have been arket is much greater than the cancer pain market, it is important that currently is in the physician's mind." Richard Sackler replied: "I are developments, please let me know."); 1997-05-28 email from Richard Sackler PDD1508224773; 1997-04-23 email from Richard Sackler, PDD1701801141.
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MA AG FAC ¶175

Cited Document: The Blizzard Of 1996

OxyContin™: The Most Significant Launch in Purdue History!

For millennia, humans knew that great changes in the fortunes of civilizations and enterprises are heralded by cataclysms in geology and weather.

Eclipses, earthquakes, volcanoes, hurricanes, and blizzards have each preceded such changes, and each upheaval has had its significance and meaning.

Soothsayers and wise men, shamans and high priestesses, each have a claim on the capacity to interpret such phenomena for the rest of us and advise us about how we should now align ourselves for the coming of the New Age.

The Blizzard of '96, coming less than four years before the change of the millennium, is without doubt an omen of change.

This unexpected surge of snow, this untimely tempest threw a wrench into the flawless planning that Jim, Ron, and dozens of others had made to bring us all together here on Sunday evening. Unfortunately Michael, Paul, Robert and I were not with you on Sunday, nor the truth, which is, that we were on a final and unexpected mission to enhance the launch of OxyContin Tablets.

Michael and I were late (and Paul and Robert are missing) not because transportation was snarled and airports were closed. We apologize for the disinformation spread here by Jim, Ron, Mark, and others, but they were acting on Michael's orders.

We were high in the Himalayas, deep in Tibet, to learn from the Wise One everything possible about the meaning of this intemperate interruption of our plans and what we should be doing to take advantage of the launch of OxyContin Tablets. It was Paul who first said that it was imprudent to depend upon our own powers of prognostication. "Let's go where the knowledge is," suggested Paul. We all wanted to be sure that we were bringing you the most authoritative information about the significance of the Blizzard of '96. "We need an expert," said Paul conclusively.

vermin, and that they borrow your watch to tell you the time."

"There is an alternative to McKinsey," said Robert Reder. "I know a Wise One in the mountains of Tibet."

I ventured, "Well, there is a chance, because Michael loves mountains, snow and skiing. Paul, Robert,

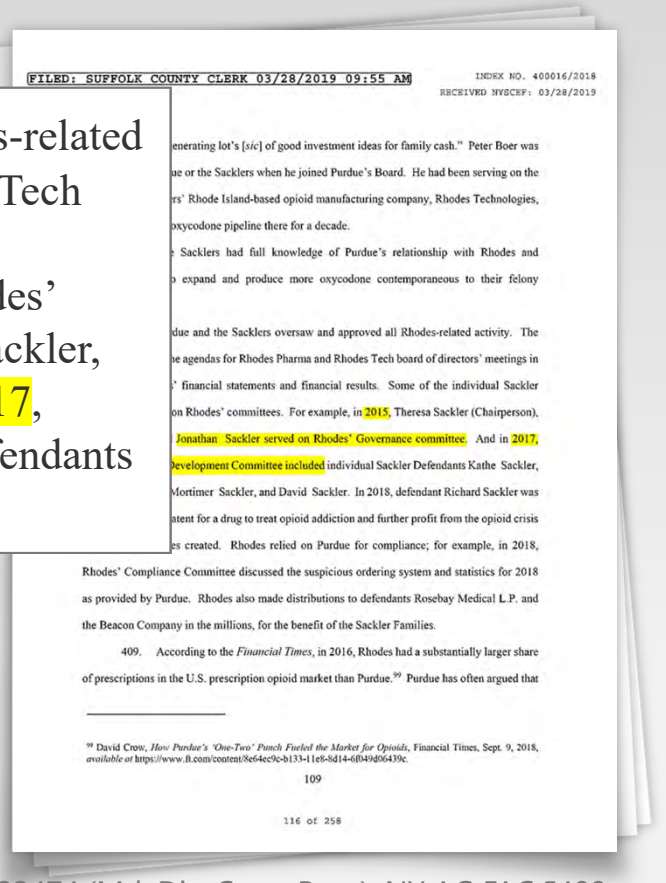
Winter 1996 PFC Newsletter (PKY180280951)

Marketing Allegations About Jonathan Sackler

Allegation: Rhodes Board Committees

New York AG FAC ¶408:

408. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler.



FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
RECEIVED NYSCEF: 03/28/2019

enerating lot's [*sic*] of good investment ideas for family cash." Peter Boer was
ue or the Sacklers when he joined Purdue's Board. He had been serving on the
rs' Rhode Island-based opioid manufacturing company, Rhodes Technologies,
oxycodone pipeline there for a decade.
Sacklers had full knowledge of Purdue's relationship with Rhodes and
expand and produce more oxycodone contemporaneous to their felony

due and the Sacklers oversaw and approved all Rhodes-related activity. The
e agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in
financial statements and financial results. Some of the individual Sackler
on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson),
Jonathan Sackler served on Rhodes' Governance committee. And in 2017,
evelopment Committee included individual Sackler Defendants Kathe Sackler,
Mortimer Sackler, and David Sackler. In 2018, defendant Richard Sackler was
atent for a drug to treat opioid addiction and further profit from the opioid crisis
es created. Rhodes relied on Purdue for compliance; for example, in 2018,
Rhodes' Compliance Committee discussed the suspicious ordering system and statistics for 2018
as provided by Purdue. Rhodes also made distributions to defendants Rosebay Medical L.P. and
the Beacon Company in the millions, for the benefit of the Sackler Families.

409. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[99] Purdue has often argued that

[99] David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, Financial Times, Sept. 9, 2018, *available at* https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

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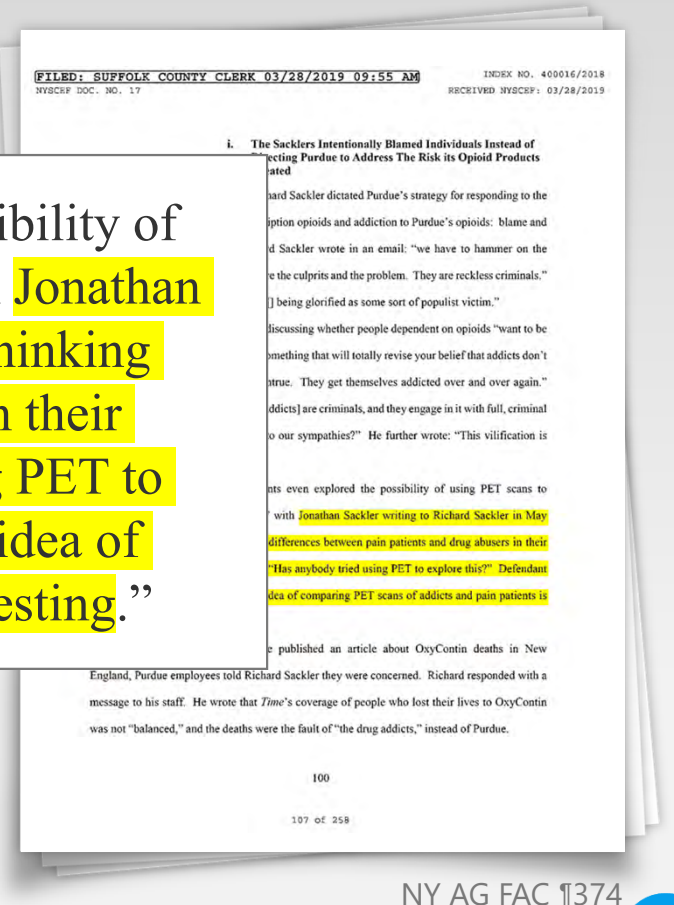
- **Jonathan Sackler never served as a Rhodes director or on any Rhodes committee**
- **Irrelevant to deceptive marketing claims**

8/8/19 J. Sackler Decl., *Consumer Protection Division v. PPLP*, Case No. 311366, OAH Case No. 1923474 (Md. Div. Cons. Prot.); NY AG FAC ¶408

Allegation: Exploring Possibility Of Using PET Scans To Identify Abusers

New York AG FAC ¶374:

374. The Sackler Defendants even explored the possibility of using PET scans to distinguish "patients" from "abusers," with Jonathan Sackler writing to Richard Sackler in May 2008 that he "was thinking about the differences between pain patients and drug abusers in their reaction to opioids." Jonathan asked, "Has anybody tried using PET to explore this?" Defendant Richard Sackler replied: "I think the idea of comparing PET scans of addicts and pain patients is very interesting."


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

i. The Sacklers Intentionally Blamed Individuals Instead of ...ecting Purdue to Address The Risk its Opioid Products ...ated

...ard Sackler dictated Purdue's strategy for responding to the ...iption opioids and addiction to Purdue's opioids: blame and ...d Sackler wrote in an email: "we have to hammer on the ...e the culprits and the problem. They are reckless criminals." ...] being glorified as some sort of populist victim." ...discussing whether people dependent on opioids "want to be ...omething that will totally revise your belief that addicts don't ...true. They get themselves addicted over and over again." ...ddicts] are criminals, and they engage in it with full, criminal ...o our sympathies?" He further wrote: "This vilification is

...nts even explored the possibility of using PET scans to ... with Jonathan Sackler writing to Richard Sackler in May ...differences between pain patients and drug abusers in their ..."Has anybody tried using PET to explore this?" Defendant ...dea of comparing PET scans of addicts and pain patients is

...e published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue.

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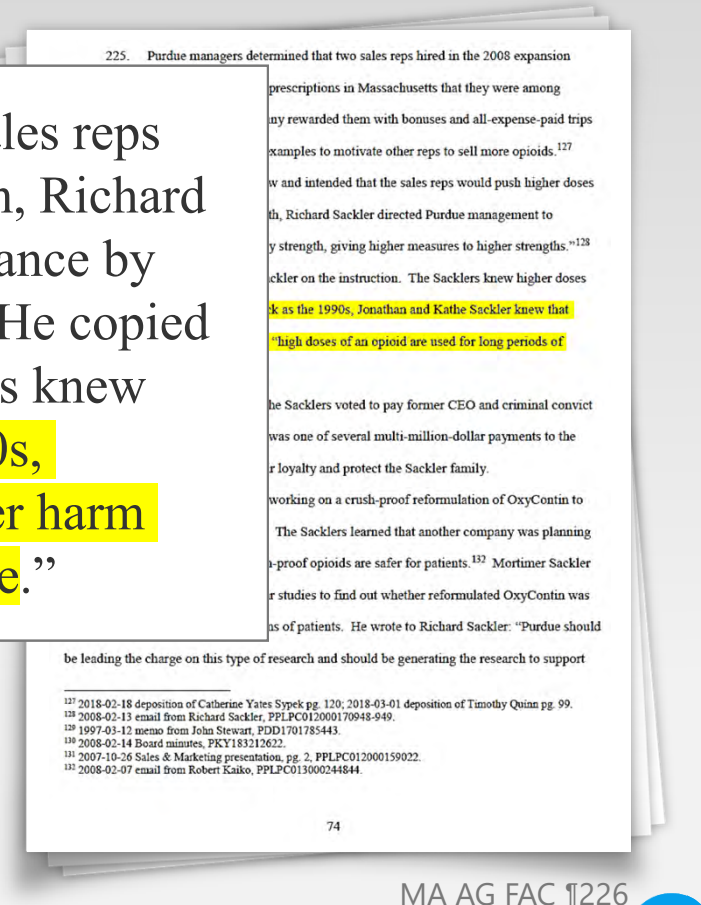
- 2008 email, no "exploration"
- OIG confirmed compliance for 2008

NY AG FAC ¶374

Allegation: Knowledge Of Opioid Risks

Massachusetts AG FAC ¶226:

226. The Sacklers also knew and intended that the sales reps would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths." He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when "high doses of an opioid are used for long periods of time."



225. Purdue managers determined that two sales reps hired in the 2008 expansion
prescriptions in Massachusetts that they were among
ny rewarded them with bonuses and all-expense-paid trips
xamples to motivate other reps to sell more opioids.[127]
w and intended that the sales reps would push higher doses
th, Richard Sackler directed Purdue management to
y strength, giving higher measures to higher strengths."[128]
ckler on the instruction. The Sacklers knew higher doses
k as the 1990s, Jonathan and Kathe Sackler knew that
"high doses of an opioid are used for long periods of

he Sacklers voted to pay former CEO and criminal convict
was one of several multi-million-dollar payments to the
r loyalty and protect the Sackler family.
working on a crush-proof reformulation of OxyContin to
The Sacklers learned that another company was planning
-proof opioids are safer for patients.[132] Mortimer Sackler
r studies to find out whether reformulated OxyContin was
s of patients. He wrote to Richard Sackler: "Purdue should
be leading the charge on this type of research and should be generating the research to support

[127] 2018-02-18 deposition of Catherine Yates Sypek pg. 120; 2018-03-01 deposition of Timothy Quinn pg. 99.
[128] 2008-02-13 email from Richard Sackler, PPLPC012000170948-949.
[129] 1997-03-12 memo from John Stewart, PDD1701785443.
[130] 2008-02-14 Board minutes, PKY183212622.
[131] 2007-10-26 Sales & Marketing presentation, pg. 2, PPLPC012000159022.
[132] 2008-02-07 email from Robert Kaiko, PPLPC013000244844.

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MA AG FAC ¶226

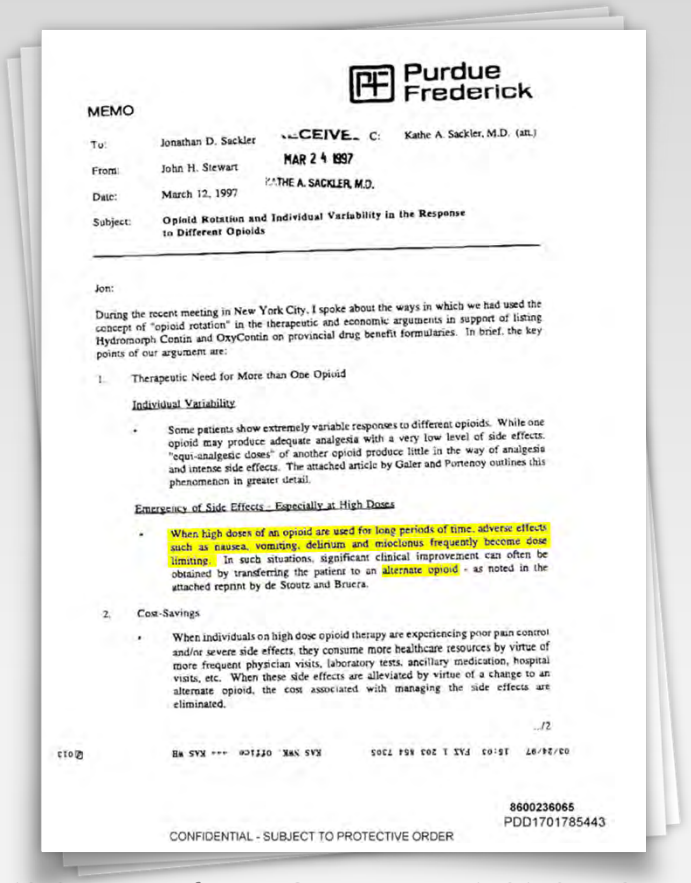
Irrelevant 1997 Memo Discusses Need For Alternate Opioid Analgesics

To: Jonathan D. Sackler
From: John H. Stewart
Date: March 12, 1997

1. Therapeutic Need for More than One Opioid

Emergency of Side Effects – Especially at High Does

- When high doses of an opioid are used for long periods of time, adverse effects such as nausea, vomiting, delirium and mioclonus frequently become dose limiting. In such situation, significant clinical improvement can often be obtained by transferring the patient to an alternate opioid – as noted in the attached reprint by de Stoutz and Bruera.



Purdue Frederick

MEMO

To: Jonathan D. Sackler — C: Kathe A. Sackler, M.D. (an.)

From: John H. Stewart

Date: March 12, 1997

RECEIVED MAR 24 1997 KATHE A. SACKLER, M.D.

Subject: Opioid Rotation and Individual Variability in the Response to Different Opioids

Jon:

During the recent meeting in New York City, I spoke about the ways in which we had used the concept of "opioid rotation" in the therapeutic and economic arguments in support of listing Hydromorph Contin and OxyContin on provincial drug benefit formularies. In brief, the key points of our argument are:

1. Therapeutic Need for More than One Opioid

Individual Variability

- Some patients show extremely variable responses to different opioids. While one opioid may produce adequate analgesia with a very low level of side effects, "equi-analgesic doses" of another opioid produce little in the way of analgesia and intense side effects. The attached article by Galer and Portenoy outlines this phenomenon in greater detail.

Emergency of Side Effects – Especially at High Doses

- When high doses of an opioid are used for long periods of time, adverse effects such as nausea, vomiting, delirium and mioclonus frequently become dose limiting. In such situations, significant clinical improvement can often be obtained by transferring the patient to an alternate opioid - as noted in the attached reprint by de Stoutz and Bruera.

2. Cost-Savings

- When individuals on high dose opioid therapy are experiencing poor pain control and/or severe side effects, they consume more healthcare resources by virtue of more frequent physician visits, laboratory tests, ancillary medication, hospital visits, etc. When these side effects are alleviated by virtue of a change to an alternate opioid, the cost associated with managing the side effects are eliminated.

.../2

8600236065
PDD1701785443

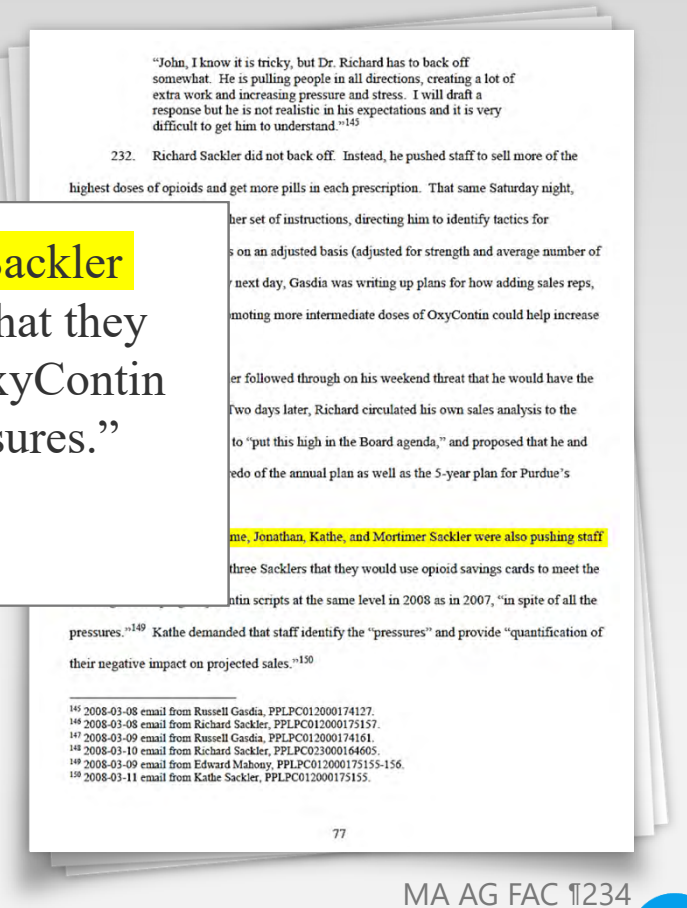
CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

3/12/97 Memo from J. Stewart (PDD1701785443)

Allegation: Pushing Staff About Sales

Massachusetts AG FAC ¶234:

234. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales. Staff told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, "in spite of all the pressures." Kathe demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."



"John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand."[145]

232. Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids and get more pills in each prescription. That same Saturday night, her set of instructions, directing him to identify tactics for s on an adjusted basis (adjusted for strength and average number of next day, Gasdia was writing up plans for how adding sales reps, moting more intermediate doses of OxyContin could help increase

er followed through on his weekend threat that he would have the Two days later, Richard circulated his own sales analysis to the to "put this high in the Board agenda," and proposed that he and edo of the annual plan as well as the 5-year plan for Purdue's

me, Jonathan, Kathe, and Mortimer Sackler were also pushing staff three Sacklers that they would use opioid savings cards to meet the ntin scripts at the same level in 2008 as in 2007, "in spite of all the pressures."[149] Kathe demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."[150]

[145] 2008-03-08 email from Russell Gasdia, PPLPC012000174127.
[146] 2008-03-08 email from Richard Sackler, PPLPC012000175157.
[147] 2008-03-09 email from Russell Gasdia, PPLPC012000174161.
[148] 2008-03-10 email from Richard Sackler, PPLPC023000164605.
[149] 2008-03-09 email from Edward Mahony, PPLPC012000175155-156.
[150] 2008-03-11 email from Kathe Sackler, PPLPC012000175155.

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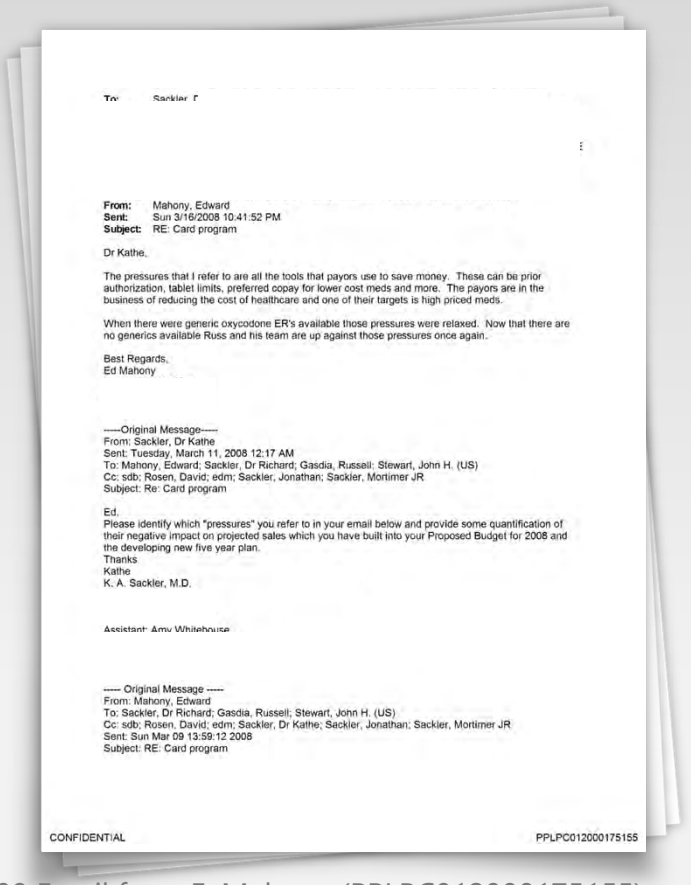
MA AG FAC ¶234

Irrelevant 2008 Email Contains No Communication From Jonathan Sackler

- He is cc'd on an information request
- Sales, not marketing
- OIG <u>confirmed compliance</u> for 2008



To: Sackler, [redacted]

From: Mahony, Edward
Sent: Sun 3/16/2008 10:41:52 PM
Subject: RE: Card program

Dr Kathe,

The pressures that I refer to are all the tools that payors use to save money. These can be prior authorization, tablet limits, preferred copay for lower cost meds and more. The payors are in the business of reducing the cost of healthcare and one of their targets is high priced meds.

When there were generic oxycodone ER's available those pressures were relaxed. Now that there are no generics available Russ and his team are up against those pressures once again.

Best Regards,
Ed Mahony

-----Original Message-----
From: Sackler, Dr Kathe
Sent: Tuesday, March 11, 2008 12:17 AM
To: Mahony, Edward; Sackler, Dr Richard; Gasdia, Russell; Stewart, John H. (US)
Cc: sdb; Rosen, David; edm; Sackler, Jonathan; Sackler, Mortimer JR
Subject: Re: Card program

Ed,
Please identify which "pressures" you refer to in your email below and provide some quantification of their negative impact on projected sales which you have built into your Proposed Budget for 2008 and the developing new five year plan.
Thanks
Kathe
K. A. Sackler, M.D.

Assistant: Amy Whitehouse

----- Original Message -----
From: Mahony, Edward
To: Sackler, Dr Richard; Gasdia, Russell; Stewart, John H. (US)
Cc: sdb; Rosen, David; edm; Sackler, Dr Kathe; Sackler, Jonathan; Sackler, Mortimer JR
Sent: Sun Mar 09 13:59:12 2008
Subject: RE: Card program

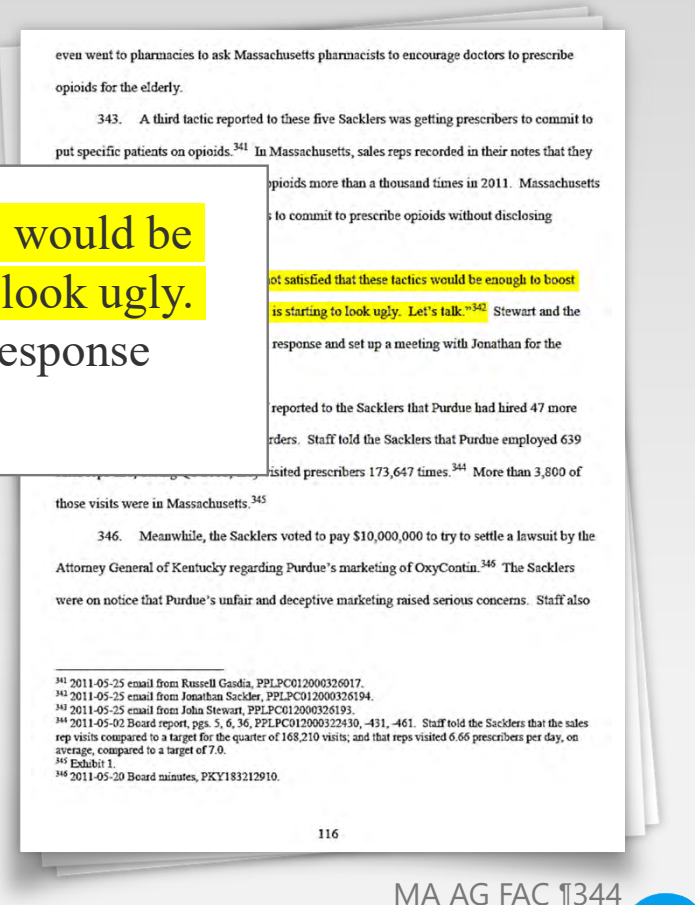
CONFIDENTIAL PPLPC012000175155

3/9/08 Email from E. Mahony (PPLPC012000175155)

Allegation: "Starting To Look Ugly"

Massachusetts AG FAC ¶344:

344. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. He wrote to John Stewart: "this is starting to look ugly. Let's talk." Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.



even went to pharmacies to ask Massachusetts pharmacists to encourage doctors to prescribe opioids for the elderly.

343. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids.[341] In Massachusetts, sales reps recorded in their notes that they ...pioids more than a thousand times in 2011. Massachusetts ...s to commit to prescribe opioids without disclosing

...ot satisfied that these tactics would be enough to boost ...is starting to look ugly. Let's talk."[342] Stewart and the ... response and set up a meeting with Jonathan for the

... reported to the Sacklers that Purdue had hired 47 more ...rders. Staff told the Sacklers that Purdue employed 639 ...isited prescribers 173,647 times.[344] More than 3,800 of those visits were in Massachusetts.[345]

346. Meanwhile, the Sacklers voted to pay $10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue's marketing of OxyContin.[346] The Sacklers were on notice that Purdue's unfair and deceptive marketing raised serious concerns. Staff also

[341] 2011-05-25 email from Russell Gasdia, PPLPC012000326017.
[342] 2011-05-25 email from Jonathan Sackler, PPLPC012000326194.
[343] 2011-05-25 email from John Stewart, PPLPC012000326193.
[344] 2011-05-02 Board report, pgs. 5, 6, 36, PPLPC012000322430, -431, -461. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 168,210 visits; and that reps visited 6.66 prescribers per day, on average, compared to a target of 7.0.
[345] Exhibit 1.
[346] 2011-05-20 Board minutes, PKY183212910.

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MA AG FAC ¶344

Irrelevant 2011 Email Concerns Butrans Sales

From: Gasida, Russell
Subject: Butrans Weekly Report for the week ending May 13, 2011

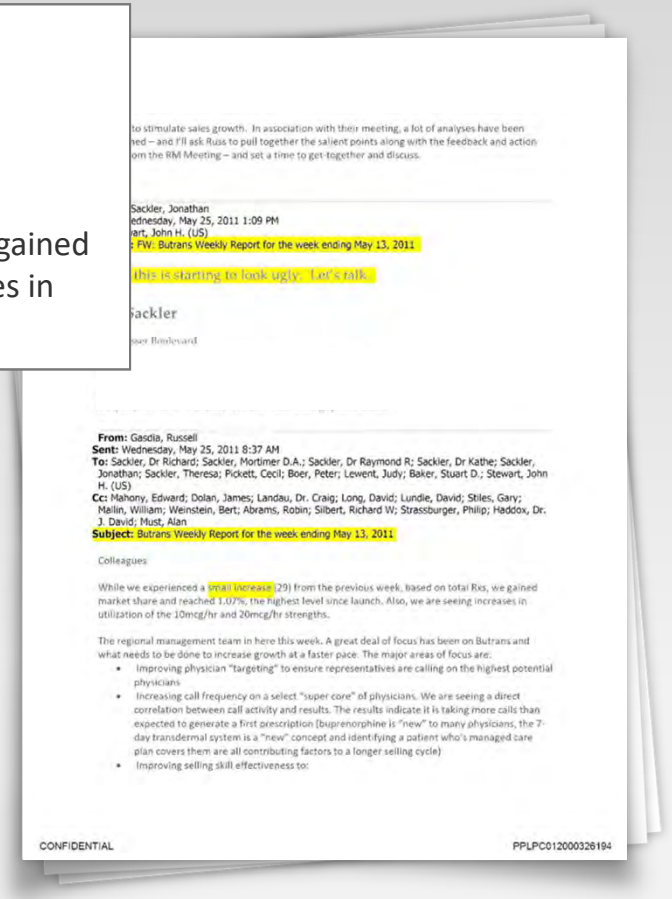
Colleagues

While we experienced a small increase (29) from the previous week, based on total Rxs, we gained market share and reached 1.07%, the highest level since launch. Also, we are seeing increases in utilization of the 10mcg/hr and 20mcg/hr strengths.

From: Sackler, Jonathan
Sent: Wednesday, May 25, 2011 1:09 PM
To: Stewart, John H. (US)
Subject: FW: Butrans Weekly Report for the week ending May 13, 2011

John, this is starting to look ugly. Let's talk.

- Butrans, not OxyContin
- Sales, not marketing
- OIG confirmed compliance for 2011

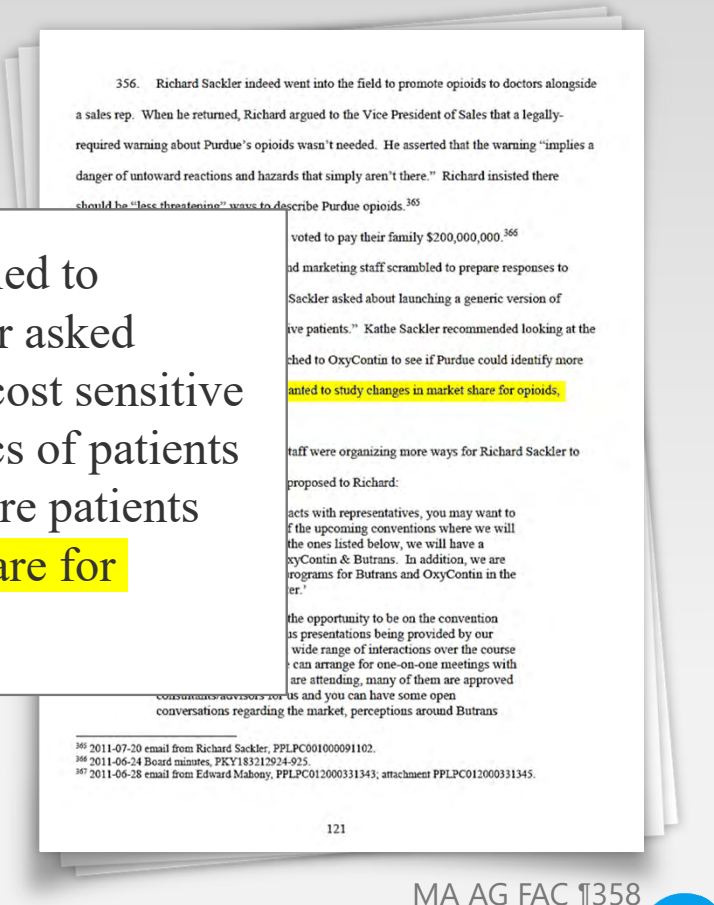


5/25/01 Email from J. Sackler (PPLPC012000326193)

Allegation: Study Changes In Market Share

Massachusetts AG FAC ¶358:

358. A few days later, sales and marketing staff scrambled to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.



356. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales rep. When he returned, Richard argued to the Vice President of Sales that a legally-required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.[365]

voted to pay their family $200,000,000.[366]

ad marketing staff scrambled to prepare responses to

Sackler asked about launching a generic version of

ive patients." Kathe Sackler recommended looking at the

ched to OxyContin to see if Purdue could identify more

anted to study changes in market share for opioids,

taff were organizing more ways for Richard Sackler to

proposed to Richard:

acts with representatives, you may want to
f the upcoming conventions where we will
the ones listed below, we will have a
xyContin & Butrans. In addition, we are
rograms for Butrans and OxyContin in the
er.'

the opportunity to be on the convention
is presentations being provided by our
wide range of interactions over the course
can arrange for one-on-one meetings with
are attending, many of them are approved
us and you can have some open
conversations regarding the market, perceptions around Butrans

[365] 2011-07-20 email from Richard Sackler, PPLPC001000091102.
[366] 2011-06-24 Board minutes, PKY183212924-925.
[367] 2011-06-28 email from Edward Mahony, PPLPC012000331343; attachment PPLPC012000331345.

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MA AG FAC ¶358

Irrelevant 2011 Request For Information Unrelated To Marketing

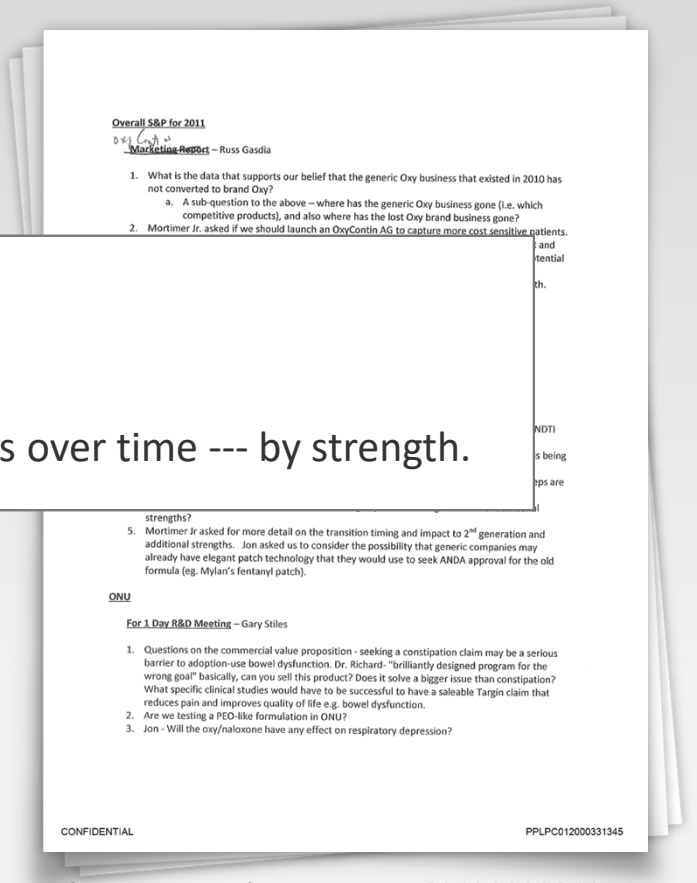
Overall S&P for 2011

OxyContin – Russ Gasdia

***

4. Jon asked for market share change over time for opioid medicines over time --- by strength.

- **OIG confirmed compliance for 2011**



Overall S&P for 2011

Marketing Report – Russ Gasdia

1. What is the data that supports our belief that the generic Oxy business that existed in 2010 has not converted to brand Oxy?
   a. A sub-question to the above – where has the generic Oxy business gone (i.e. which competitive products), and also where has the lost Oxy brand business gone?
2. Mortimer Jr. asked if we should launch an OxyContin AG to capture more cost sensitive patients.

strengths?

5. Mortimer Jr asked for more detail on the transition timing and impact to 2nd generation and additional strengths. Jon asked us to consider the possibility that generic companies may already have elegant patch technology that they would use to seek ANDA approval for the old formula (eg. Mylan's fentanyl patch).

ONU

For 1 Day R&D Meeting – Gary Stiles

1. Questions on the commercial value proposition - seeking a constipation claim may be a serious barrier to adoption-use bowel dysfunction. Dr. Richard- "brilliantly designed program for the wrong goal" basically, can you sell this product? Does it solve a bigger issue than constipation? What specific clinical studies would have to be successful to have a saleable Targin claim that reduces pain and improves quality of life e.g. bowel dysfunction.
2. Are we testing a PEO-like formulation in ONU?
3. Jon - Will the oxy/naloxone have any effect on respiratory depression?

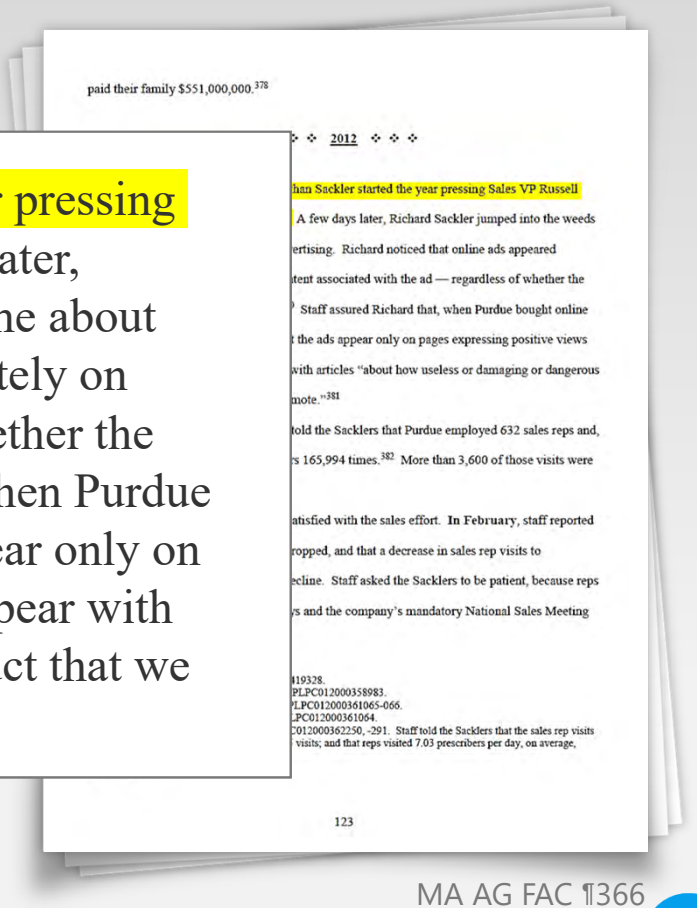
CONFIDENTIAL PPLPC012000331345

6/28/11 Email from E. Mahony w/attachment (PPLPC012000331345)

Allegation: Pressing For Sales Updates

Massachusetts AG FAC ¶366:

366. In January 2012, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler jumped into the weeds with the sales staff, this time about advertising. Richard noticed that online ads appeared indiscriminately on webpages with content associated with the ad — regardless of whether the association was positive or negative. Staff assured Richard that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids, and would not appear with articles "about how useless or damaging or dangerous is our product that we are trying to promote."


paid their family $551,000,000.[378]

2012

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tent associated with the ad — regardless of whether the

Staff assured Richard that, when Purdue bought online

the ads appear only on pages expressing positive views

with articles "about how useless or damaging or dangerous

mote."[381]

told the Sacklers that Purdue employed 632 sales reps and,

s 165,994 times.[382] More than 3,600 of those visits were

atisfied with the sales effort. In February, staff reported

ropped, and that a decrease in sales rep visits to

ecline. Staff asked the Sacklers to be patient, because reps

s and the company's mandatory National Sales Meeting

19328.
PLPC012000358983.
PLPC012000361065-066.
LPC012000361064.
C012000362250, -291. Staff told the Sacklers that the sales rep visits
visits; and that reps visited 7.03 prescribers per day, on average,

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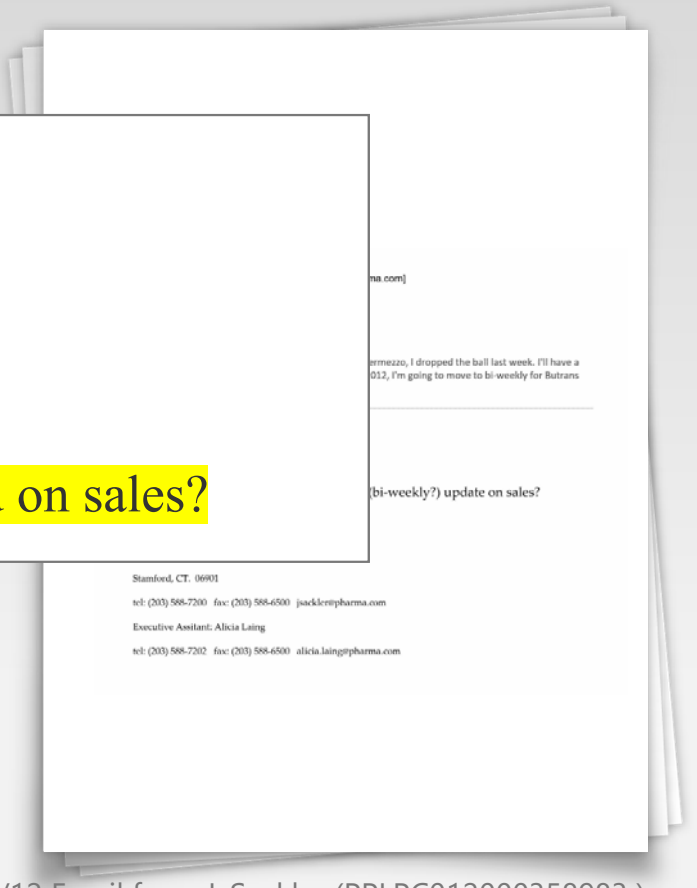
MA AG FAC ¶366

Irrelevant 2012 Request For Resumption Of Butrans Sales Update

From: Sackler, Jonathan
Sent: Monday, January 09, 2012 04:55 PM
To: Gasdia, Russell
Subject: Butrans

Russ, are you going to resume a weekly (bi-weekly?) updated on sales?

- Butrans, not OxyContin
- Sales, not marketing
- OIG confirmed compliance for 2012

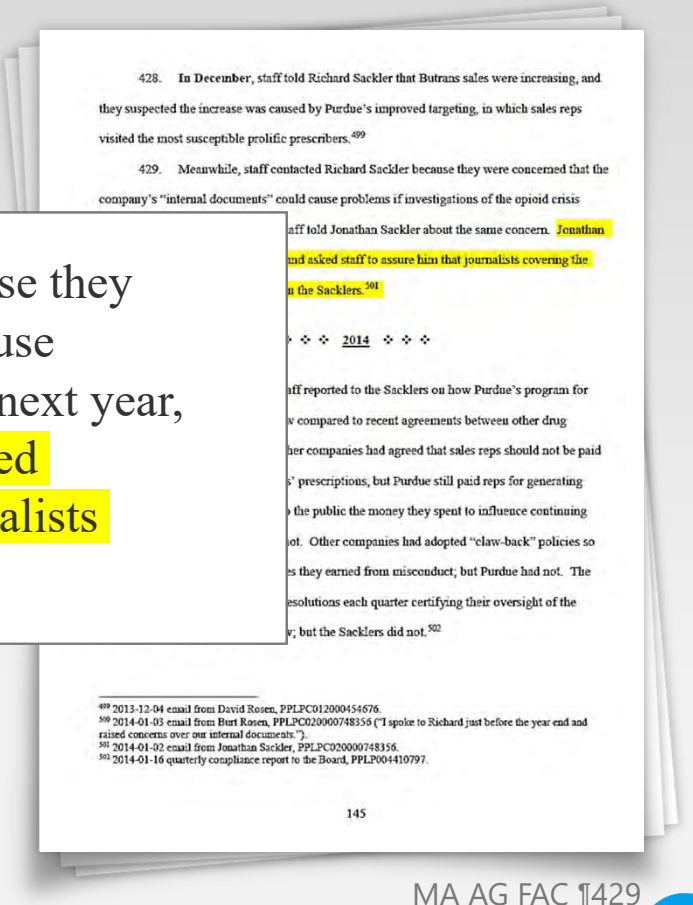


1/9/12 Email from J. Sackler (PPLPC012000358983)

Allegation: Studied News Reports

Massachusetts AG FAC ¶429:

429. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.



428. In December, staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales reps visited the most susceptible prolific prescribers.[499]

429. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis

aff told Jonathan Sackler about the same concern. Jonathan

nd asked staff to assure him that journalists covering the

u the Sacklers.[501]

❖ ❖ ❖ 2014 ❖ ❖ ❖

aff reported to the Sacklers on how Purdue's program for

v compared to recent agreements between other drug

her companies had agreed that sales reps should not be paid

s' prescriptions, but Purdue still paid reps for generating

the public the money they spent to influence continuing

ot. Other companies had adopted "claw-back" policies so

s they earned from misconduct; but Purdue had not. The

esolutions each quarter certifying their oversight of the

v; but the Sacklers did not.[502]

[499] 2013-12-04 email from David Rosen, PPLPC012000454676.
[500] 2014-01-03 email from Burt Rosen, PPLPC020000748356 ("I spoke to Richard just before the year end and raised concerns over our internal documents.").
[501] 2014-01-02 email from Jonathan Sackler, PPLPC020000748356.
[502] 2014-01-16 quarterly compliance report to the Board, PPLP004410797.

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MA AG FAC ¶429

Irrelevant 2014 Observation About Lack Of Press Focus On IR Oxycodone

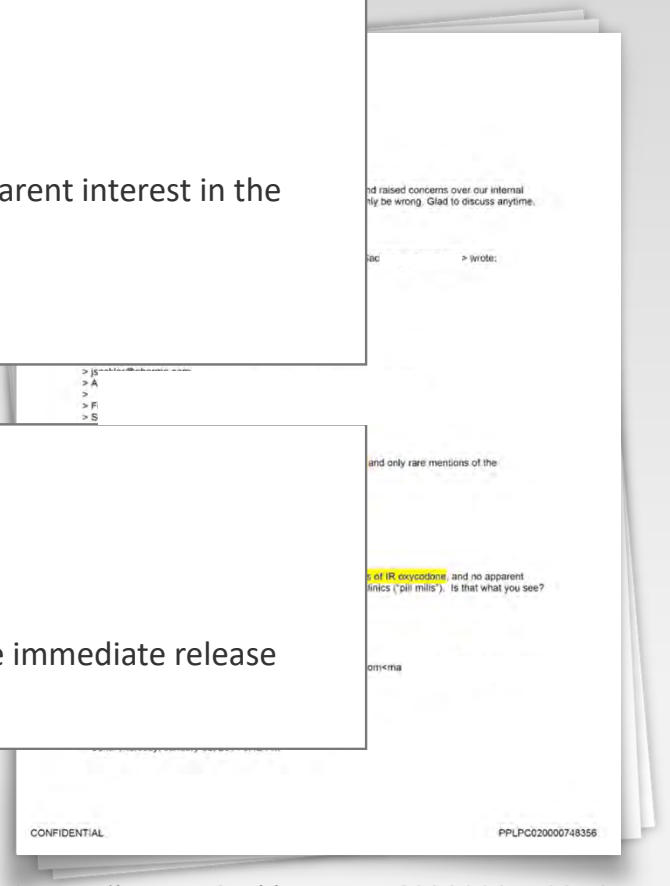
From: Sackler, Jonathan
Sent: Thursday, January 02, 2014 5:14 PM
To: Walsh, Kathy
Subject: RE: Search Results: Oxycodone IR follow up

Yes, it was helpful. My takeaway: no apparent focus on makers of IR oxycodone, and no apparent interest in the distribution chain EXCEPT in the case of FL pain clinics ("pill mills"). Is that what you see?

Jon Sackler

From: Walsh, Kathy
Sent: Friday, January 03, 2014 11:22 AM
To: Sackler, Jonathan
Subject: RE: Search Results: Oxycodone IR follow up

Agreed, so far no focus on the manufacturers of IR oxycodone and only rare mentions of the immediate release version of the drug in media reports.



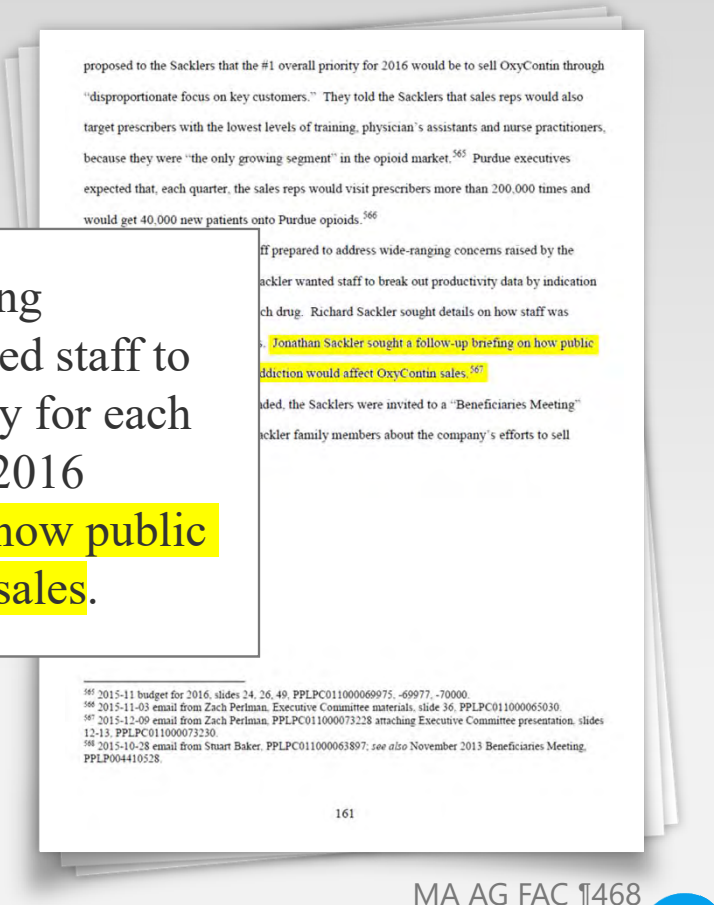
- Nothing to do with the family or marketing

1/2/14 Emails w/ J. Sackler (PPLPC020000748356)

Allegation: Request For Briefing On Public Health Initiatives

Massachusetts AG FAC ¶468:

468. In December, staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff was calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.


proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through "disproportionate focus on key customers." They told the Sacklers that sales reps would also target prescribers with the lowest levels of training, physician's assistants and nurse practitioners, because they were "the only growing segment" in the opioid market.[565] Purdue executives expected that, each quarter, the sales reps would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.[566]

ff prepared to address wide-ranging concerns raised by the
ackler wanted staff to break out productivity data by indication
ch drug. Richard Sackler sought details on how staff was
. Jonathan Sackler sought a follow-up briefing on how public
ddiction would affect OxyContin sales.[567]

ded, the Sacklers were invited to a "Beneficiaries Meeting"
ackler family members about the company's efforts to sell

[565] 2015-11 budget for 2016, slides 24, 26, 49, PPLPC011000069975, -69977, -70000.
[566] 2015-11-03 email from Zach Perlman, Executive Committee materials, slide 36, PPLPC011000065030.
[567] 2015-12-09 email from Zach Perlman, PPLPC011000073228 attaching Executive Committee presentation, slides 12-13, PPLPC011000073230.
[568] 2015-10-28 email from Stuart Baker, PPLPC011000063897; *see also* November 2013 Beneficiaries Meeting, PPLP004410528.

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MA AG FAC ¶468

2015 Request For Briefing On Market Impact Of CDC Guidelines

Budget action items (2/5)

December followup

Request	Who requested
Follow up briefing on OxyContin market impact of CDC guidelines	J. Sackler

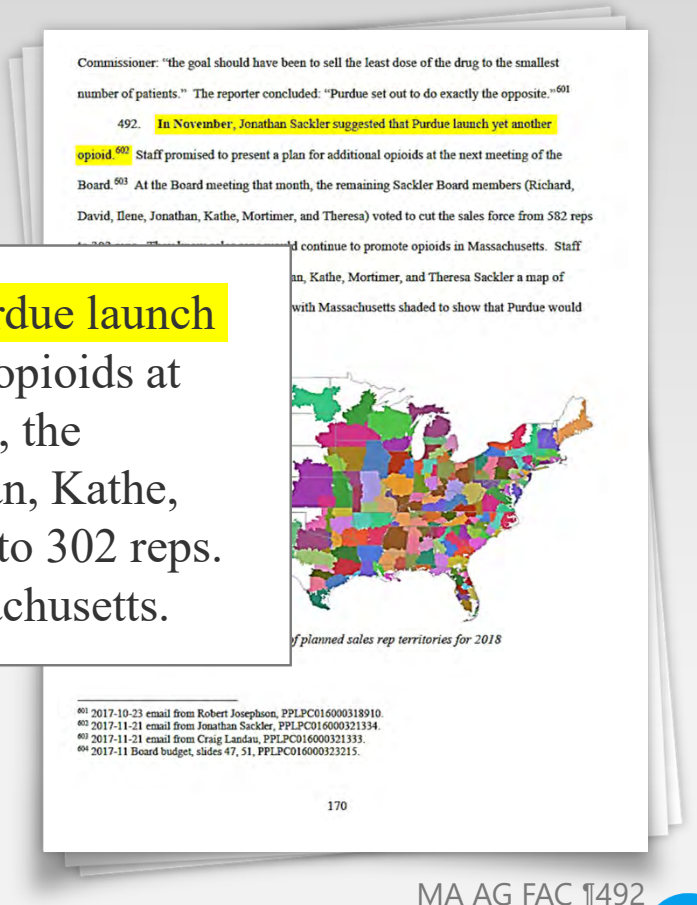
- Purdue distributed the CDC Guidelines to more than 150,000 health care providers

12/10/15 Executive Committee Presentation, p.13 (PPLPC011000073230)

Allegation: Proposed A New Opioid

Massachusetts AG FAC ¶492:

492. In November, Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board.[603] At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps to 302 reps. They knew sales reps would continue to promote opioids in Massachusetts.


Commissioner: "the goal should have been to sell the least dose of the drug to the smallest number of patients." The reporter concluded: "Purdue set out to do exactly the opposite."[601]

492. In November, Jonathan Sackler suggested that Purdue launch yet another opioid.[602] Staff promised to present a plan for additional opioids at the next meeting of the Board.[603] At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps

d continue to promote opioids in Massachusetts. Staff

an, Kathe, Mortimer, and Theresa Sackler a map of

with Massachusetts shaded to show that Purdue would

f planned sales rep territories for 2018

[601] 2017-10-23 email from Robert Josephson, PPLPC016000318910.
[602] 2017-11-21 email from Jonathan Sackler, PPLPC016000321334.
[603] 2017-11-21 email from Craig Landau, PPLPC016000321333.
[604] 2017-11 Board budget, slides 47, 51, PPLPC016000323215.

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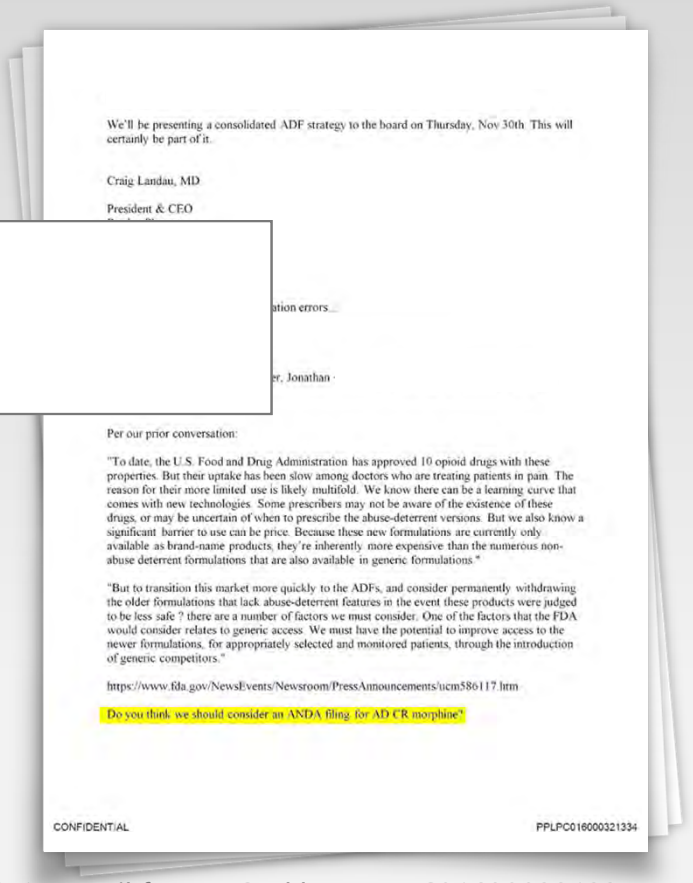
MA AG FAC ¶492

Irrelevant Question: Should Purdue Consider Abuse-Deterrent Morphine?

Do you think we should consider an ANDA filing for AD CR morphine?

- Jon

- Never pursued
- Irrelevant to deceptive marketing claims



We'll be presenting a consolidated ADF strategy to the board on Thursday, Nov 30th. This will certainly be part of it.

Craig Landau, MD

President & CEO

ation errors...

er, Jonathan ·

Per our prior conversation:

"To date, the U.S. Food and Drug Administration has approved 10 opioid drugs with these properties. But their uptake has been slow among doctors who are treating patients in pain. The reason for their more limited use is likely multifold. We know there can be a learning curve that comes with new technologies. Some prescribers may not be aware of the existence of these drugs, or may be uncertain of when to prescribe the abuse-deterrent versions. But we also know a significant barrier to use can be price. Because these new formulations are currently only available as brand-name products, they're inherently more expensive than the numerous non-abuse deterrent formulations that are also available in generic formulations."

"But to transition this market more quickly to the ADFs, and consider permanently withdrawing the older formulations that lack abuse-deterrent features in the event these products were judged to be less safe ? there are a number of factors we must consider. One of the factors that the FDA would consider relates to generic access. We must have the potential to improve access to the newer formulations, for appropriately selected and monitored patients, through the introduction of generic competitors."

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm

Do you think we should consider an ANDA filing for AD CR morphine?

CONFIDENTIAL

PPLPC016000321334

11/21/17 Email from J. Sackler (PPLPC016000321334)

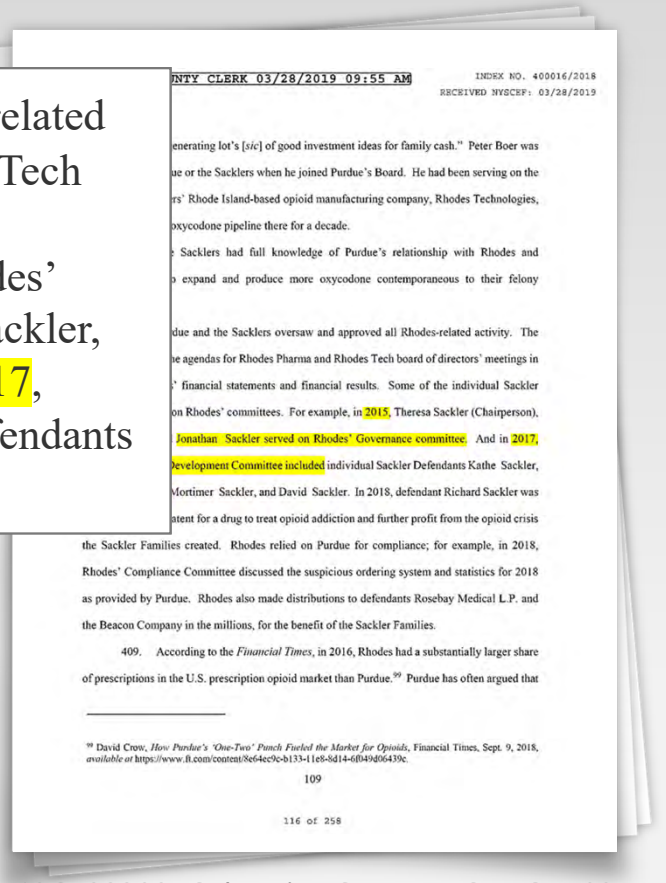
No Allegations About Beverly Sackler

Marketing Allegations About David Sackler

Allegation: Rhodes Board Committees

New York AG FAC ¶408:

408. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler.


NTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
RECEIVED NYSCEF: 03/28/2019

enerating lot's [*sic*] of good investment ideas for family cash." Peter Boer was
ue or the Sacklers when he joined Purdue's Board. He had been serving on the
rs' Rhode Island-based opioid manufacturing company, Rhodes Technologies,
oxycodone pipeline there for a decade.
Sacklers had full knowledge of Purdue's relationship with Rhodes and
expand and produce more oxycodone contemporaneous to their felony

due and the Sacklers oversaw and approved all Rhodes-related activity. The
e agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in
financial statements and financial results. Some of the individual Sackler
on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson),
Jonathan Sackler served on Rhodes' Governance committee. And in 2017,
evelopment Committee included individual Sackler Defendants Kathe Sackler,
Mortimer Sackler, and David Sackler. In 2018, defendant Richard Sackler was
atent for a drug to treat opioid addiction and further profit from the opioid crisis
the Sackler Families created. Rhodes relied on Purdue for compliance; for example, in 2018,
Rhodes' Compliance Committee discussed the suspicious ordering system and statistics for 2018
as provided by Purdue. Rhodes also made distributions to defendants Rosebay Medical L.P. and
the Beacon Company in the millions, for the benefit of the Sackler Families.

409. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[99] Purdue has often argued that

[99] David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, Financial Times, Sept. 9, 2018, *available at* https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

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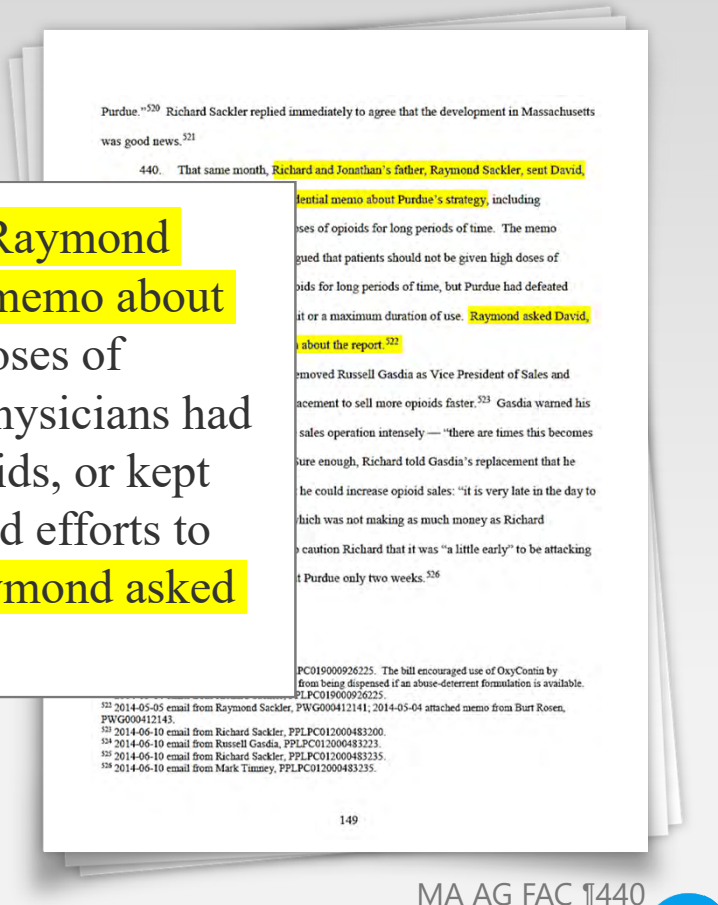
- David Sackler was never a Rhodes director and never served on a Rhodes Committee
- Irrelevant to deceptive marketing claims

9/13/19 D. Sackler Decl., *Colorado v. PPLP*, No.18CV33300 (Colo. Dist. Ct.); NY AG FAC ¶408

Allegation: Received A Memo Regarding "Strategy"

Massachusetts AG FAC ¶440:

440. That same month, Richard and Jonathan's father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy, including specifically putting patients on high doses of opioids for long periods of time. The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum dose limit or a maximum duration of use. Raymond asked David, Jonathan, and Richard to talk with him about the report.


Purdue."[520] Richard Sackler replied immediately to agree that the development in Massachusetts was good news.[521]

440. That same month, Richard and Jonathan's father, Raymond Sackler, sent David,

ential memo about Purdue's strategy, including

ses of opioids for long periods of time. The memo

gued that patients should not be given high doses of

ids for long periods of time, but Purdue had defeated

it or a maximum duration of use. Raymond asked David,

about the report.[522]

moved Russell Gasdia as Vice President of Sales and

acement to sell more opioids faster.[523] Gasdia warned his

sales operation intensely — "there are times this becomes

ure enough, Richard told Gasdia's replacement that he

he could increase opioid sales: "it is very late in the day to

hich was not making as much money as Richard

caution Richard that it was "a little early" to be attacking

t Purdue only two weeks.[526]

PC019000926225. The bill encouraged use of OxyContin by from being dispensed if an abuse-deterrent formulation is available. PLPC019000926225.

[522] 2014-05-05 email from Raymond Sackler, PWG000412141; 2014-05-04 attached memo from Burt Rosen, PWG000412143.
[523] 2014-06-10 email from Richard Sackler, PPLPC012000483200.
[524] 2014-06-10 email from Russell Gasdia, PPLPC012000483223.
[525] 2014-06-10 email from Richard Sackler, PPLPC012000483235.
[526] 2014-06-10 email from Mark Timney, PPLPC012000483235.

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MA AG FAC ¶440

Irrelevant History Of The Abuse-Deterrent Formula

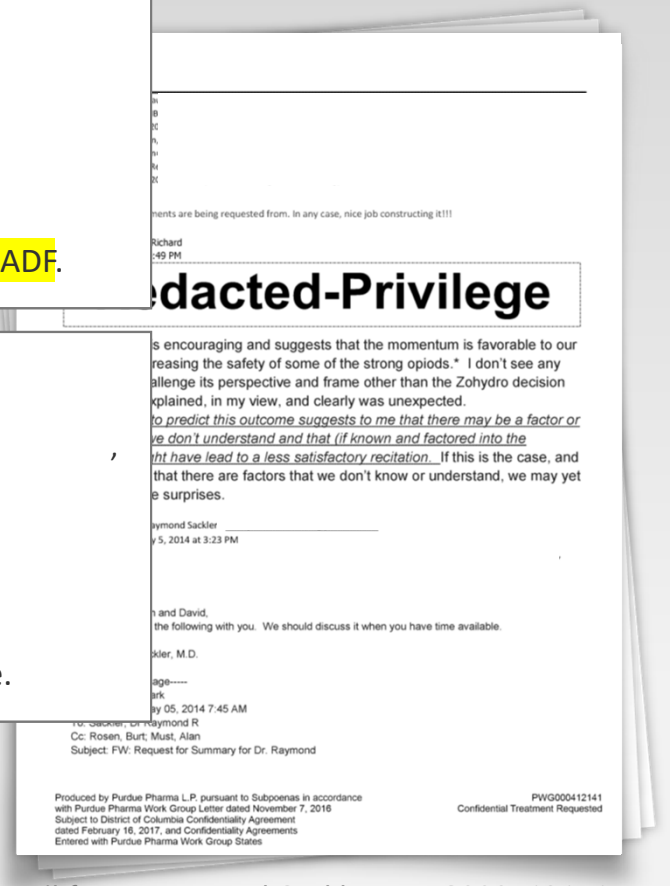
From: Timney, Mark
Sent: Monday, May 05, 2014 7:45 AM
To: Sackler, Dr Raymond R

Dr. Raymond,

As discussed, please find a brief history and update regarding the support being received on ADF.

From: <Sackler>, Raymond Sackler
Date: Monday, May 5, 2014 at 3:23 PM
To: "Sackler, Jonathan" , "Richard S. Sackler" ,
David Sackler
Subject: FW: Request for Summary for Dr. Raymond

Dear Richard, Jon and David,
I wanted to share the following with you. We should discuss it when you have time available.



5/5/14 Email from Raymond Sackler (PWG000412141)

Board Members Did Not Personally Participate In Marketing

- Board did not approve the content of any marketing material
- Board did not direct or encourage any misstatements
- Board relied on approval of all marketing and advertising material (1) Medical, (2) Legal, and (3) Regulatory Affairs
- Board relied on outside counsel's monitoring of Purdue's Compliance Program
- Board relied on OIG's confirmations of compliance (2007-12)
- Board relied on management's confirmations that marketing complied with state and federal law (2007-18)
- Board relied on monitoring of sales calls by District Managers, Legal and Compliance
- Board relied on compliance audits of key risk activities

"In performing his duties, a director shall be entitled to rely on information, opinions, reports or statements … prepared or presented by … officers or employees of the corporation … whom the director believes to be reliable and competent in the matters presented …."

N.Y. Bus. Corp. Law §717

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 3: Diversion

April 26, 2021

Negligent Diversion Claims

Claimants' Allegation: Purdue's Diversion Efforts Were Insufficient

NY AG FAC ¶853:

> 853. Each Defendant is strictly liable for violating the [New York Controlled Substances Act] in each separate instance in which it: (i) failed to maintain effective controls to prevent the diversion of controlled substances; (ii) failed to report suspicious orders for controlled substances; (iii) failed to report actual or alleged incidents of known or possible diversion of controlled substances; (iv) failed to provide truthful statements in its licensing filings with New York authorities; (v) and/or failed to notify New York authorities when its actions and/or omissions caused it to violate the NYCSA.

NY AG FAC ¶853

NY AG FAC ¶874:

> 874. Each of the Defendants breached its duties through its . . . violations of the New York Controlled Substances Act, in the course of its manufacture, distribution, sale, and/or marketing of opioid drugs within the state.

NY AG FAC ¶874

No allegation the Directors personally participated in Purdue's anti-diversion activities — and they did not

The Directors Responsibly Monitored But Did Not Personally Participate in Purdue's Anti-Diversion Efforts

- Directors monitored but did not personally participate in Purdue's anti-diversion activities — they had no role in deciding which prescribers to place in Region Zero
- The Board monitored anti-diversion activities based on information from management, including that:
  - Purdue was vigorously implementing its Abuse Deterrence & Detection (ADD) Program, specifically including Region Zero
  - Sales reps were trained in the ADD Program and Region Zero requirements
  - Management monitored the ADD Program
  - The ADD Program was working to stop diversion
  - Multiple Departments were working to stop diversion and ensure compliance with DEA requirements

"In performing his duties, a director shall be entitled to rely on information, opinions, reports or statements … prepared or presented by … officers or employees of the corporation … whom the director believes to be reliable and competent in the matters presented …."

N.Y. Bus. Corp. Law §717

DOJ's Allegation: Family Directors Should Have Known of Diversion

DOJ alleges in Addendum A to the Sackler Settlement Agreement:

"3. Although the Named Sacklers knew that the legitimate market for Purdue's opioids had contracted, the Named Sacklers nevertheless requested that Purdue executives recapture lost sales and increase Purdue's share of the opioid market."

"4. As a result of these requests, from at least 2013-2018, Purdue developed an aggressive marketing program [Evolve 2 Excellence (or E2E), conceived by McKinsey & Co.] that focused on detailing over 100,000 doctors and nurse practitioners each year, including thousands of prescribers that the Named Sacklers knew or should have known were prescribing opioids that were not for a medically accepted indication; were unsafe, ineffective, and medically unnecessary; and that were diverted for uses that lacked a legitimate medical purpose."

DOJ/Sackler Settlement Agreement, Addendum A, ¶¶3-4

DOJ's Allegations Are Demonstrably Untrue

- The Board was advised there was a huge, multibillion-dollar legitimate market for Purdue to pursue
- The Board was continuously advised by management that Purdue was operating in compliance with law — and for 5 years this was confirmed by the OIG of HHS
- The Board's focus on increasing sales — on the understanding it was being done in compliance with law — was perfectly appropriate
- The Board relied on McKinsey's marketing advice, which McKinsey said simply brought "best industry practices" to Purdue
- The resulting marketing program, E2E, targeted the legitimate market for Purdue's opioids and emphasized OxyContin's abuse-deterrent properties

The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue

Annual Prescriptions and Dollars in Various Segments of the Analgesic Market

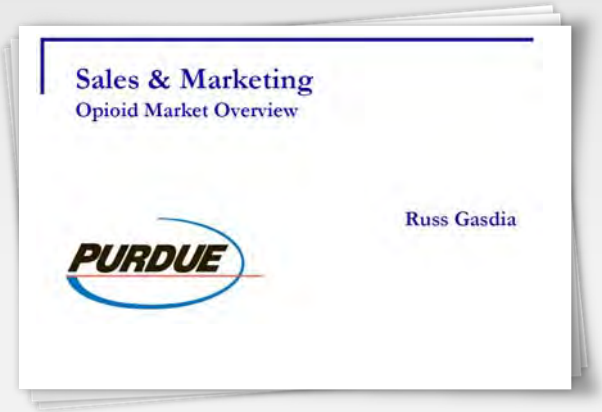
(IMS MAT August 2012)

	Dollars	% Change	TRxs	% Change
Non-Opioid/Non-NSAID	$3.9 Billion	7.6%	50.6 million	8.8%
Extended-Release Opioids	$5.3 Billion	-2.8%	26.2 million	-0.1%
Immediate-Release SEOs	$1.4 Billion	-11.6%	23.8 million	10.8%
Combination Opioids	$1.5 Billion	5.5%	189.9 million	-2.5%

2012

Total market: $12.1B

Purdue's sales: $2.8B



Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

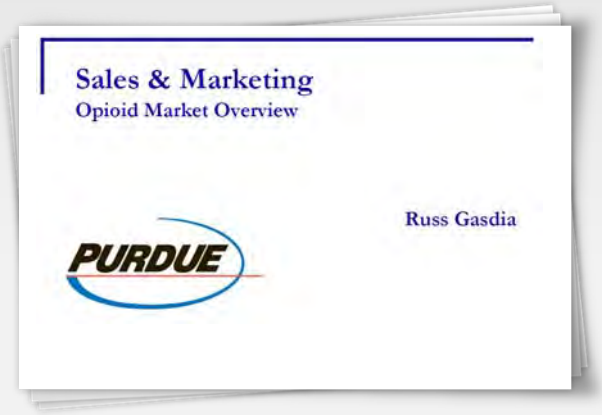
The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue

Extended-Release Opioid Competitive Landscape

Brand Name	Chemical Name	Company	Brand	Generic
Avinza®	Morphine sulfate extended-release capsules	Pfizer	√	
Butrans®	Buprenorphine transdermal system	Purdue	√	
Exalgo®	Hydromorphone hydrochloride extended-release tablets	Mallinckrodt	√	
Embeda®*	Morphine sulfate and naltrexone extended-release capsules	Pfizer	√	
Duragesic®	Fentanyl transdermal system	Janssen	√	√
Kadian®	Morphine sulfate extended-release capsules	Actavis	√	√
MS Contin®	Morphine sulfate controlled-release tablets	Purdue	√	√
Nucynta® ER	Tapentadol extended-release oral tablets	Janssen	√	
Opana® ER	Oxymorphone hydrochloride extended-release tablets	Endo	√	√**
OxyContin®	Oxycodone hydrochloride controlled-release tablets	Purdue	√	
Dolophine®	Methadone hydrochloride tablets	Roxane	√	√

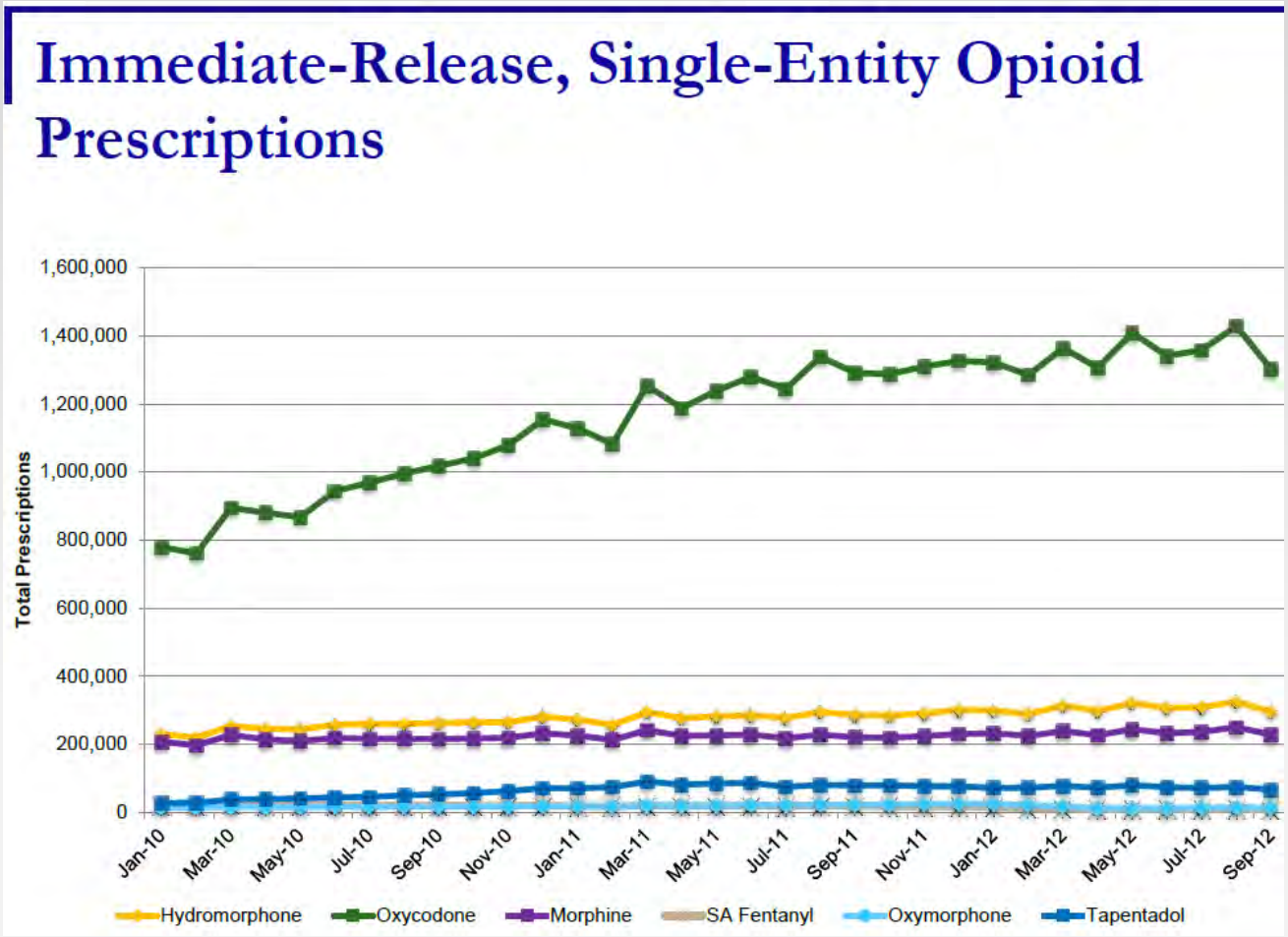
2012

Extend-Release Opioids: $5.3 billion market



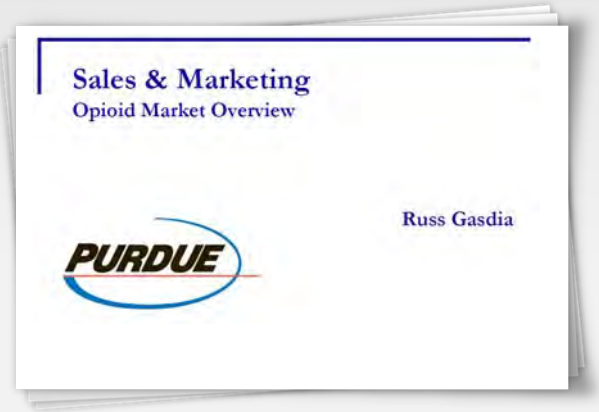
Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue



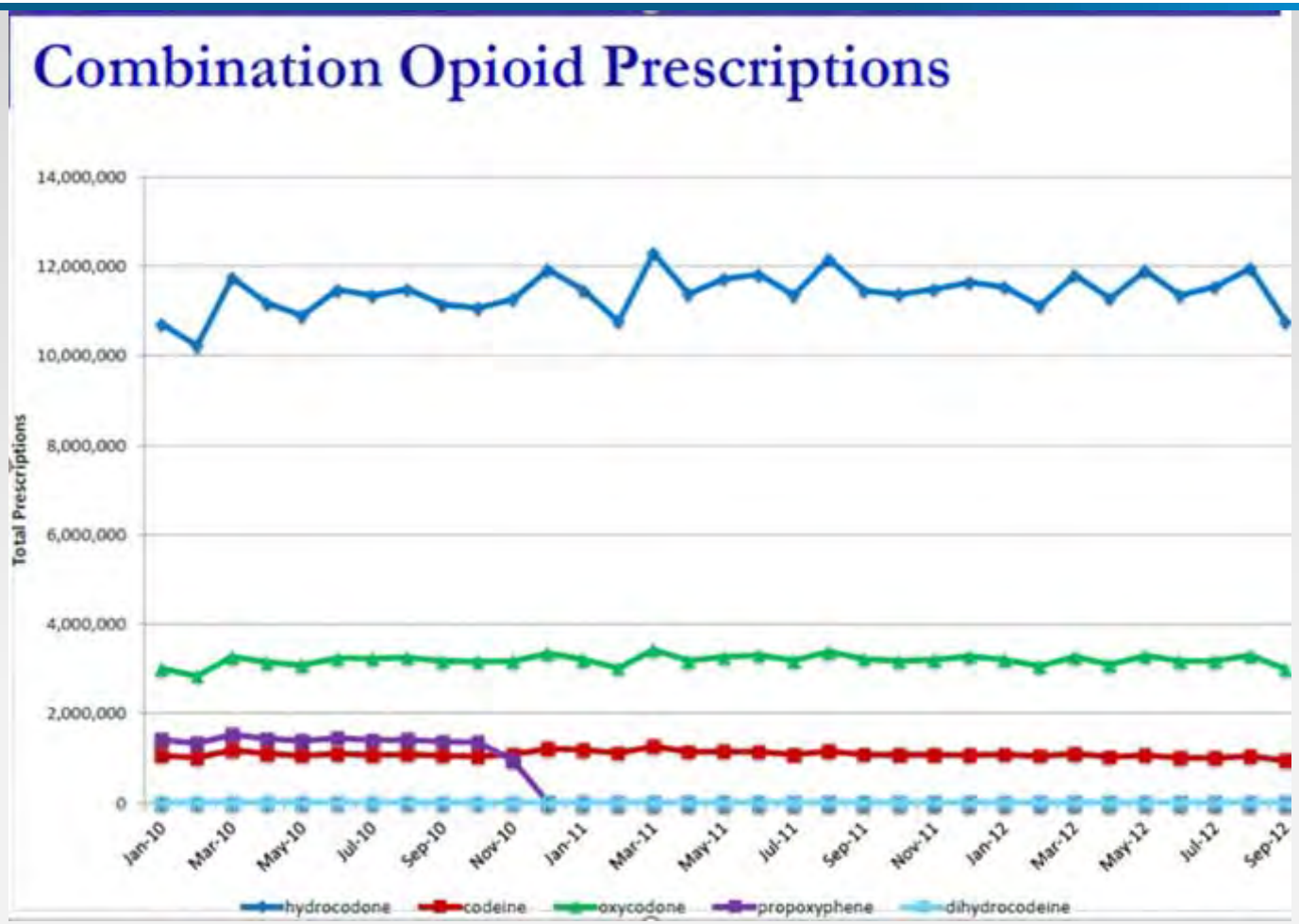
2012

Immediate-Release Opioids: $1.4 billion market



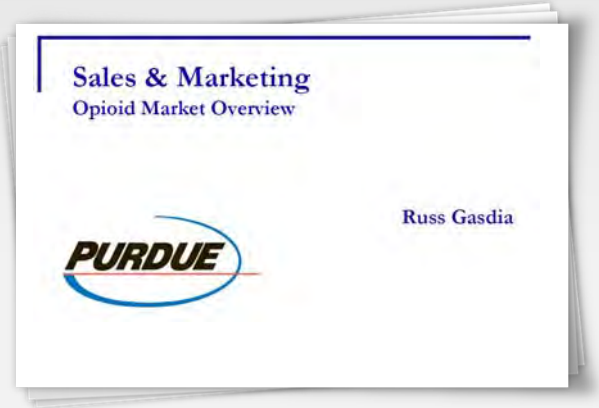
Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue



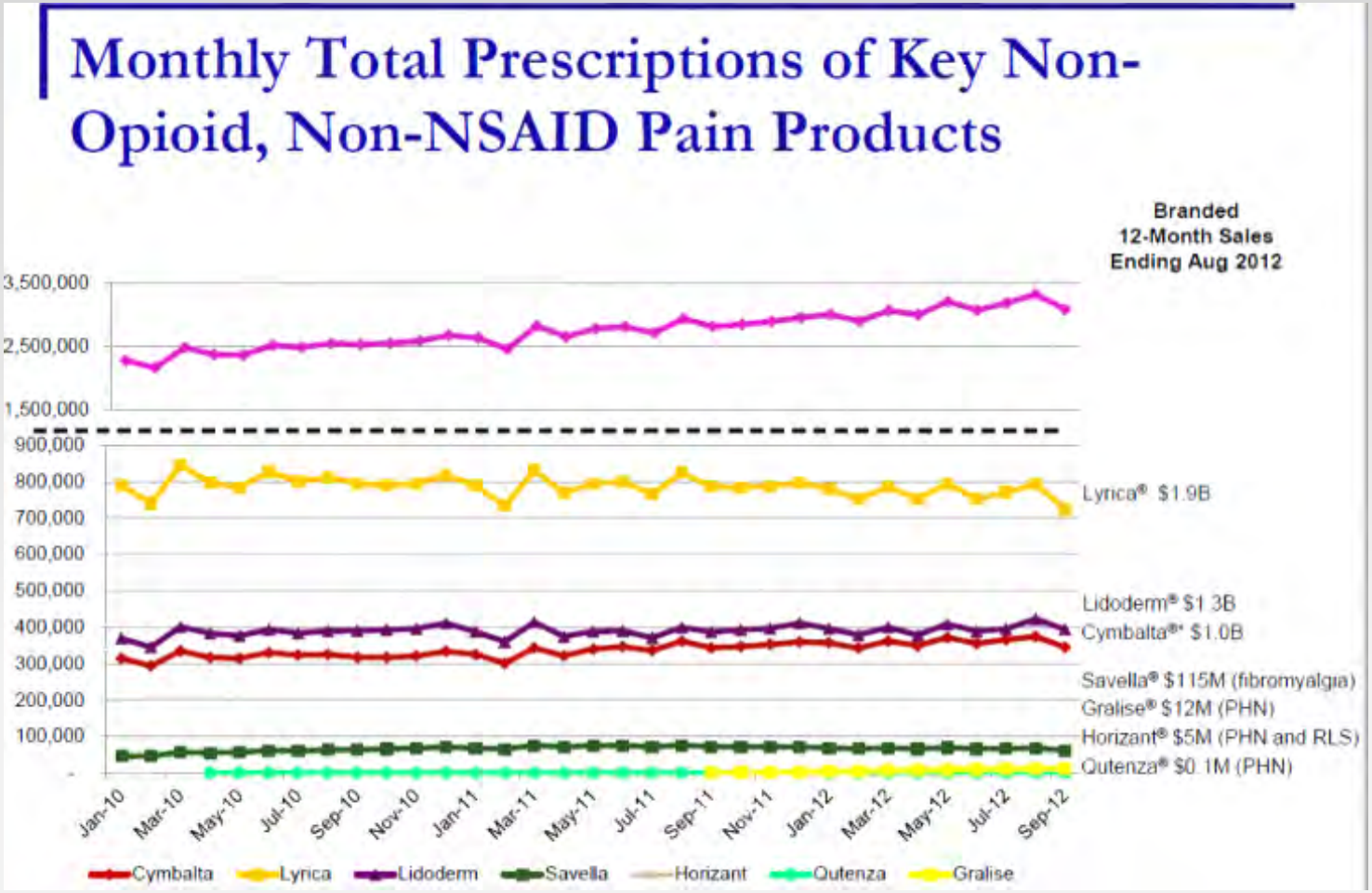
2012

Combination Medications: $1.5 billion market



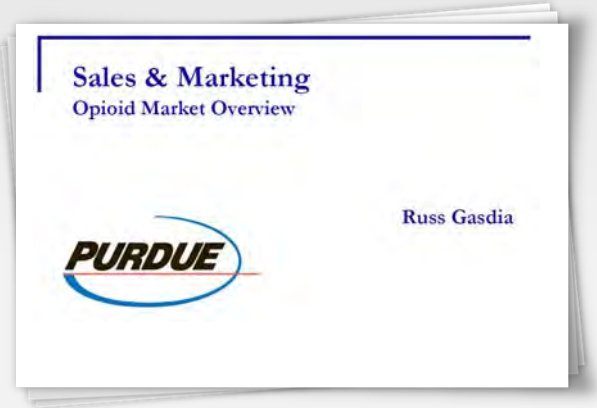
Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue



2012

Key Non-Opioid, Non-NSAIDs: > $3.9 billion market

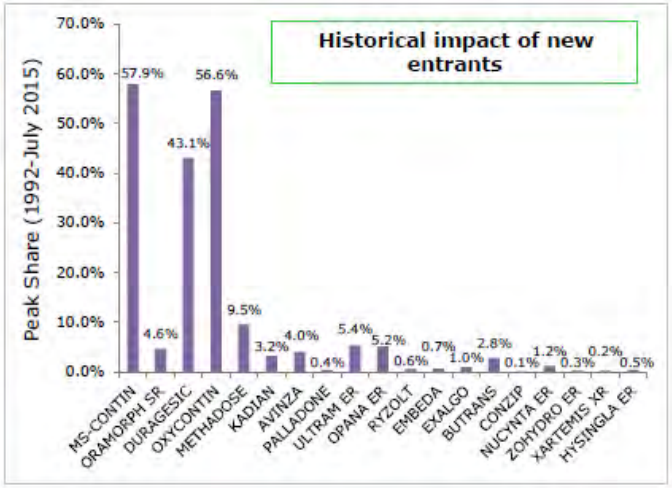


Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

The Board Was Advised There Was a Huge Legitimate Market for Purdue to Pursue

More EROs are expected to enter the market in 2016

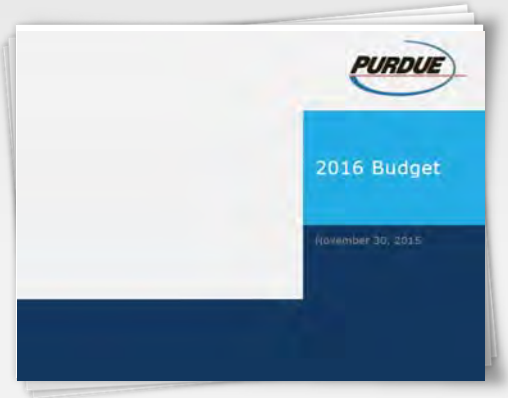
Product (Company)	PDUFA	Commentary
Belbuca (Endo)	Approved	▪ Buprenorphine ▪ Buccal delivery
Vantrela ER (Teva)	Q4 2015	▪ ER Hydrocodone ▪ Potential to be blocked
ALO-02 (Pfizer)	Q1 2016	▪ Oxycodone Naltrexone ▪ Embeda experienced limited success
Xtampza ER (Collegium)	Tentative Approval	▪ Oxycodone ▪ Targeting dysphasia patients
MorphaBond ER (Inspirion)	Approved	▪ Morphine ▪ Abuse Deterrent Properties



Impact of new entrants:

- Projected peak share 0.9% to 2.2%
- Peak sales $60MM to $150MM
- Impact on portfolio is $32MM

New EROs Continued to be Introduced



Nov. 30, 2015 Budget Presentation to Board (PPLPC063000003207)

The Board Understood That Abuse-Deterrent OxyContin Was a Success—Abuse and Diversion Fell Substantially after Its Introduction

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially

- **DOJ alleges:**

  "Purdue's profits declined in 2010 after the introduction of its Reformulated OxyContin.... The Named Sacklers and Purdue executives tracked Purdue's lost sales closely and regularly scrutinized sales reports and related data. They attributed the majority of the decline to two trends: (i) individuals abusing opioids moving from OxyContin to opioids that were easier to abuse ... and (ii) increased scrutiny of prescribers, pharmacists, and other actors in the opioid distribution chain." (DOJ/Sackler Settlement Agreement, Addendum A ¶2)

- **The Board considered it a great success that abuse and diversion fell after the introduction of the abuse-deterrent formulation ("ADF") of OxyContin**

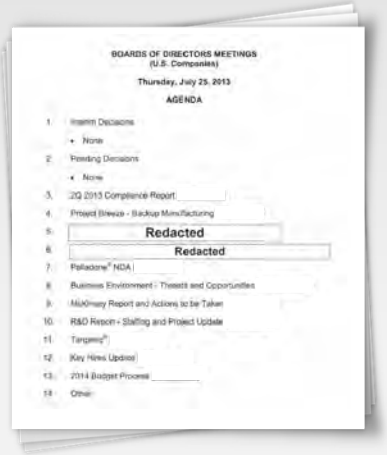
- **The Board had authorized over $1 billion in anti-abuse initiatives, including the ADF**

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially

Positive Impact of AD OxyContin

- Positive Media Coverage of Abuse-Deterrent Formulations
- Meaningful Reduction in Abuse - Especially Parenteral
- Fewer Pharmacy Thefts Reported by Law Enforcement
- Positive Reputation and Relationships with FDA and DEA
- Opportunity to link AD Formulations with Broader Anti-Abuse Initiatives
- Opportunity to Build on Expertise with ADFs

PURDUE


BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Thursday, July 25, 2013

AGENDA

1. Interim Decisions
   - None
2. Pending Decisions
   - None
3. 2Q 2013 Compliance Report
4. Project Breeze - Backup Manufacturing
5. Redacted
6. Redacted
7. Palladone® NDA
8. Business Environment - Threats and Opportunities
9. McKinsey Report and Actions to be Taken
10. R&D Retool - Staffing and Project Update
11. Targiniq®
12. Key News Updates
13. 2014 Budget Process
14. Other

PPLP004409860 (July 25, 2013 Presentation to Board)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially

Summary of Findings from Ongoing Epidemiology Studies*

- Reduced abuse relative to original OxyContin (consistent, durable)
- Reduced diversion and "doctor-shopping"
- Improved safety for patients
- Improved safety from accidental exposures

Proof of concept for abuse-deterrent tablets demonstrated

*OxyContin and other prescription opioids remain subject to abuse

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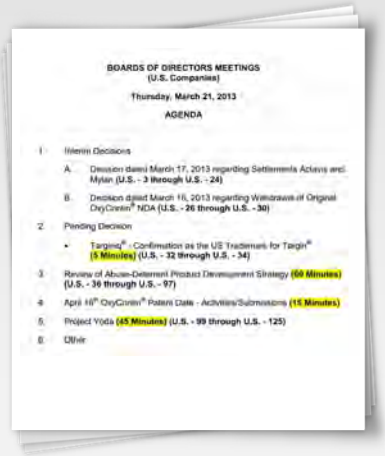
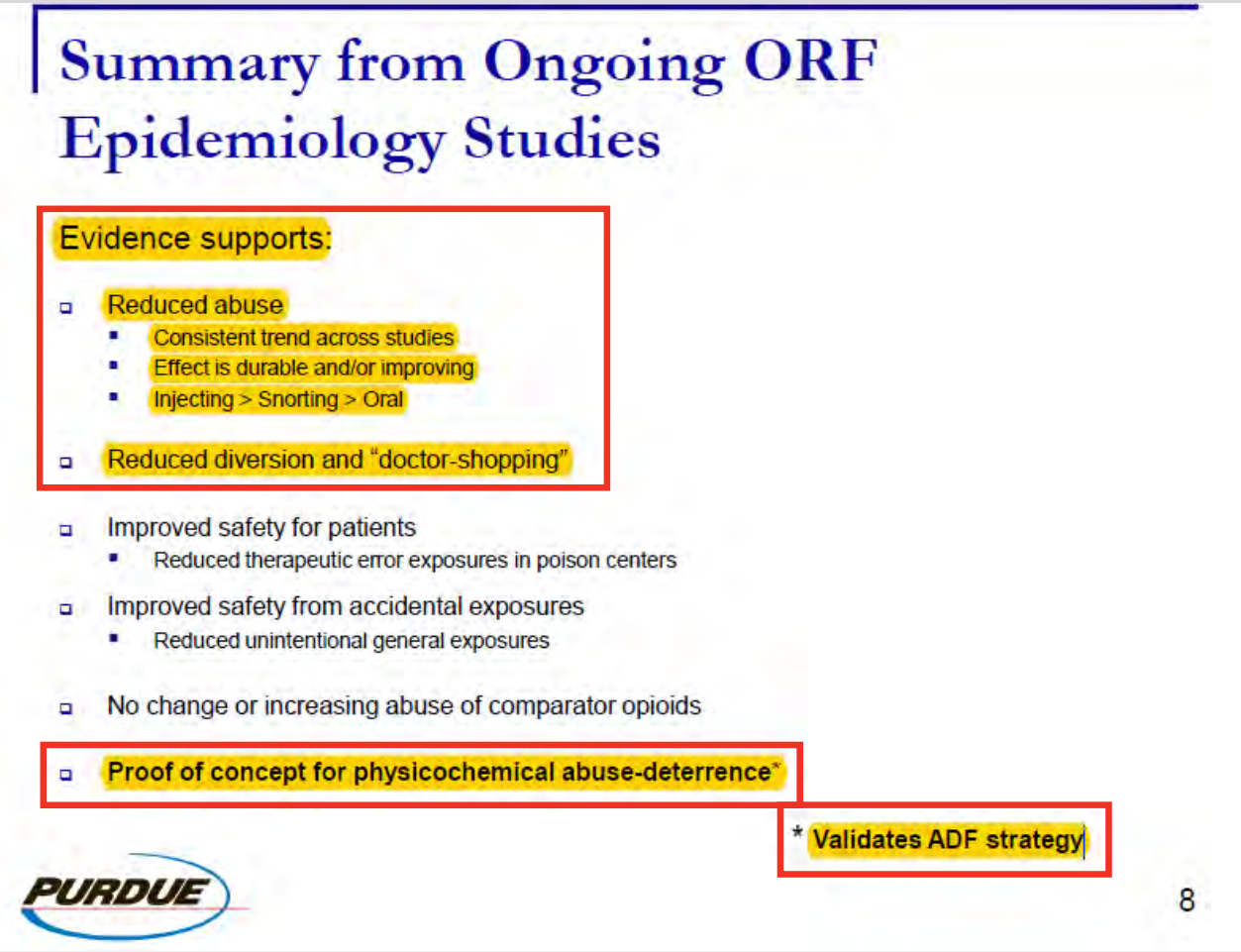

BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Thursday, March 21, 2013

AGENDA

PPLPC044000041968 (Mar. 21, 2013 Presentation to Board)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially



Summary from Ongoing ORF Epidemiology Studies

Evidence supports:

- Reduced abuse
  - Consistent trend across studies
  - Effect is durable and/or improving
  - Injecting > Snorting > Oral
- Reduced diversion and "doctor-shopping"
- Improved safety for patients
  - Reduced therapeutic error exposures in poison centers
- Improved safety from accidental exposures
  - Reduced unintentional general exposures
- No change or increasing abuse of comparator opioids
- **Proof of concept for physicochemical abuse-deterrence***

* Validates ADF strategy

PURDUE

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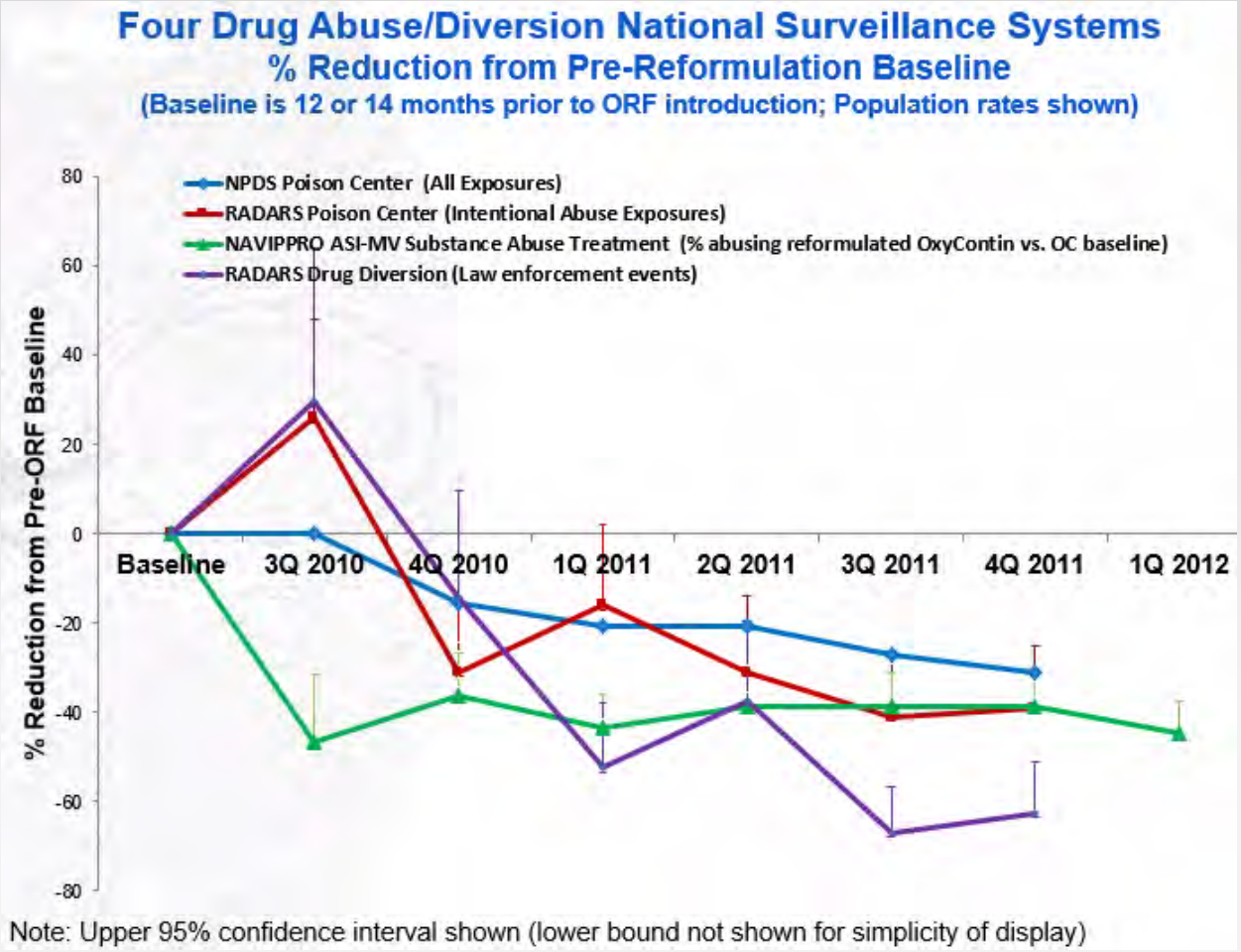
PPLP004409195 (Nov. 3, 2012 Purdue Presentation to Beneficiaries)

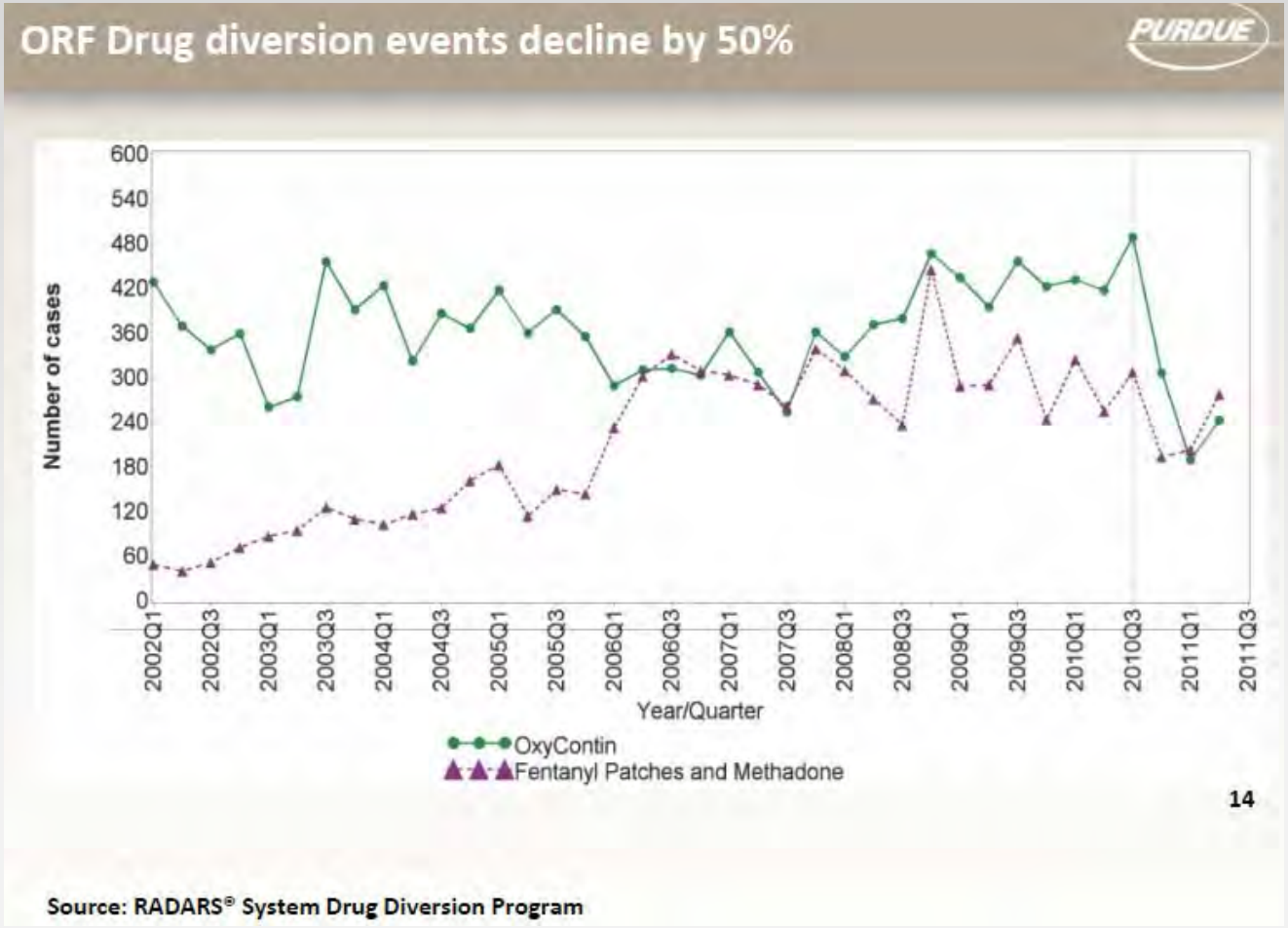
The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially



Note: Upper 95% confidence interval shown (lower bound not shown for simplicity of display)

June 18, 2012
Presentation to Board
(PPLPC057000011188)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Diversion Fell Substantially

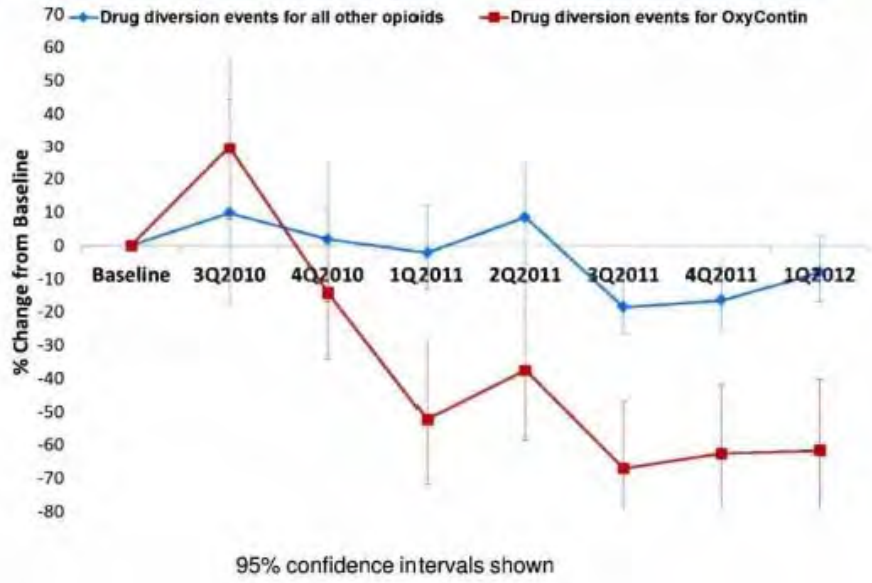


Attachment to Exec. Comm. Notes
Sent to Board on Oct. 25, 2011
(PURDUE-COR-00032185)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Diversion Fell Substantially

Drug Diversion/Law Enforcement Events in RADARS® System

% Reduction from Baseline
(Baseline is 12 months prior to ORF introduction; Population-adjusted rates)



95% confidence intervals shown

PURDUE

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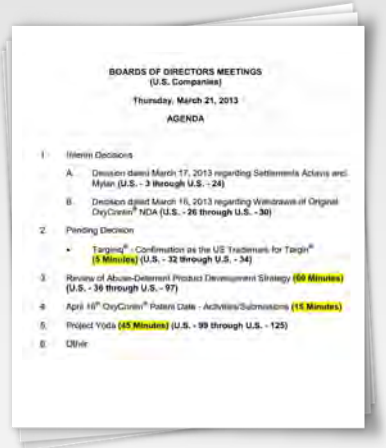


BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Thursday, March 21, 2013

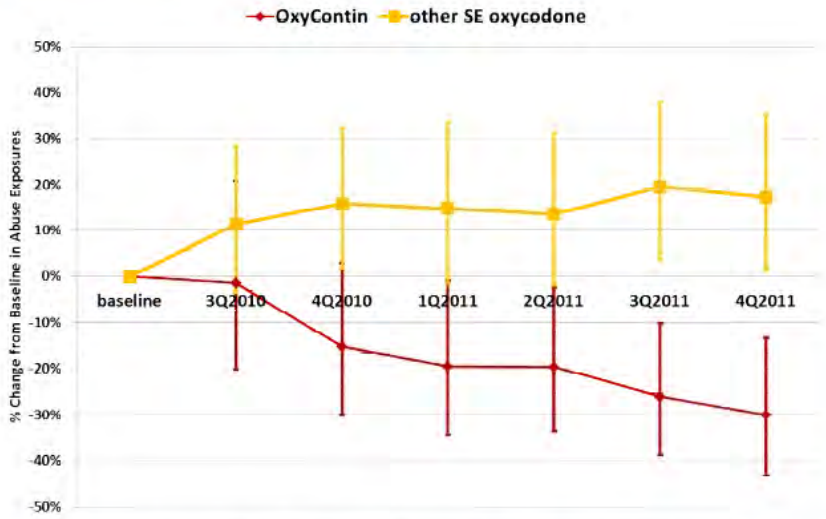
AGENDA

PPLPC044000041964
(Mar. 21, 2013
Presentation to Board)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse Fell Substantially

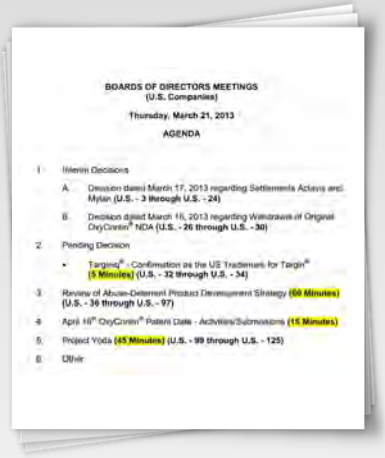
Poison Center Data from National Poison Data System

% Reduction from Baseline in Number of Intentional Abuse Exposures
(Baseline is 12 months prior to ORF introduction)



Source: National Poison Data System. Note: Baseline is average of 4 quarters from 3Q2009 to 2Q2010. 95% CI shown

Confidential



BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Thursday, March 21, 2013

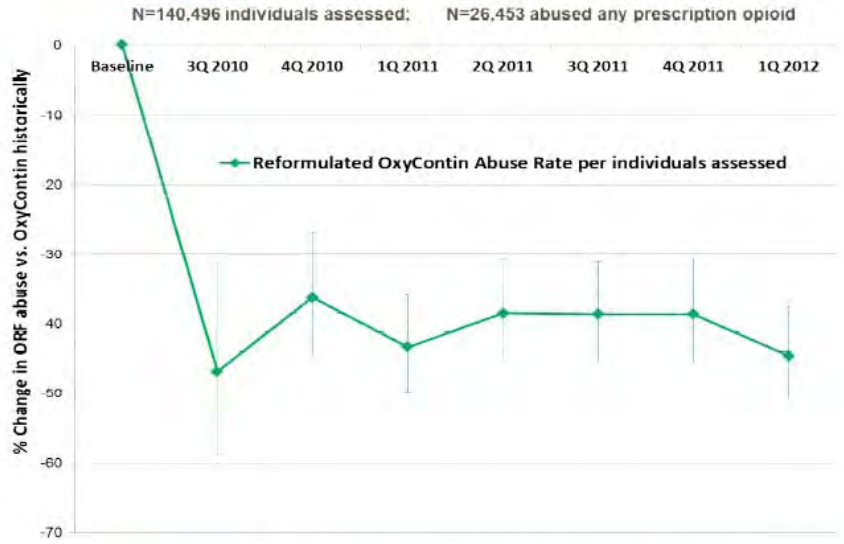
AGENDA

PPLPC044000041962
(Mar. 21, 2013
Presentation to Board)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse Fell Substantially

Abuse by Individuals Assessed for Substance Abuse Treatment

% Reduction from Baseline in NAVIPPRO® System
(Baseline is 14 months prior to ORF introduction)



95% confidence intervals shown; Baseline is average rate per individuals assessed over 14 months.

PURDUE

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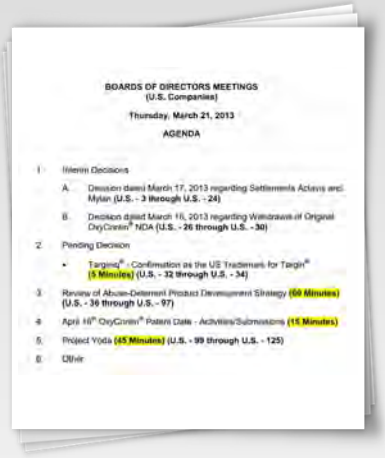
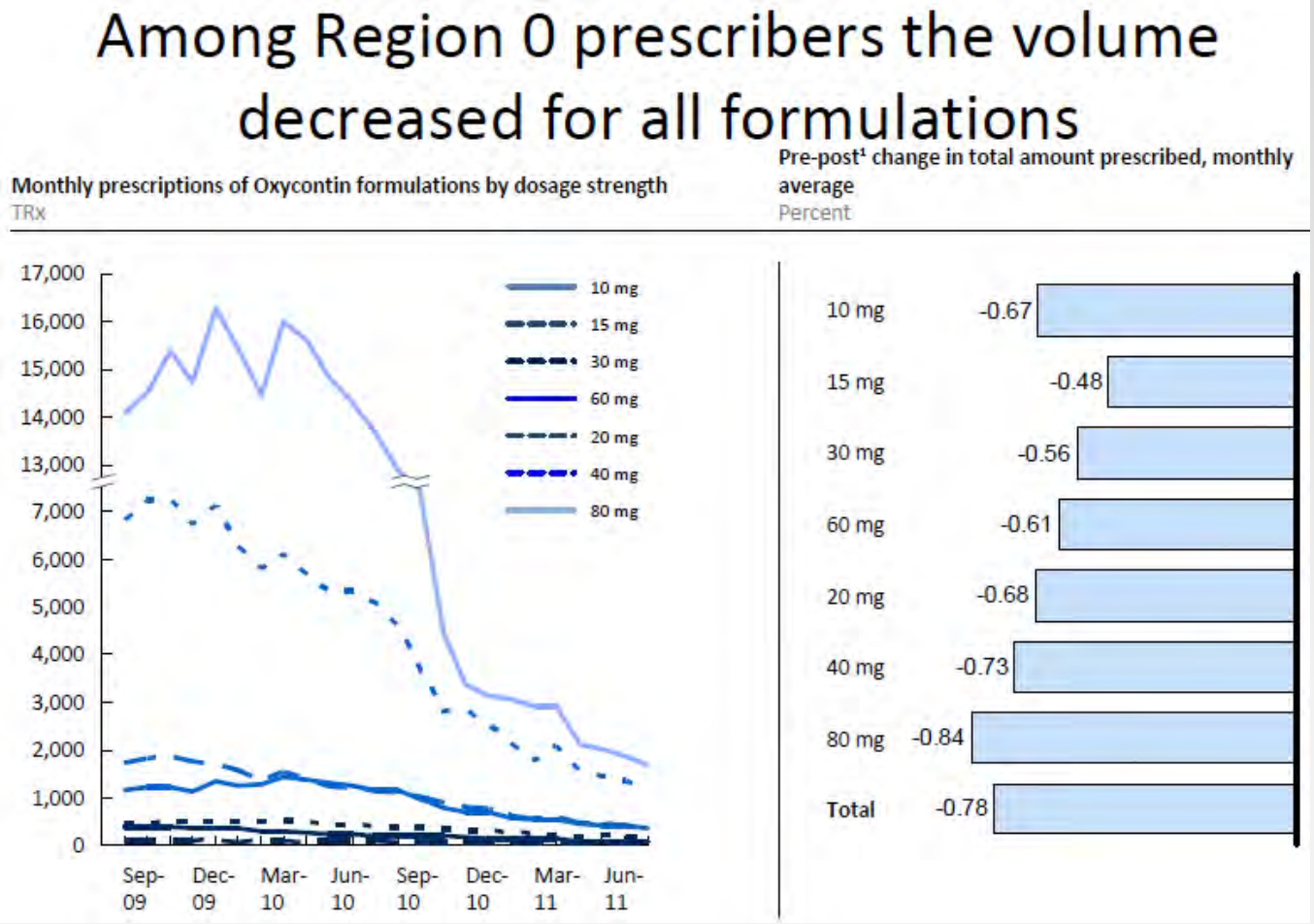

BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Thursday, March 21, 2013

AGENDA

PPLPC044000041961
(Mar. 21, 2013
Presentation to Board)

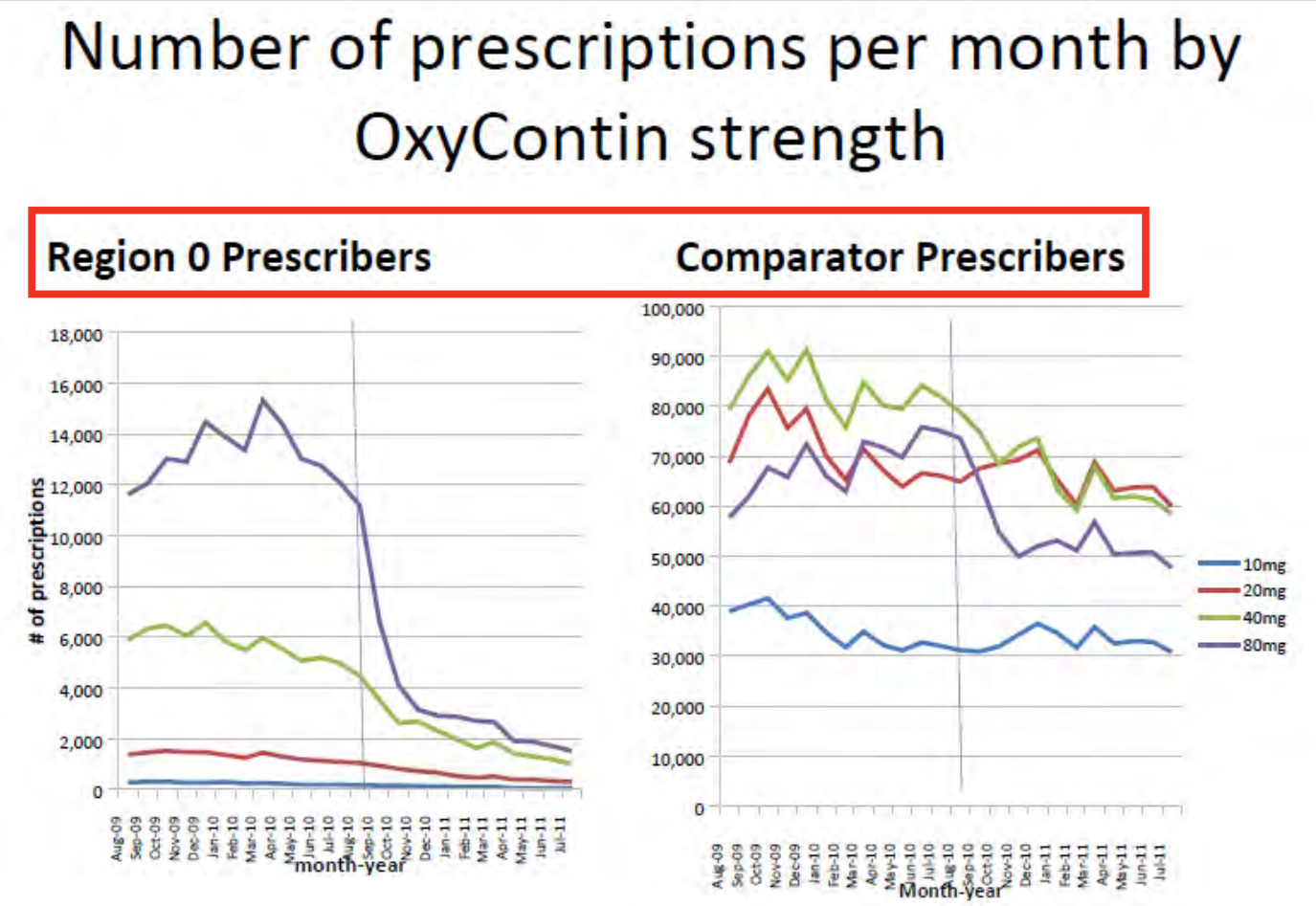
The Board Understood That Abuse-Deterrent OxyContin Was a Success — Prescriptions by Region Zero Prescribers Fell Substantially



- **Region Zero was a list of suspicious prescribers identified through Purdue's Abuse Diversion & Detection (ADD) Program**
- **Purdue sales reps did not call on Region Zero prescribers, but Purdue could not prevent them from prescribing OxyContin**

Attachment to Exec. Comm. Notes Sent to Board Oct. 25, 2011 (PPLPC042000024694)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Prescriptions by Region Zero Prescribers Fell Substantially

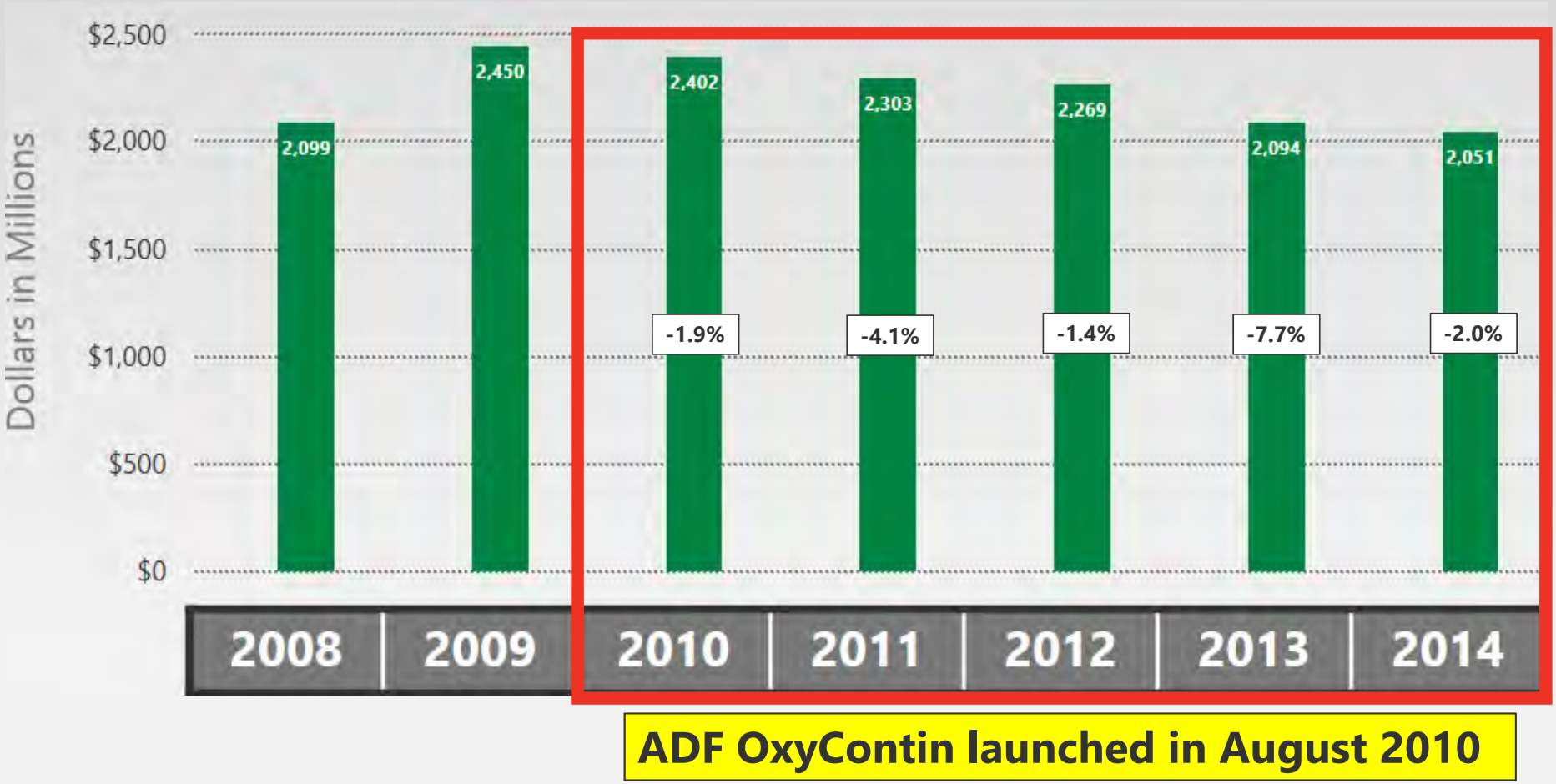


Attachment to Exec. Comm. Notes Sent to Board Oct. 25, 2011 (PPLPC042000024694)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Abuse and Diversion Fell Substantially

- Purdue sales began to decline in 2010 — for multiple reasons — and that prompted focus on sales
- The Board was advised that the Company's marketing campaign — E2E — was designed to encourage HCPs to identify and convert to OxyContin appropriate patients not currently on OxyContin
- As sales fell, the Board dramatically increased Purdue's cash on hand to ensure the vitality of the Company

The Decline in Purdue Sales Began in 2010 and Was Gradual



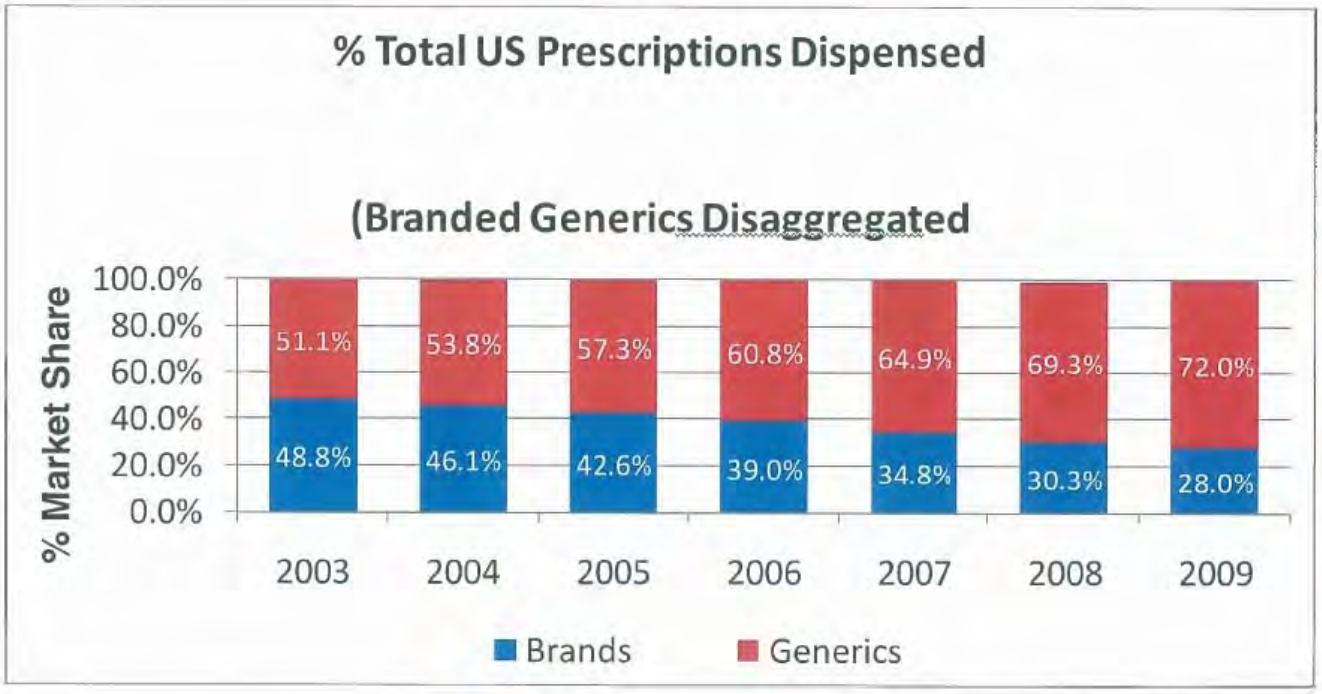
ADF OxyContin launched in August 2010

The Board Understood There Were Multiple Reasons for the Sales Decline

- The overall share of generic prescriptions was rising
- New, competing long-acting opioids were entering the market
- New entrants were targeting OxyContin
- The total market share held by branded extended-release opioids ("EROs") like OxyContin was falling

The Board Understood There Were Multiple Reasons for the Sales Decline

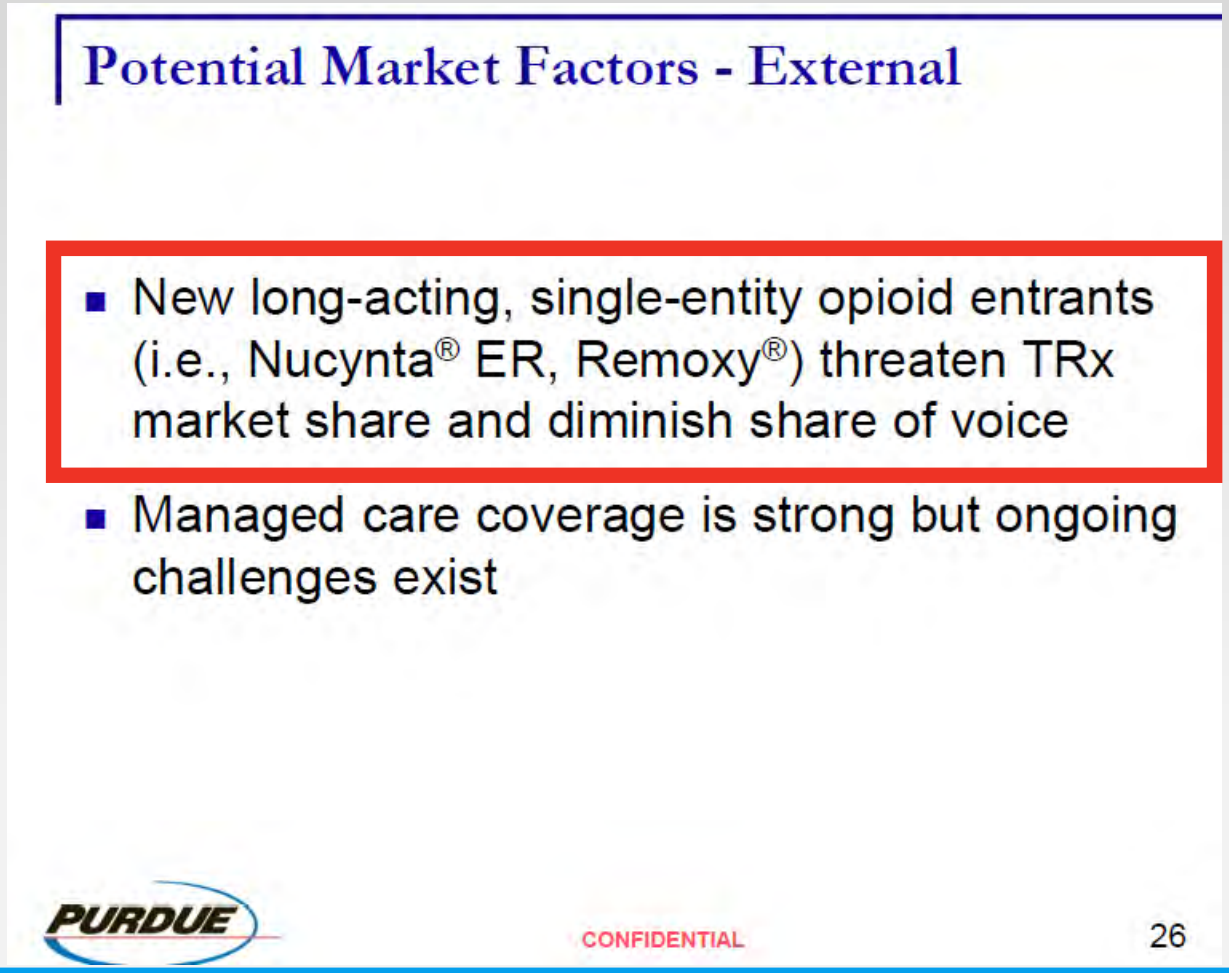
Overall Generic Share of Rx's is Increasing



Source: IMS "Perspective on the US Pharmaceutical Market A New Reality"

Nov. 2010 Full Budget Presentation (PPLP004404901)

The Board Understood There Were Multiple Reasons for the Sales Decline



Nov. 2010 Sales & Marketing Presentation (PPLP004404901)

The Board Understood There Were Multiple Reasons for the Sales Decline

Nucynta® ER is Targeting OxyContin® Tablets

POWERFUL PAIN MANAGEMENT

Mean change in pain intensity at Week 12 from baseline as measured by Numerical Rating Scale (NRS)[1]

*In a double-blind study, eligible patients were randomized 1:1:1 (N=981) to receive NUCYNTA® ER, oxycodone CR, or placebo. The intent-to-treat population[1] included 958 patients. Primary efficacy analysis is based on the last observation carried forward (LOCF) imputation method. Treatment comparisons used ANCOVA model and were based on least squares mean difference from placebo.

Incidence of treatment-emergent adverse events (TEAEs) reported in at least 5% of patients in any treatment group[11]

System/Organ Class Dictionary-Derived Term	% of Patients (N=965) Placebo (n=319)	NUCYNTA® ER (n=318)	Oxy [illegible] CR[1] (n=328)
Gastrointestinal Disorders	26	44	62
Nausea	9	20	35
Vomiting	2	9	19
Constipation	5	14	27
Diarrhea	7	6	2
Dry Mouth	2	8	4
Dyspepsia	3	5	2
Nervous System Disorders	23	40	45
Dizziness	6	12	17
Somnolence	3	13	16
Headache	14	20	17
Psychiatric Disorders	9	15	18
Insomnia	3	4	8
General Disorders	10	16	19
Fatigue	4	7	7
Skin and Subcutaneous Tissue Disorders	5	14	28
Hyperhidrosis	0	4	5
Skin Pruritus	2	7	17

Discontinuation rates due to TEAEs[1]
placebo 4%
NUCYNTA® ER 17%
oxycodone CR 32%

Nucynta ER Promotional Support

- ~1,000 Sales Representatives
- Web Site
- Competitive Savings Card Program
- Speaker's Programs

Prescriber Overlap

Nucynta IR Prescribers: 53,713
OxyContin Prescribers: 209,328
***Overlap* = 33,885**

PURDUE

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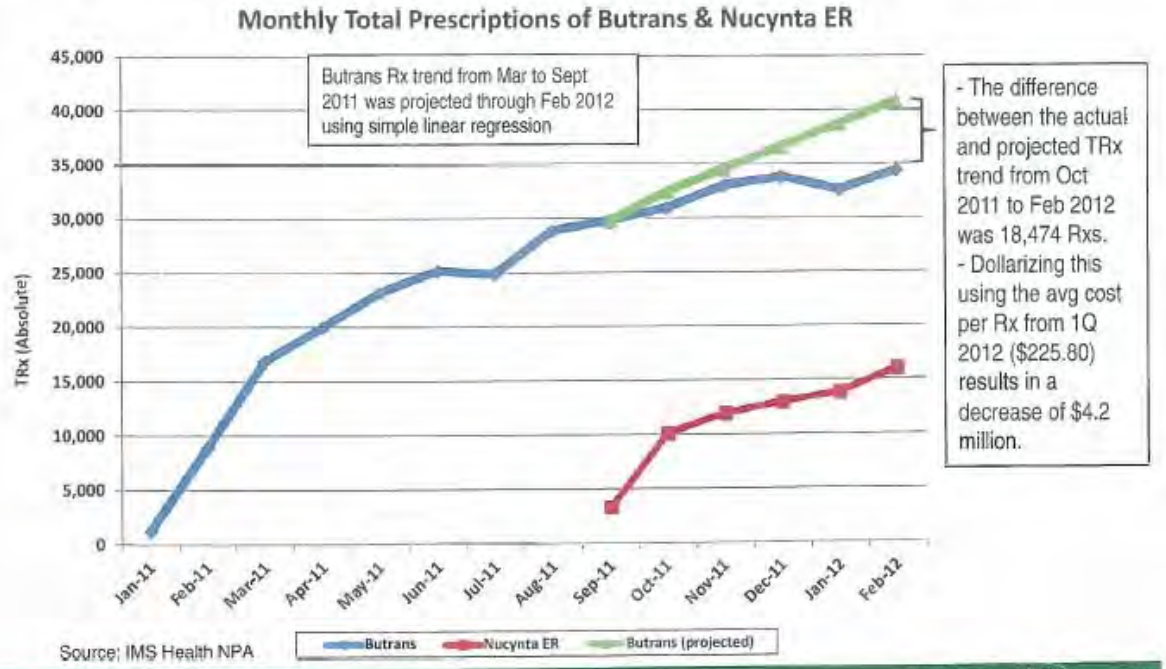
Oct. 2011 Full Budget Presentation at PPLPUCC003392177

The Board Understood There Were Multiple Reasons for the Sales Decline

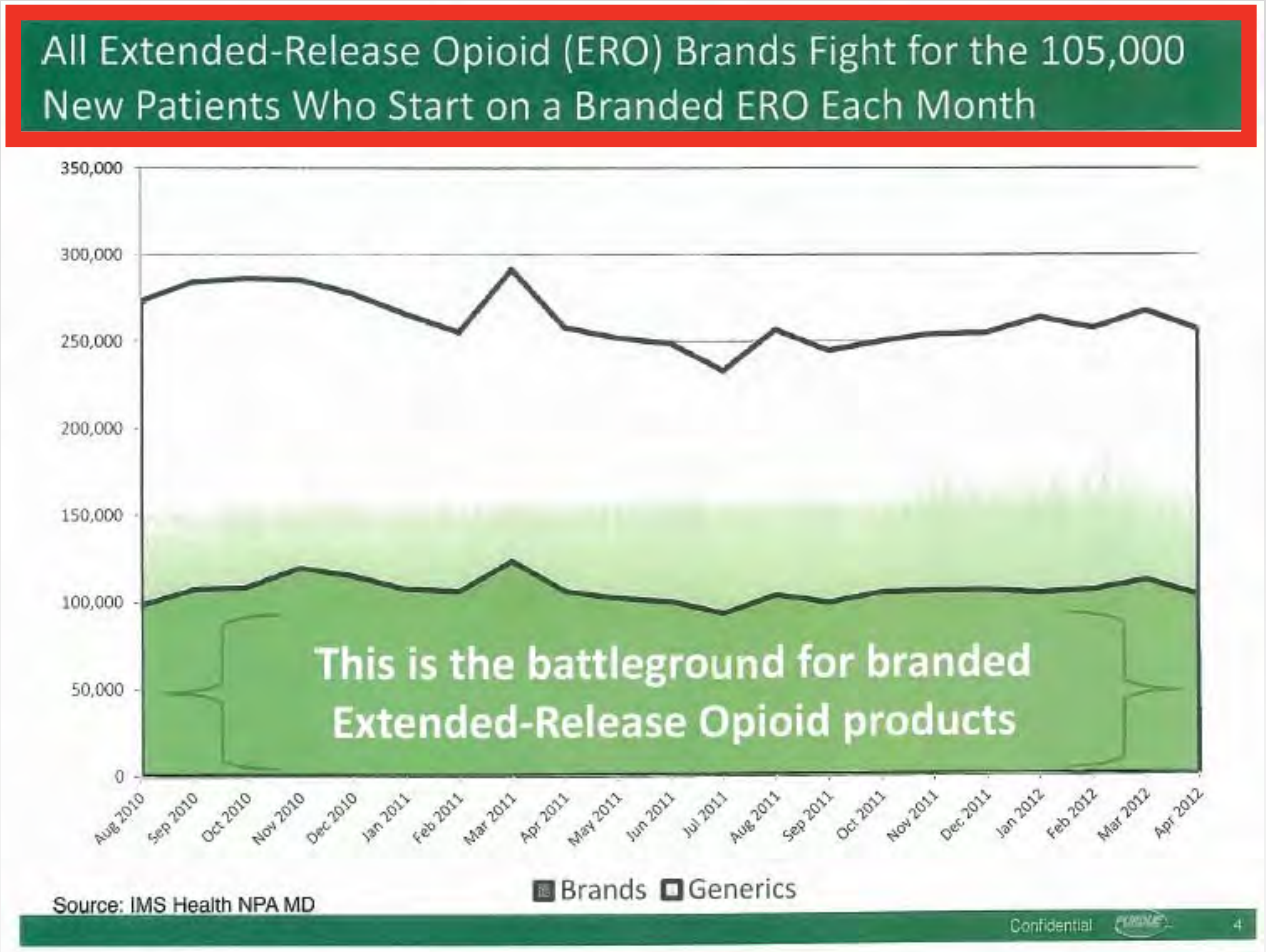
Nucynta® ER has Slowed Butrans® Monthly TRxs

Butrans 2012 budget assumed Nucynta ER would launch January 2012. Nucynta ER actual launch was September 2011.



June 2012 Full Budget Presentation

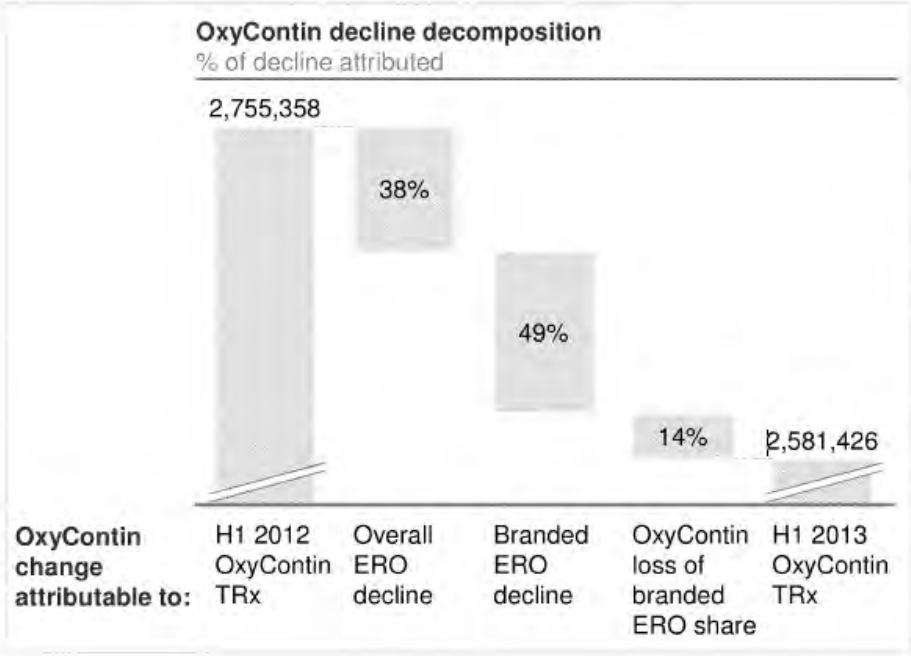
The Board Understood There Were Multiple Reasons for the Sales Decline



June 2012 Full Budget Presentation
(PPLPUCC001174050 at slide 4)

The Board Understood There Were Multiple Reasons for the Sales Decline

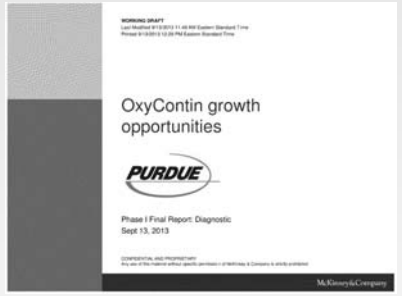
OxyContin's recent decline can largely be attributed to decline in branded ERO market



While OxyContin has lost share of branded ERO, the largest portion of OxyContin's decline can be attributed to overall decline in ERO and branded ERO

SOURCE: IMS

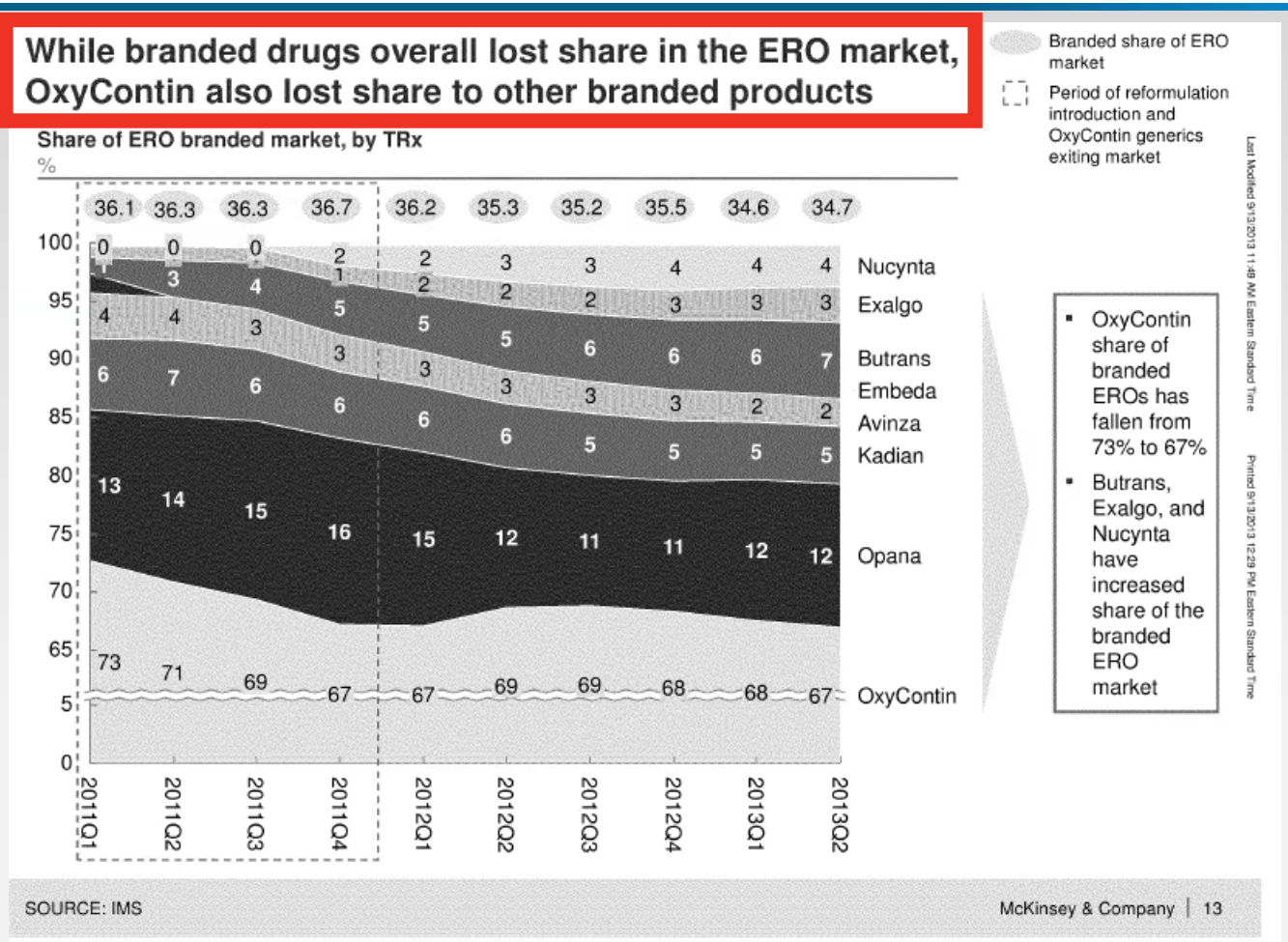
McKinsey & Company | 12

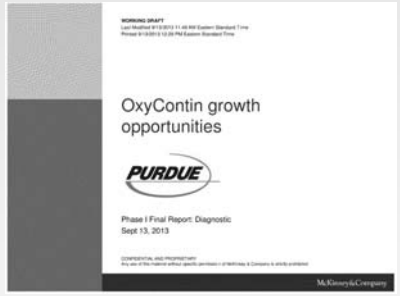


Sept. 13, 2013 McKinsey Deck
PURDUE-COR-00016506

The Board Understood There Were Multiple Reasons for the Sales Decline

While branded drugs overall lost share in the ERO market, OxyContin also lost share to other branded products





Sept. 13, 2013 McKinsey Deck
PURDUE-COR-00016507

The Board Understood There Were Multiple Reasons for the Sales Decline

Events Potentially Impacting the Extended Release Opioid Market

- Competitive
  - Increased Genericization: Opana® ER, Exalgo®, Generic OER Agreements
  - Re-launch of Embeda®
  - Approval/Launch of Targiniq
  - Approval/Launch of Zohydro
  - Approval/Launch of ER oxycodone/APAP

Nov. 2013 Year End Budget Book (PPLP004409973)

The Board Understood There Were Multiple Reasons for the Sales Decline

Events Potentially Impacting the Extended Release Opioid Market

- Legislation + Market Events
  - Affordable Care Act
  - State legislation, such as in WA
  - Support for abuse deterrent formulations (e.g., STOPP Act)
  - Restrictions on APAP doses beginning in Jan 2014
  - Hydrocodone combinations to schedule II
  - e-prescribing for Schedule II products
  - DEA pressure on physicians and pharmacies
  - Other pressures (e.g. PROP)

Nov. 2013 Year End Budget Book (PPLP004409973)

The Board Understood There Were Multiple Reasons for the Sales Decline

External Market Dynamics

		Market Impact
Opioid Rescheduling	• Rescheduling of hydrocodone and tramadol could: – Reduce the overall size of the hydrocodone IR market – Reduce barriers to switching hydrocodone IR patients to EROs – Improve relative accessibility of Butrans (currently CIII)	↑↓
Managed Care	• Increasing pressure from managed care organizations resulting in: – Tighter utilization management including more use of exclusion lists – Demands for higher rebates on branded products • Managed care taking more active role in opioid abuse management (e.g., BCBS Tennessee)	↓
Policy	• Class-wide and state-level regulatory changes (e.g., limiting daily dose, mandated reporting) • DEA guidelines may result in reduction / limitation of supply to wholesale distributors and retail pharmacy chains reducing patient access • However, some state legislation favoring ADP products (i.e., Massachusetts)	↑↓
Abuse Deterrent Properties (ADP)	• FDA guidance / regulations on abuse deterrence has been favorable for OxyContin to date • Competitors are launching abuse deterrent technologies which could confuse the marketplace and dilute Purdue's ADP differentiation	↑↓
Integrated Delivery Networks (IDNs)	• Increasing prevalence and evolving business models for IDNs could impact current pain management practices including potential to limit access to branded products	↑↓

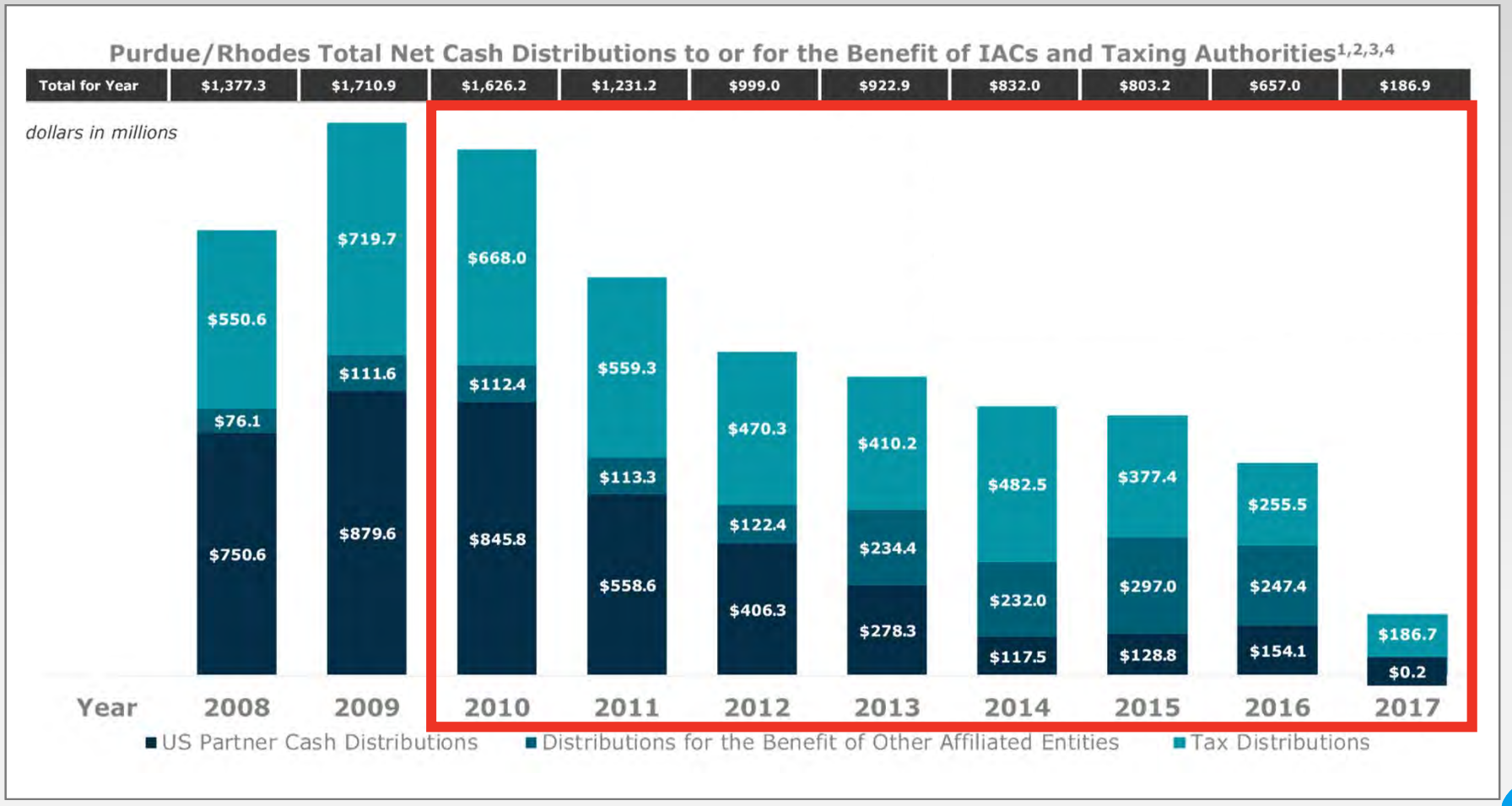
OxyContin 2014 Budget Proposal (PPLP004409973)

The Board Responded By Leaving Enormous Amounts Of Cash in Purdue <u>After</u> Distributions To Ensure The Company's Vitality

Sources: PPLPC031001244649 (2008-12); PPLPC051000265076 (2013-14); PPLPC045000018249 (2015); PPLPC032000398822 (2016)

ADF OxyContin launched in August 2010

The Board Cut Distributions As It Left More and More Cash in Purdue



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11 (SDNY (Bankr.) No. 19-23649-rdd Doc 654-1)

The Board Understood McKinsey Brought Industry Best Practices to Purdue's Marketing

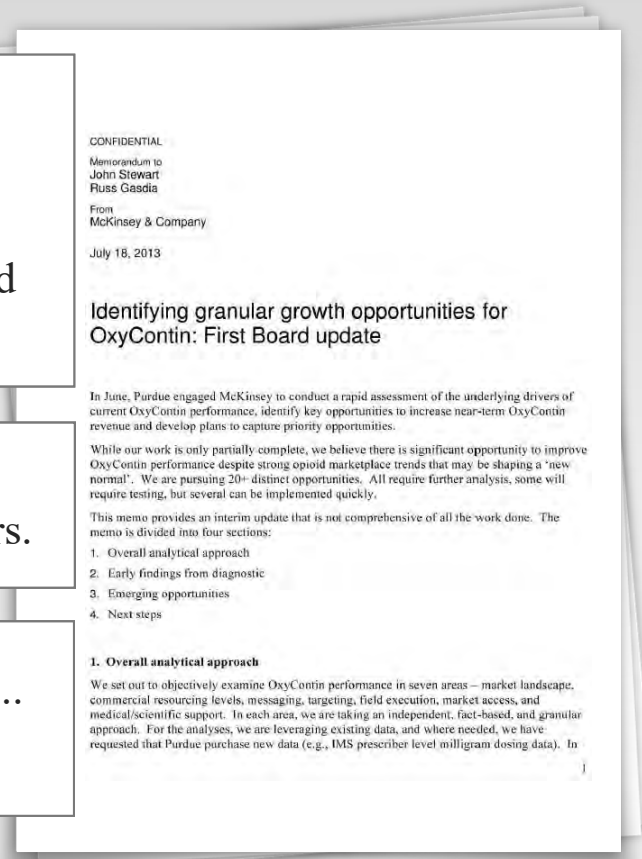
The Board Understood That McKinsey Brought Industry Best Practices to Purdue

July 18, 2013 McKinsey Report to Board:

These ideas are primarily about implementing industry best practices in execution. These best practices can be adapted for Purdue and rolled out quickly. These include: higher call productivity, fully delivery of OxyContin P1s, higher reach of decile 6-10 prescribers, greater adherence to call lists, and field training on how to appropriately engage medical.

Industry best practice targets physicians based on a composite value incorporating TRx and NBRx, as well as access and other behavioral indicators.

Best practice field force optimization requires a significant holistic approach ... with robust analysis of many factors....



CONFIDENTIAL

Memorandum to
John Stewart
Russ Gasdia

From
McKinsey & Company

July 18, 2013

Identifying granular growth opportunities for OxyContin: First Board update

In June, Purdue engaged McKinsey to conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities.

While our work is only partially complete, we believe there is significant opportunity to improve OxyContin performance despite strong opioid marketplace trends that may be shaping a 'new normal'. We are pursuing 20+ distinct opportunities. All require further analysis, some will require testing, but several can be implemented quickly.

This memo provides an interim update that is not comprehensive of all the work done. The memo is divided into four sections:

1. Overall analytical approach
2. Early findings from diagnostic
3. Emerging opportunities
4. Next steps

1. Overall analytical approach

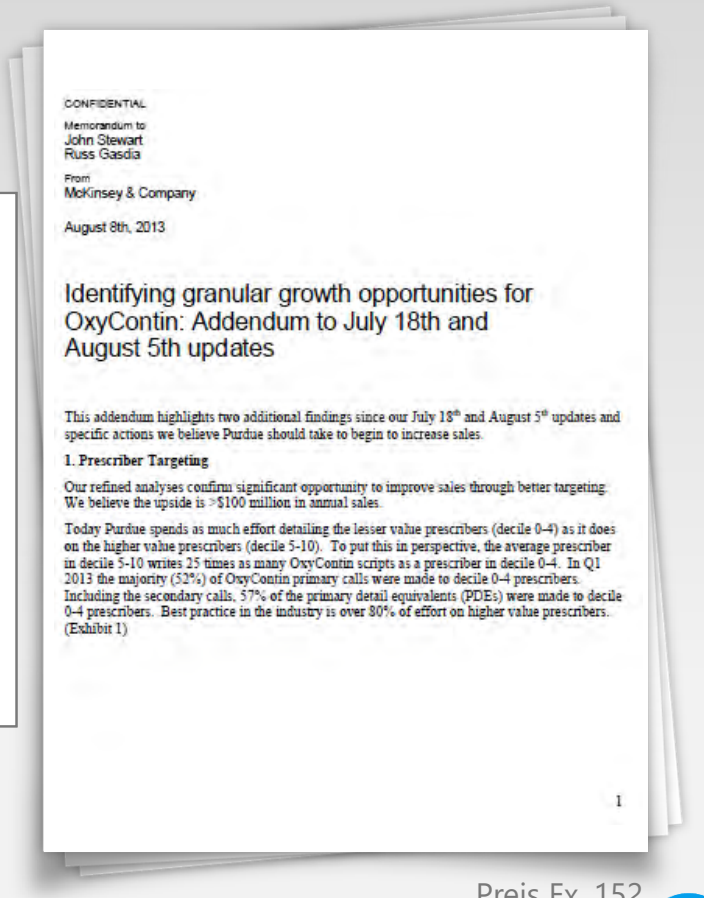
We set out to objectively examine OxyContin performance in seven areas – market landscape, commercial resourcing levels, messaging, targeting, field execution, market access, and medical/scientific support. In each area, we are taking an independent, fact-based, and granular approach. For the analyses, we are leveraging existing data, and where needed, we have requested that Purdue purchase new data (e.g., IMS prescriber level milligram dosing data). In

July 25, 2013 Board Book (PPLP004409781)

The Board Understood That McKinsey Brought Industry Best Practices to Purdue

August 8, 2013 McKinsey Report:

Today Purdue spends as much effort detailing the lesser value prescribers (decile 0-4) as it does on the higher value prescribers (decile 5-10). To put this in perspective, the average prescriber in decile 5-10 writes 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on higher value prescribers.



CONFIDENTIAL

Memorandum to
John Stewart
Russ Gasdia

From
McKinsey & Company

August 8th, 2013

Identifying granular growth opportunities for OxyContin: Addendum to July 18th and August 5th updates

This addendum highlights two additional findings since our July 18th and August 5th updates and specific actions we believe Purdue should take to begin to increase sales.

1. Prescriber Targeting

Our refined analyses confirm significant opportunity to improve sales through better targeting. We believe the upside is >$100 million in annual sales.

Today Purdue spends as much effort detailing the lesser value prescribers (decile 0-4) as it does on the higher value prescribers (decile 5-10). To put this in perspective, the average prescriber in decile 5-10 writes 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on higher value prescribers. (Exhibit 1)

1

Preis Ex. 152

The Board Understood That McKinsey and E2E Stressed OxyContin's Abuse-Deterrent Properties

Work Streams/Issue Teams

Training and Communications

- Prepare for full implementation - at the 2014 National Sales Meeting
- Conduct ongoing internal communications regarding the transformative changes and associated benefits
- Identify, write-up and communicate supporting analytics from the "internal pilots" and other sources

Messaging

- OxyContin® sales and marketing messaging/positioning
- Payer "pull through" improvements
- Messaging about abuse-deterrent formulations/properties
- Liaise with R&D and Corporate Affairs to develop information in support of messaging efforts.

Alternative promotion strategies

- Call centers, video detailing, relationship marketing, and other approaches to "no-see" and "low-see" prescribers

Pharmacy/Trade

- Alternative distribution methods, if the current shortages don't show clear signs of resolution
- Communication of pharmacy policy changes and their potential impact
- Active liaison with wholesalers and chain pharmacies

OxyContin Growth Opportunities Action Plan

September 12th, 2013

Sept. 12, 2013 Presentation to Board (PPLPC063000002005)

The Board Understood That McKinsey and E2E Stressed OxyContin's Abuse-Deterrent Properties

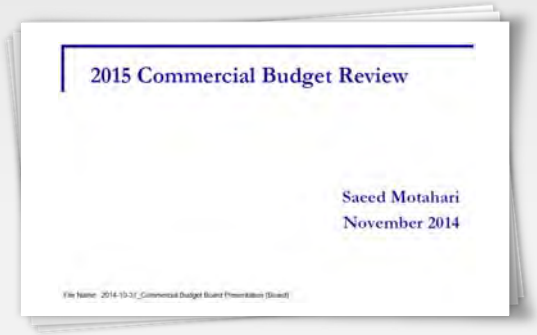
2015 Brand Strategy and Forecast

- OxyContin remains the dominant branded ERO; however, the regulatory, payer and competitive landscape will put increasing pressure on OxyContin

- Four strategies will drive OxyContin success:
  - **Drive profitable access**
  - **Improve Managed Care Pull-through**
  - **Increase oxycodone IR conversions**
  - Elevate the **importance of abuse deterrence**

- The current forecast projects a **2015 gross sales of $1,620M and net sales of $1,001M** (-29% & -36% lower than 2014 LE respectively)
  - Decline driven by settlements ($313M), share decline ($153M) in part due to Hysingla ER, higher rebate rates ($102M) and change in strength and tab mix ($99M), but offset in part by 6% price increase of $109M
  - The product contribution has **improved by $118M** vs. 10 Year Plan despite shifting of AGs

- 2015 **S&P budget of $92.8M** (-14% vs 2014 LE)
  - Marketing $21.3M (-1.5% vs 2014 LE)
  - Sales Force $86.1 (-17% vs 2014 LE)



Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -408)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

Brand Vision and Goals

Vision: Leverage ADF leadership and Managed Care coverage to strengthen first line ERO from IR oxycodone switches

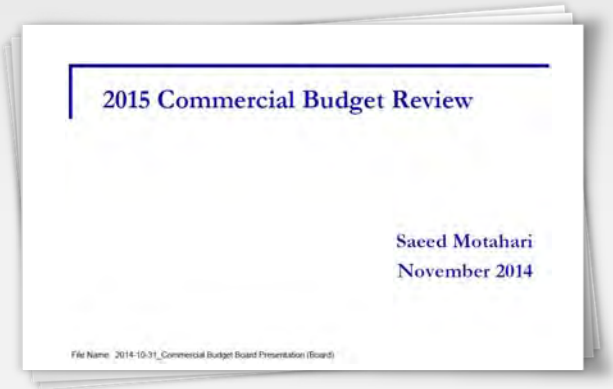
2015 Objectives:

- Gross Sales: $1,620M
- Net Sales: $1,001M
- 4.8M Rxs[1]

Strategic Pillars

1. Drive Profitable Access	2. Improve Managed Care Pull-through	3. New Patient Starts	4. ADP in Prescribing
Focus on profitable access by driving optimal access / contracting via strategic account segmentation	Enhance uptake in regions with high managed care coverage but are under-indexed	Drive new patient starts by focusing on IR oxycodone conversions	Elevate the importance of abuse deterrence as a key driver for ERO prescribing

ADF = Abuse-Deterrent Formulation



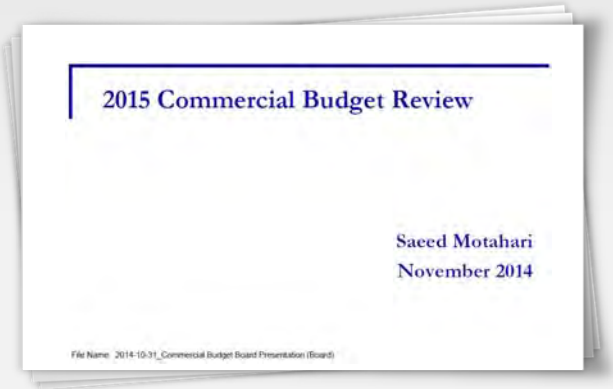
Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -412)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

68% of IR oxycodone conversions go to other ERO molecules:
Opportunity to increase IR oxycodone to OxyContin® conversion rate

SWITCHED FROM/ADDED TO PRODUCT	OXYCODONE PLAIN, OXYCODONE COMBOS	
Switched To/Added On Product	**Sum of MAT TRxs Mar2014**	**% of Total**
OXYCONTIN*	266,970	32.0%
GENERIC 2X/DAY MORPHINE	225,771	27.1%
TRANS. FENTANYL	174,057	20.9%
METHADONE	61,323	7.4%
OPANA ER/GENERICS	52,057	6.2%
BUTRANS*	23,850	2.9%
EXALGO*	13,398	1.6%
NUCYNTA ER*	10,466	1.3%
KADIAN*	3,870	0.5%
AVINZA*	1,891	0.2%
ZOHYDRO ER*	168	0.0%
TOTAL BRANDED PRODUCTS*	**320,613**	**38.5%**
TOTAL ALL PRODUCTS	**833,821**	**100.0%**

Each 0.1% increase in the IR oxycodone to ERO conversion rate equals $350k in gross sales



Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -409)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

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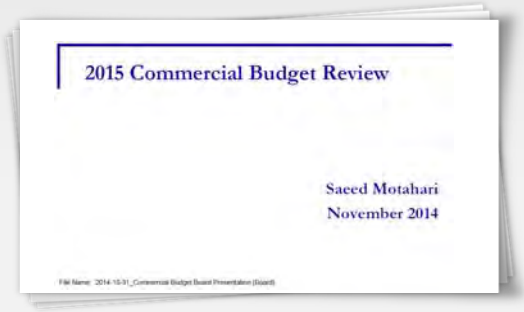
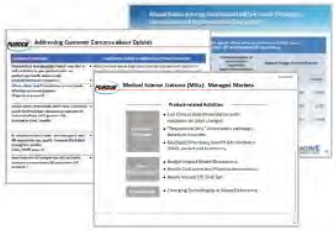


Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -408)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

Tier 4 Abuse Deterrence Labeling

4.

	Objective	Description	Deliverable
a)	Increase promotional efforts on OxyContin Abuse Deterrence Studies to raise awareness	• Sales force to proactively communicate aspects of abuse deterrence studies	
b)	Highlight the financial impact of OxyContin reformulation to payers	• Develop data and materials to support proactive and reactive conversations with payers regarding the financial impact of abuse deterrence • Empower MSLs with additional materials for various interactions	
c)	Increase awareness of Abuse Deterrence through Non-Personal Channels	• Drive awareness of OxyContin Abuse Deterrence Studies / Tier 4 Label through medical publications, med-education conferences etc.	

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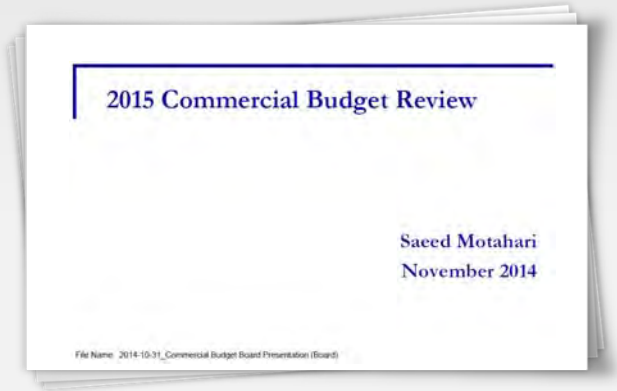
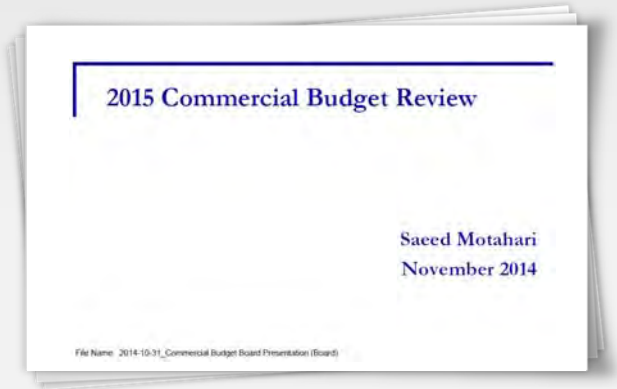


Nov. 2014 Budget Presentation to Board (PPLP004411383)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

OxyContin Strategic Pillars and Objectives

1. Drive Profitable Access	2. Improve Managed Care Pull-through	3. New Patient Starts	4. ADP in Prescribing
a) Rebate based on data-driven, profitable levels	a) Enhance pull-through efforts via close team collaboration of field sales and account management teams	a) Target molecule to molecule switch from IR oxycodone to OxyContin	a) Leverage Tier 4 labeling in appropriate promotions
b) Streamline contracting processes	b) Target pull-through "identify / prioritize" efforts in territories that are under-indexed vs. national average in spite of favorable managed care coverage	b) Target HCPs with high NBRx share and a high oxycodone to non-OxyContin switch rate	b) Highlight the financial impact of OxyContin reformulation to payers
c) Customize value propositions based on segment needs		c) Educate payers on the benefits of maintaining a patient on same ERO molecule to minimize access barriers	c) Equip sales force to effectively communicate OxyContin Abuse Deterrence clinical information
d) Identify and engage key healthcare stakeholders & influencers			d) Increase promotional efforts on OxyContin Abuse Deterrence Studies to raise awareness

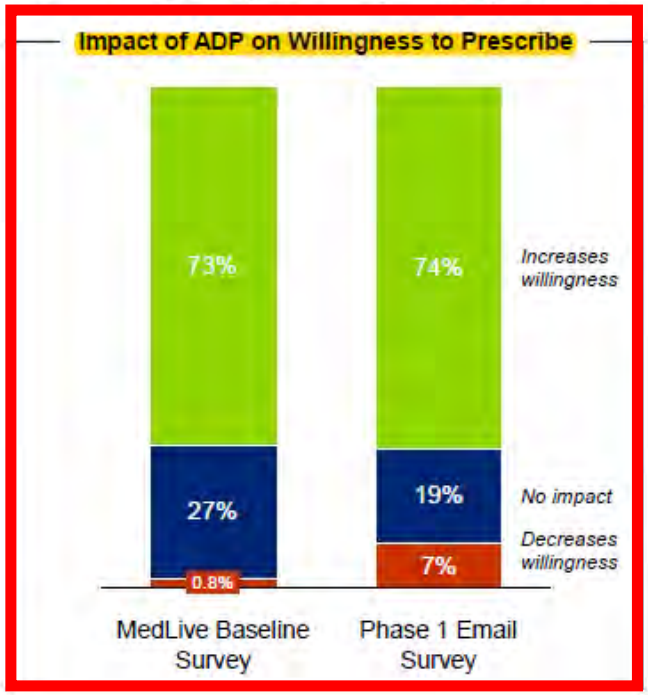


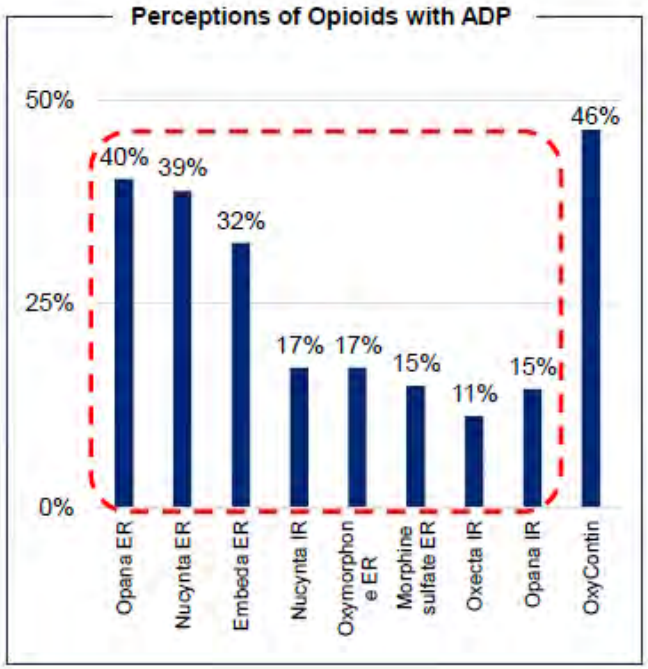
Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -413)

The Board Understood That E2E Targeted The Legitimate Pain Market for OxyContin

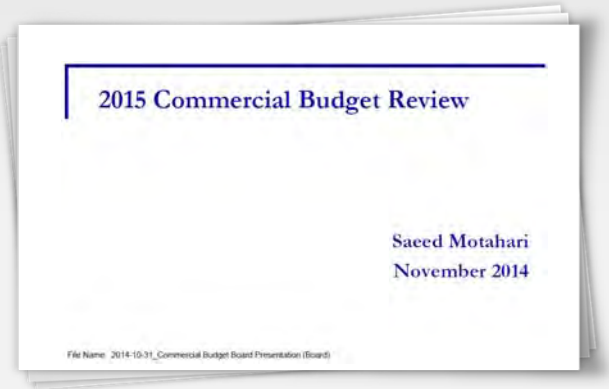
Opportunity to further differentiate OxyContin® versus other EROs and educate on ADPs

Although ~3/4 of physicians indicate an increased willingness to prescribe opioids that have ADPs, misperceptions regarding pain medications and ADFs are common





ADP = Abuse-Deterrent Properties


2015 Commercial Budget Review

Saeed Motahari
November 2014

Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -410)

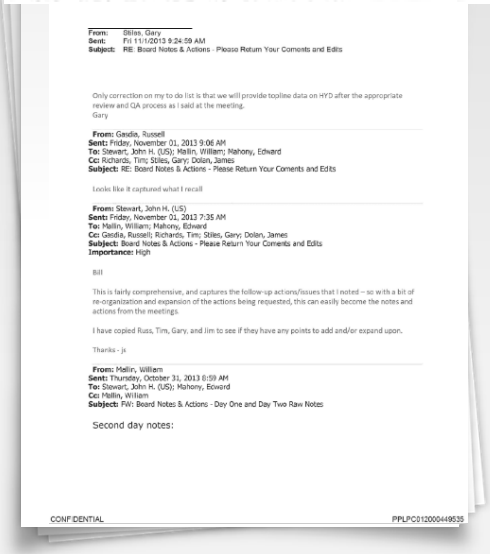
The Board Instructed That E2E Target The Legitimate Pain Market for OxyContin

Notes from 10/30/13 Board Meeting

From: Mallin, William
Sent: Wednesday, October 30, 2013 8:19 AM
To: Stewart, John H. (US); Mahony, Edward
Cc: Mallin, William
Subject: Board Notes & Actions - Day One Raw Notes

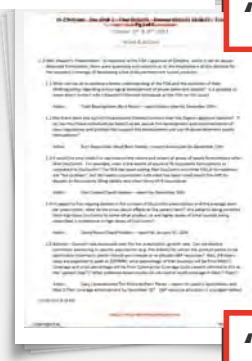
Gents:

Raw notes from the meeting day one. We can review for the meaningful actions once today is completed.



Purdue U.S. Budget Presentation
October 29th & 30th, 2013

Notes & Actions



"not just push to obtain scripts"

1. Must focus on sales force incentives (behaviors) not just push to obtain scripts – integrate this across the entire culture not just sales – language, attitude, etc – do well by doing good (Dr K/Judy)

"do well by doing good"

"be driven to be of high value to patients and physicians"

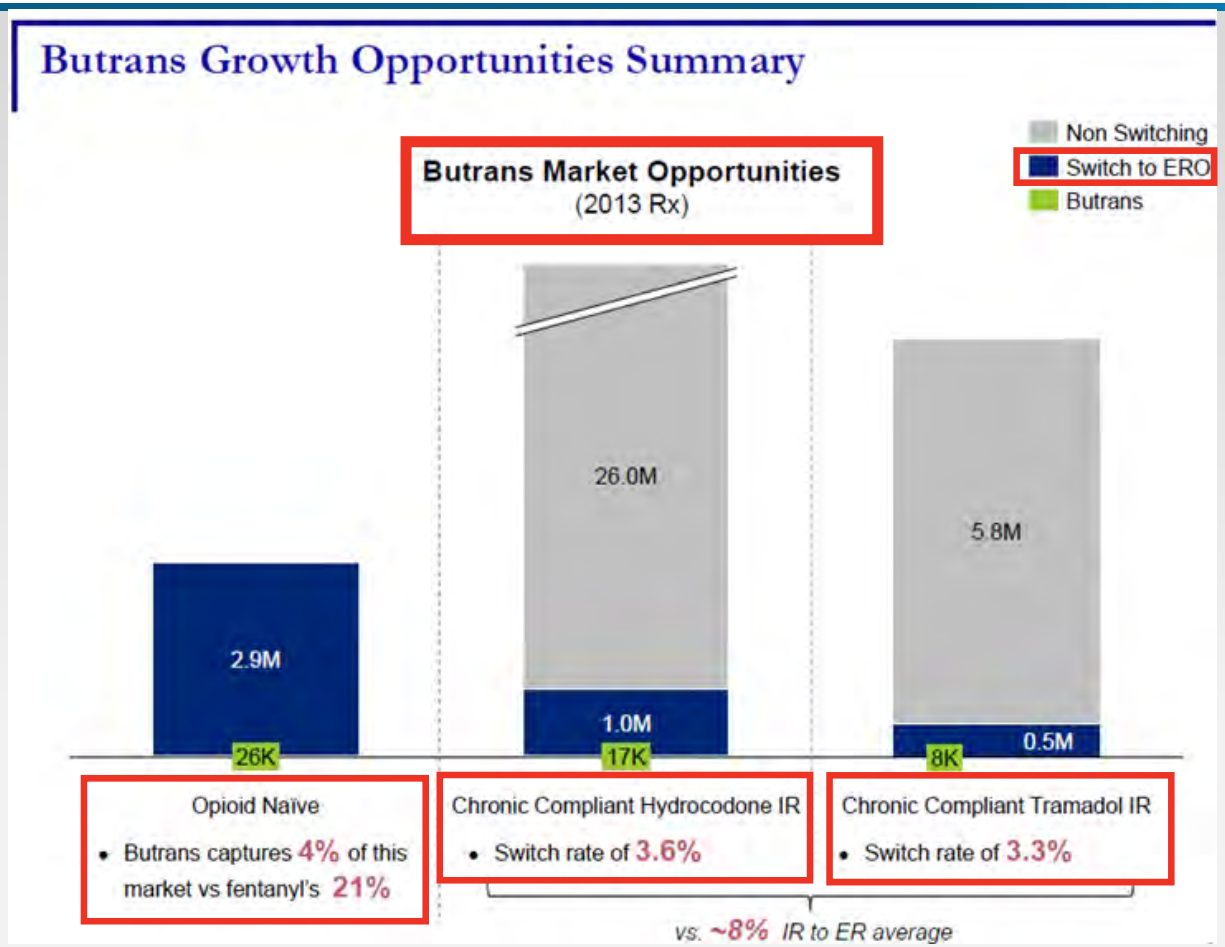
2.3 In regard to the E2E Project, the following comments/questions were raised:

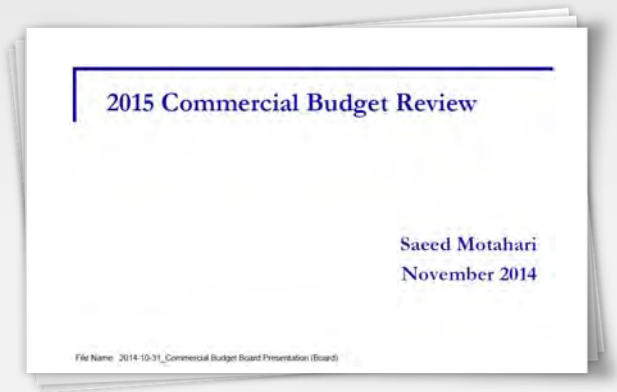
i. In terms of incentives, the salesforce (and indeed the entire organization) should be driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products.

"not simply to increase prescriptions for Purdue products"

PPLPC012000449535, PPLPC012000452390

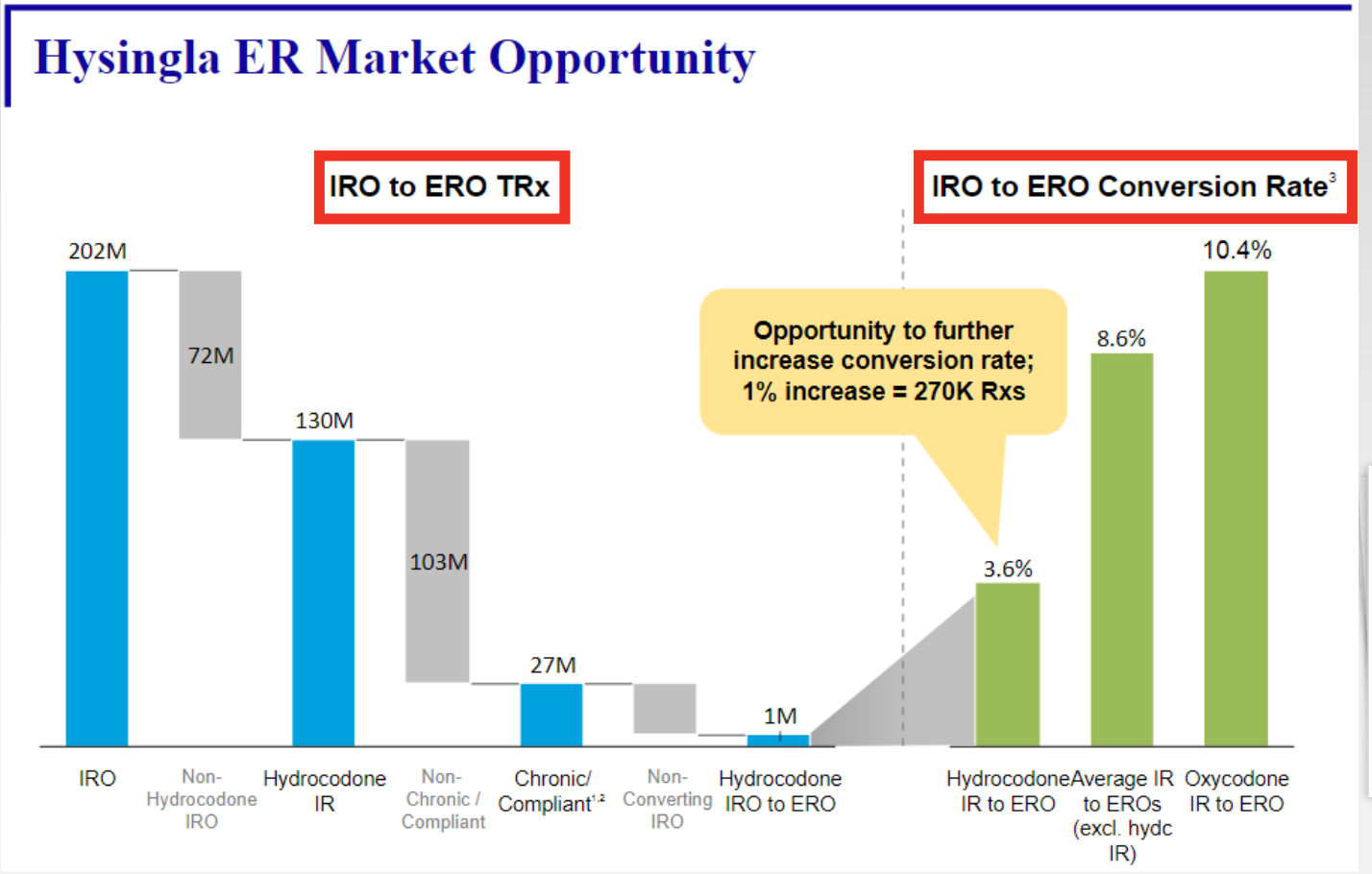
The Board Understood That E2E Targeted The Legitimate Pain Market for Butrans

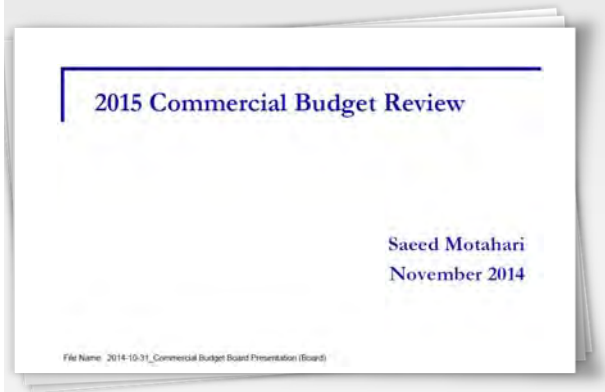




Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -428)

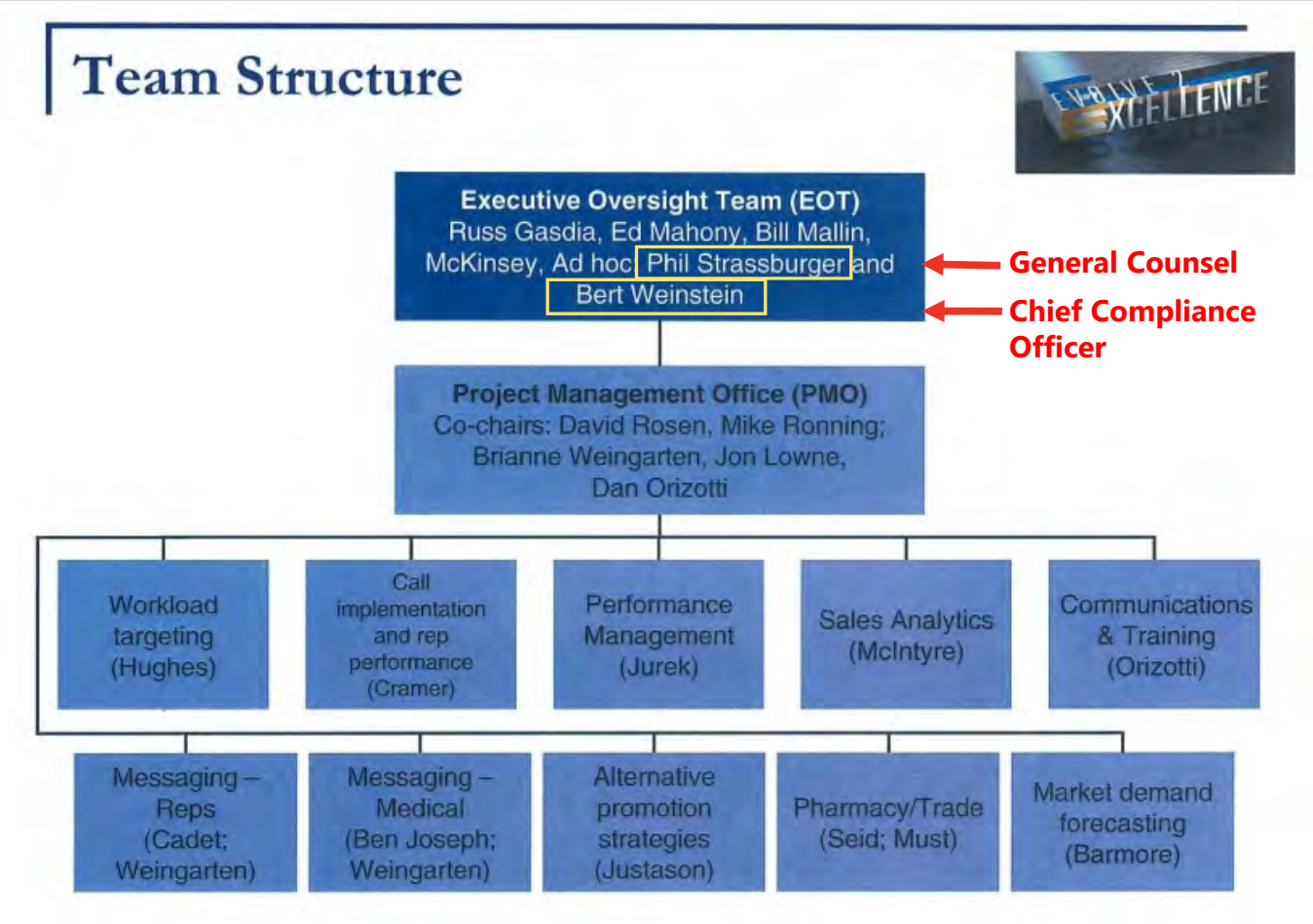
The Board Understood That E2E Targeted The Legitimate Pain Market for Hysingla

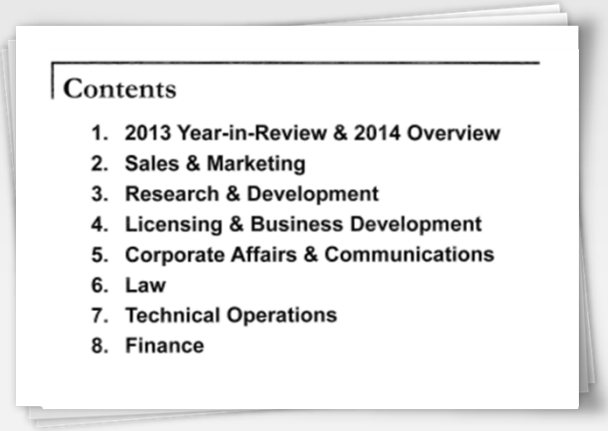




Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -444)

The Board Understood That Compliance Was Built into the Oversight of E2E





Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -022)

DOJ's Allegations Against the Family Depend Entirely on McKinsey/E2E — And Discard All of the States' Marketing Claims

- In Purdue's Addendum A, DOJ alleges that Purdue engaged in marketing misconduct from 2010-2018 (Purdue Addendum A ¶¶4, 9, 25, 40-41, 45)
- But in Sackler Addendum A, DOJ limits its allegations against the former Directors to the period 2013-2018 (Sackler Addendum A ¶¶4, 5, 23)
- Significance:

1. DOJ recognizes that the Board was entitled to rely on assurances from the OIG of HHS that Purdue was operating in compliance with the CIA from 2007-12
2. DOJ's allegations against the former Directors depend entirely on McKinsey/E2E — and are disproved by the evidence discussed above
3. DOJ rejected all of the States' prepetition claims of deceptive marketing because McKinsey/E2E are not alleged to have involved deception

DOJ Falsely Alleges That A "Titration Up Marketing Campaign" Was Presented to the Board

DOJ alleges:

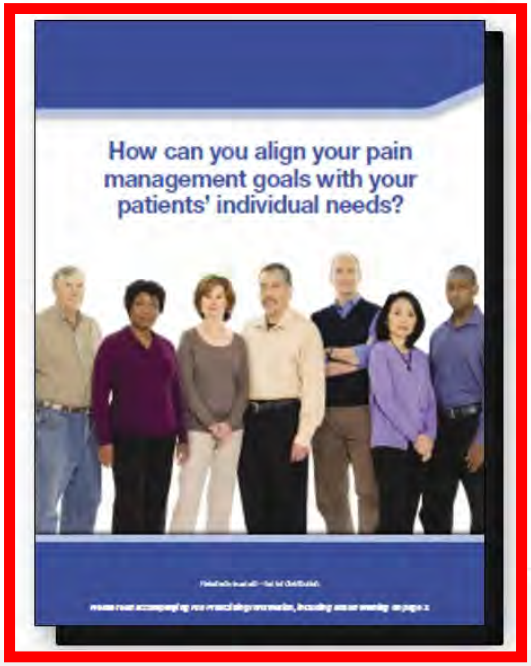
> "113. At the November 2013 meeting concerning Purdue's 2014 budget, a Purdue executive discussed with the Board the company's plans to 'refine the message' of the company's titration up marketing campaign and specifically referenced the 'Individualize the Dose' campaign, a Conversion & Titration Guide, and the S.T.A.R.T. principles to 'highlight important elements of titration throughout the course of treatment." (DOJ/Sackler Settlement Agreement, Addendum A, ¶113)

- **No "Titration Up Marketing Campaign" was ever presented to the Board**
- **DOJ's allegations distort the "Individualize the Dose" campaign, the "Conversion & Titration Guide" and "S.T.A.R.T." principles**
- **The Board was told titration was to go up or down as appropriate for the patent**

No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Refining Our Message

Evolution of the *"Individualize the Dose"* Campaign



Campaign/ Message Refresh:

- Refreshed creative
- Refine promotional messages
  - Initiation/ Conversion
  - Titration
  - Managed Care Access/ Pull Through
  - Abuse Deterrent Formulation
  - Purdue's heritage in Pain Management

From the cited Nov. 2013 budget presentation to the Board


Contents

1. 2013 Year-in-Review & 2014 Overview
2. Sales & Marketing
3. Research & Development
4. Licensing & Business Development
5. Corporate Affairs & Communications
6. Law
7. Technical Operations
8. Finance

Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -059)

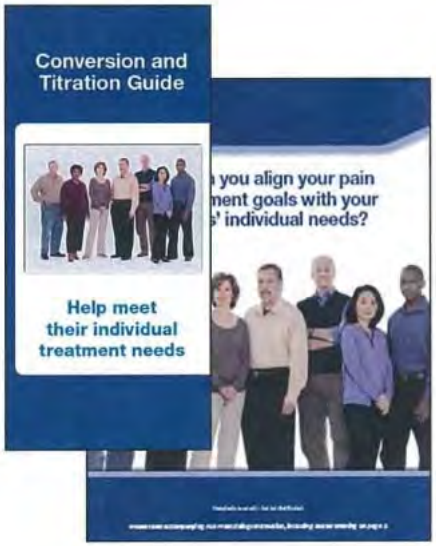
No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Improving New Patient Starts

Help HCPs identify appropriate patients for OxyContin® and how to initiate therapy

Patient Profiles:

Conversion & Titration Guide



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Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -060)

No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Encouraging Appropriate Titration of OxyContin®

S›T›A›R›T Principles:

- The objective of the **S.T.A.R.T. Principles** is to provide a suggested framework and talking points for the appropriate initiation and titration of OxyContin.
- Collectively, they are intended to highlight important elements of titration throughout the course of treatment.

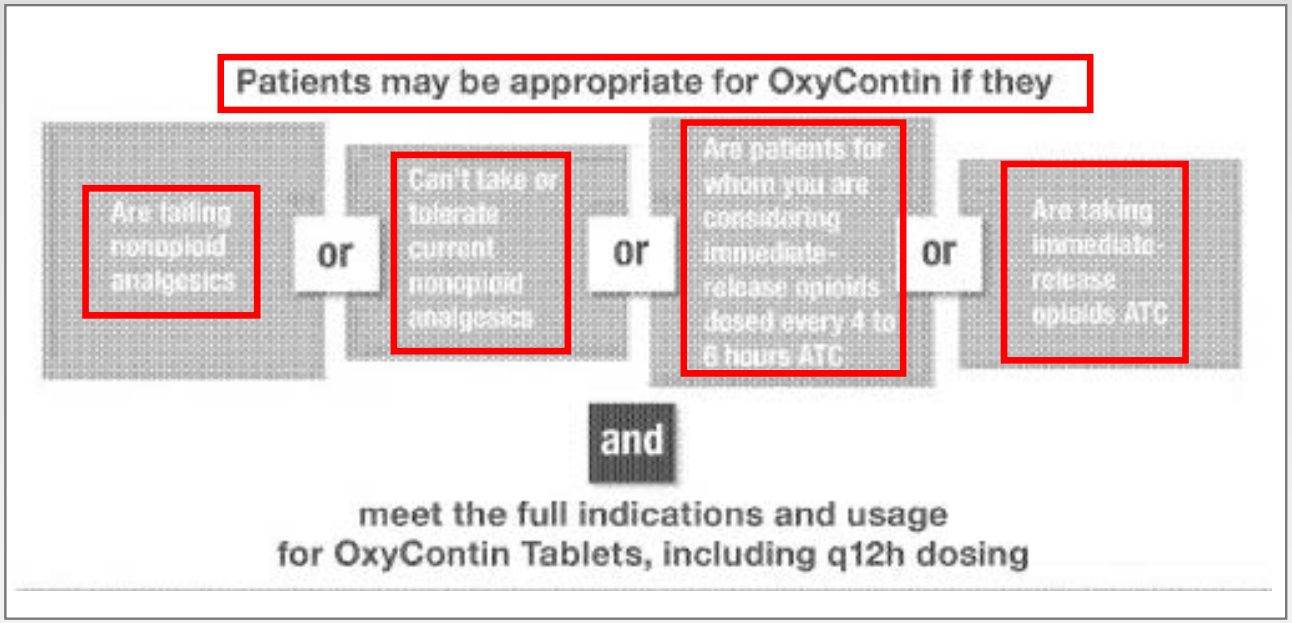
"Tailor the dose based on the reassessment, titrating up or down
- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced"

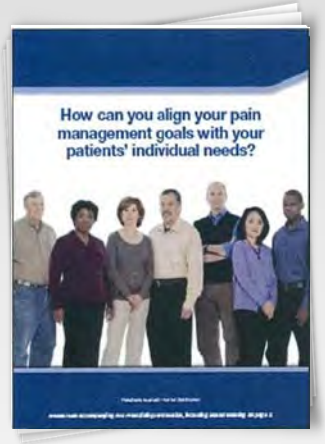
From the cited Nov. 2013 budget presentation to the Board

Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -063)

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications





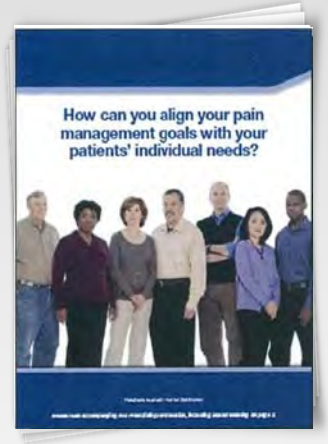
Individualize the Dose Brochure
PAZ000046439 at -442

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

To convert from other opioids to OxyContin

- **Determine** a patient's estimated 24-hour oxycodone requirement
- **Refer** to published potency data in clinical practice guidelines published by authorities in the field of pain medicine, but such ratios are approximations and there is substantial interpatient variation
- It is safer to **underestimate** a patient's 24-hour oral oxycodone requirement and provide rescue medication (e.g., immediate-release oxycodone) than to overestimate
- **Begin with half** of the estimated daily oxycodone requirement as the initial daily OxyContin estimate, then divide into two doses taken 12 hours apart
- Manage inadequate analgesia by **supplementation** with immediate-release oxycodone



Individualize the Dose Brochure
PAZ000046439 at -446

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

S T A R T

Supplement with an immediate-release analgesic, such as:

- IR oxycodone for patients being converted to OxyContin from other opioids to manage inadequate analgesia
- IR opioid or nonopioid medication for patients who experience breakthrough pain that may require rescue medication

Titrate every 1-2 days as needed

- Steady-state plasma concentrations are approximated in 1 day

Adjust the dose by 25%-50%

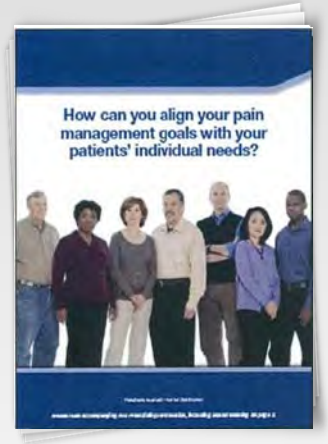
- Total daily dose usually can be increased by 25% to 50% of current dose as clinical need dictates, while maintaining q12h dosing

Reassess the patient's analgesia and tolerability throughout treatment

- If the level of pain increases, attempt to identify the source of increased pain, while adjusting the OxyContin dose

Tailor the dose based on the reassessment, titrating up or down

- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced
- Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions



Individualize the Dose Brochure

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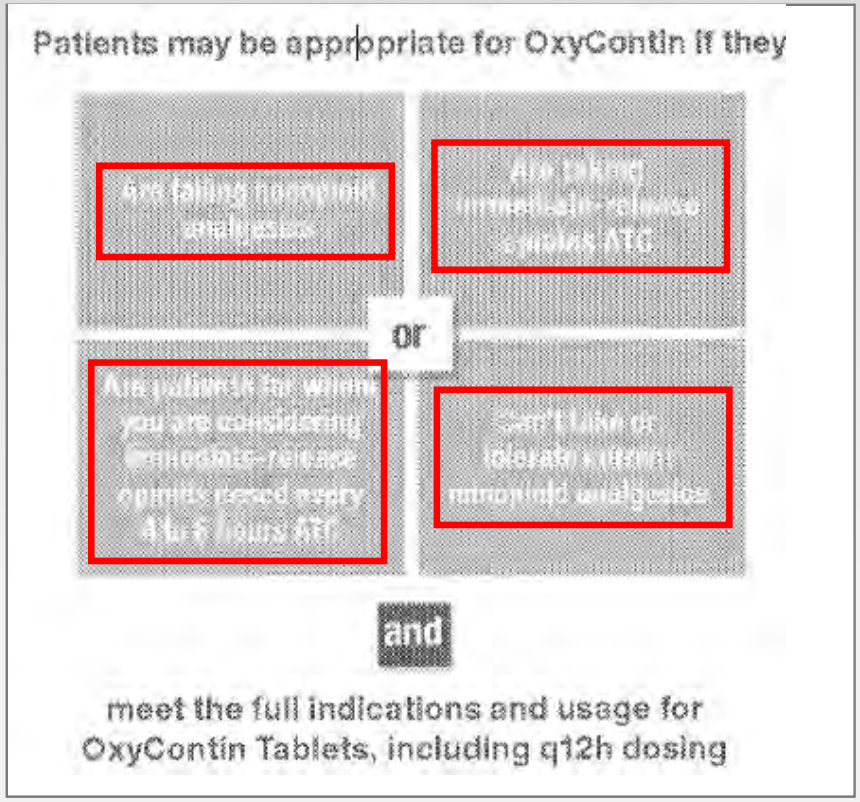
- "Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications



Conversion & Titration Guide
PAK000971874, at -879

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

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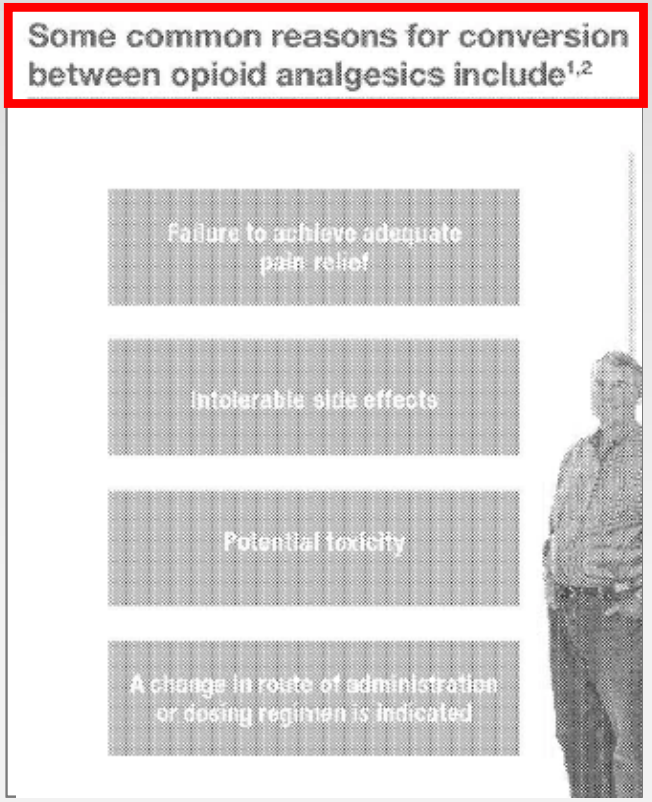


Conversion & Titration Guide
PAK000971874, at -881

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

> "**When initiating OxyContin as the first opioid analgesic** in patients taking nonopioid analgesics who require ATC [around-the-clock] therapy, OxyContin **10 mg q12h is a reasonable starting dose**"

Conversion & Titration Guide
PAK000971874 at -883

- 10 mg is the lowest dose of OxyContin on the market

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

To convert from other opioids to OxyContin

- **Determine** a patient's estimated 24-hour oxycodone requirement

***

- It is safer to **underestimate** a patient's 24-hour oral oxycodone requirement and provide rescue medication (e.g., immediate-release oxycodone) than to overestimate
- **Begin with half** the estimate daily oxycodone requirement as the initial daily dose

To convert from other oral oxycodone formulations to OxyContin, consider the following

- **Determine** the patient's total daily oral oxycodone dose
- **Administer** one-half of the patient's total daily oral oxycodone dose as OxyContin q12h

Conversion & Titration Guide
PAK000971874 at -884, -885

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

"The purpose of titration is to adjust the dose to obtain an appropriate balance between management of pain and opioid related adverse reactions"

"Titrate every 1-2 days as needed"

"Tailor the dose based on the reassessment, titrating up or down

- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced"

The purpose of titration is to adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

START

Supplement with an immediate-release analgesic, such as:

- IR oxycodone for patients being converted to OxyContin from other opioids to manage inadequate analgesia
- IR opioid or non-opioid medication for patients who experience breakthrough pain that may require rescue medication

Titrate every 1-2 days as needed

- Steady-state plasma concentrations are approximated in 1 day

Adjust the dose by 25%- 50%

- Total daily dose usually can be increased by 25% to 50% of current dose as clinical need dictates while maintaining q12h dosing

Reassess the patient's analgesia and tolerability throughout treatment

- If the level of pain increases, attempt to identify the source of increased pain, while adjusting the OxyContin dose

Tailor the dose based on the reassessment, titrating up or down

- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced
- Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions

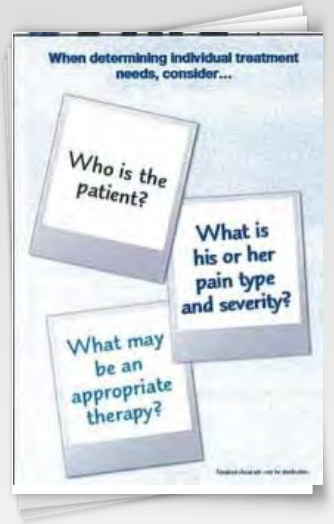
Conversion & Titration Guide
PAK000971874 at -891

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications

Patients may be appropriate for OxyContin if they

- Are failing nonopioid analgesics **or**
- Can't take or tolerate current nonopioid analgesics **or**
- Are patients for whom you are considering immediate-release opioids dosed every 4 to 6 hours ATC [around the clock] **or**
- Are taking immediate-release opioids ATC **and**
- **Meet the full indications and usage for OxyContin Tablets, including q12h dosing**



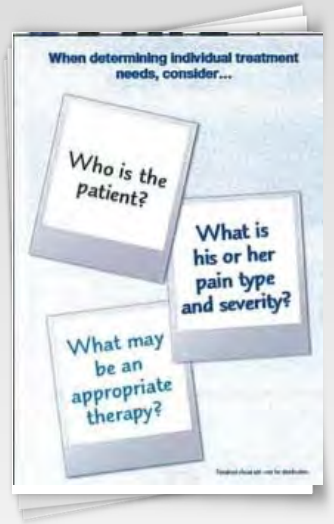
Patient Profiles
PAK000971389 at -391

No "Titration Up Marketing Campaign" Is Reflected in the Depicted Brochures — Titration Was to Go Up or Down, As Appropriate

- "Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

Sam should be started on the lowest appropriate dose and titrated as clinical need dictates

- Monitor closely for respiratory depression, especially within the first 12-72 hours of initiating therapy with OxyContin
- Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions while maintaining an every-twelve-hour dosing regimen



Patient Profiles
PAK000971389 at -392

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

The Board Was Advised That Purdue Was Vigorously Implementing Its ADD Program, Including Region Zero

- Region Zero was the name of Purdue's Do-Not-Call list

Region 0 prescribers

- Prescribers identified through Purdue's Abuse and Diversion Detection (ADD) program
  - designed to ensure that the company does not promote Purdue's products in circumstances where there is a concern about potential abuse or diversion related activities

Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion?

Purdue Presentation Sent to Board Oct. 25, 2011 (PPLPC042000024694)

- Government entities knew about the Region Zero program and required that Purdue keep it in place

Region Zero Used Objective Criteria To Identify Suspicious Prescribers

2002	– "Excessive number of patients for the practice type" – "Atypical pattern of prescribing techniques or locations" – "Information . . . that a healthcare professional or patients . . . are diverting medication" – "A prescriber writing a large number of prescriptions for patients who receive prescriptions and pay with cash" – "Sudden unexplained change in prescribing or dispensing patterns" – "Allegations that patients from a given practice have overdosed on medications" – "Allegations that prescriber, dispenser, staff or patient has or is actively abusing medications" – "Unlicensed individual is signing prescriptions or dispensing medications" – "Large number of patients who travel hundreds of miles for their prescriptions without rational explanation" – "Reports of frequent early requests for new prescriptions made long before the initial prescription would normally be completed" – "Credible allegations that a healthcare professional is under active investigation related to abuse or diversion by any law enforcement or regulatory authority" (PPLP003430434)
2003	– "A healthcare professional who moves his or her practice from one state to another on more than one occasion within a couple of years" (PDD1503493410)
2007	– "A Prescriber with an atypical patient population from that customarily observed in such an office based on this location and other attendant circumstances" (PPLP00342999)
2015	– "A Prescriber lacks understanding about the risks associated with prescribing opioids" – "Facts that suggest that the Prescriber's patients are seeking opioids for misuse and abuse, including but not limited to facts that a Prescriber has failed to comply with his or her state's prescription monitoring program" (PPLP004035073)

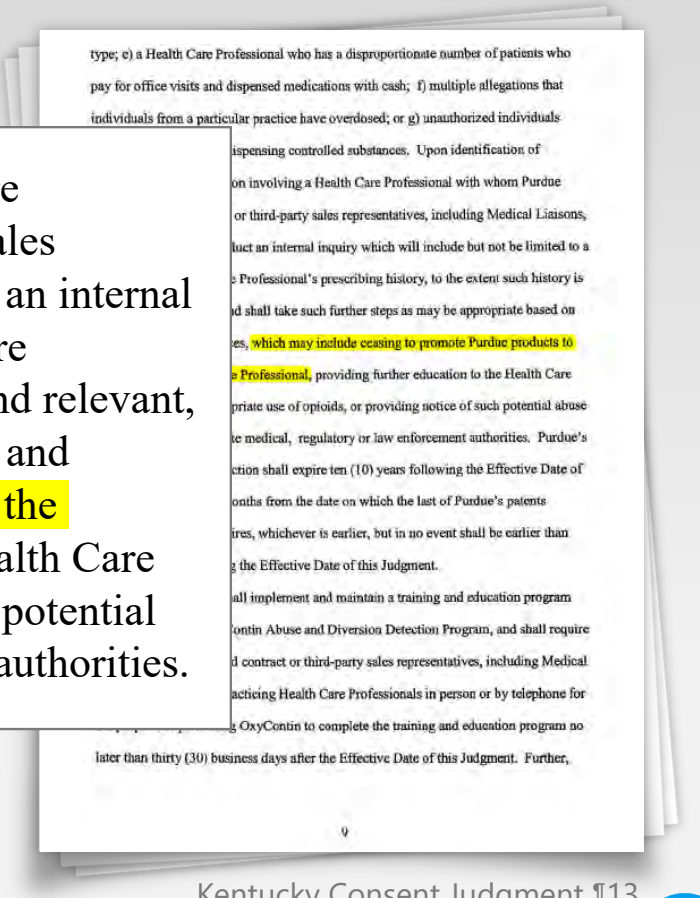
The Board Understood That Government Entities Required Purdue To Keep Region Zero In Place And Approved Purdue's Implementation Of It

- **Purdue was required to keep the Region Zero program in place for 10 years by the 2007 consent judgments** *(e.g.*, Kentucky Consent Judgment ¶13)
- **New York separately required Purdue to maintain Region Zero in 2015** (AOD)
- **An auditor approved by the New York Attorney General ("NYAG"") reviewed and endorsed Purdue's implementation of Region Zero in 3 Annual Reports** (2016 – 2018)
- **Purdue sent Annual Reports about Region Zero to the Ohio AG as designee of all Consent Judgment States**
- **On request, Purdue provided government officials with information about prescribers on its Region Zero list**

E.g., 10/10/13 Purdue Letter to Tenn. AG; 5/18/09 Purdue Letter to VA AG

Purdue Was Required To Keep the ADD Program and Region Zero In Place For 10 Years By 2007 Consent Judgments

Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees or its contract or third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history, to the extent such history is available and relevant, and shall take such further steps as may be appropriate based, on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.


type; e) a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medications with cash; f) multiple allegations that individuals from a particular practice have overdosed; or g) unauthorized individuals
ispensing controlled substances. Upon identification of
on involving a Health Care Professional with whom Purdue
or third-party sales representatives, including Medical Liaisons,
luct an internal inquiry which will include but not be limited to a
Professional's prescribing history, to the extent such history is
d shall take such further steps as may be appropriate based on
es, which may include ceasing to promote Purdue products to
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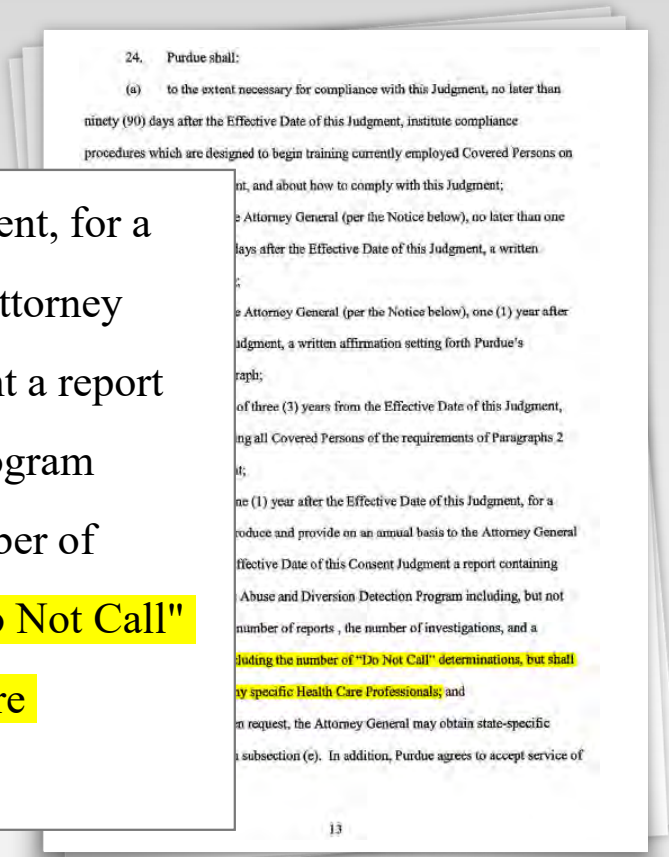
priate use of opioids, or providing notice of such potential abuse
te medical, regulatory or law enforcement authorities. Purdue's
ction shall expire ten (10) years following the Effective Date of
onths from the date on which the last of Purdue's patents
ires, whichever is earlier, but in no event shall be earlier than
the Effective Date of this Judgment.
all implement and maintain a training and education program
ontin Abuse and Diversion Detection Program, and shall require
d contract or third-party sales representatives, including Medical
acticing Health Care Professionals in person or by telephone for
OxyContin to complete the training and education program no
later than thirty (30) business days after the Effective Date of this Judgment. Further,
9

Kentucky Consent Judgment ¶13

Purdue Annually Reported About Region Zero For 3 Years, But Was Required Not To Name Any Specific HCP In The Annual Reports

(e) beginning one (1) year after the Effective Date of this Judgment, for a period of three (3) years, produce and provide on an annual basis to the Attorney General on the anniversary of the Effective Date of this Consent Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports , the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and



24. Purdue shall:

(a) to the extent necessary for compliance with this Judgment, no later than ninety (90) days after the Effective Date of this Judgment, institute compliance procedures which are designed to begin training currently employed Covered Persons on

nt, and about how to comply with this Judgment;

e Attorney General (per the Notice below), no later than one

lays after the Effective Date of this Judgment, a written

;

e Attorney General (per the Notice below), one (1) year after

udgment, a written affirmation setting forth Purdue's

raph;

of three (3) years from the Effective Date of this Judgment,

ng all Covered Persons of the requirements of Paragraphs 2

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ny specific Health Care Professionals; and

n request, the Attorney General may obtain state-specific

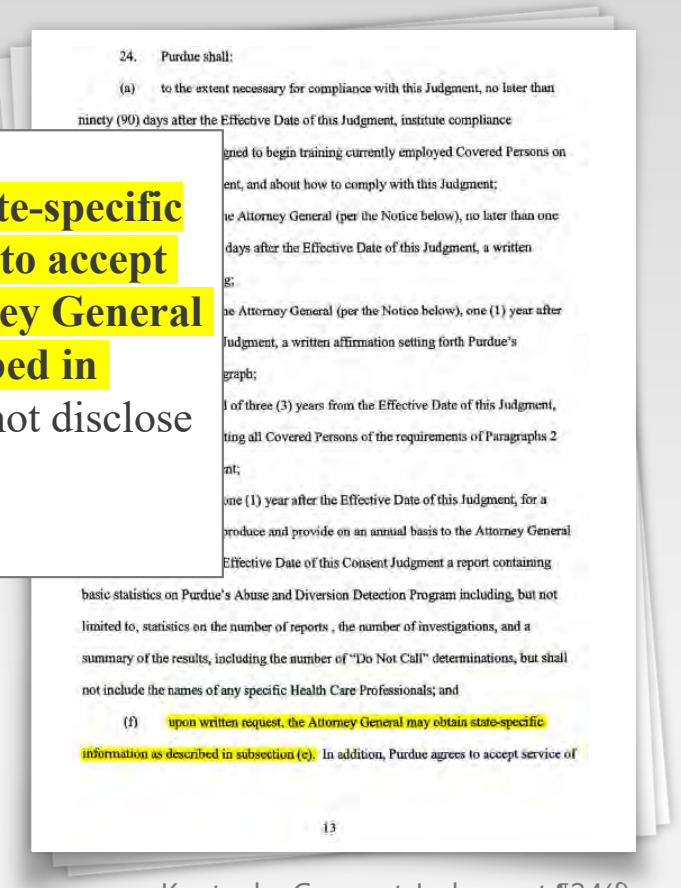
subsection (e). In addition, Purdue agrees to accept service of

13

Kentucky Consent Judgment ¶24(e)

AGs Could Request State-Specific Information And Purdue Was Required To Provide It

(f) **upon written request, the Attorney General may obtain state-specific information as described in subsection (e). In addition, Purdue agrees to accept service of a civil investigative demand or similar process by the Attorney General requesting the names of any specific Health Care Professionals described in subsection (e).** The Attorney General in receipt of such information shall not disclose it except as provided by law.



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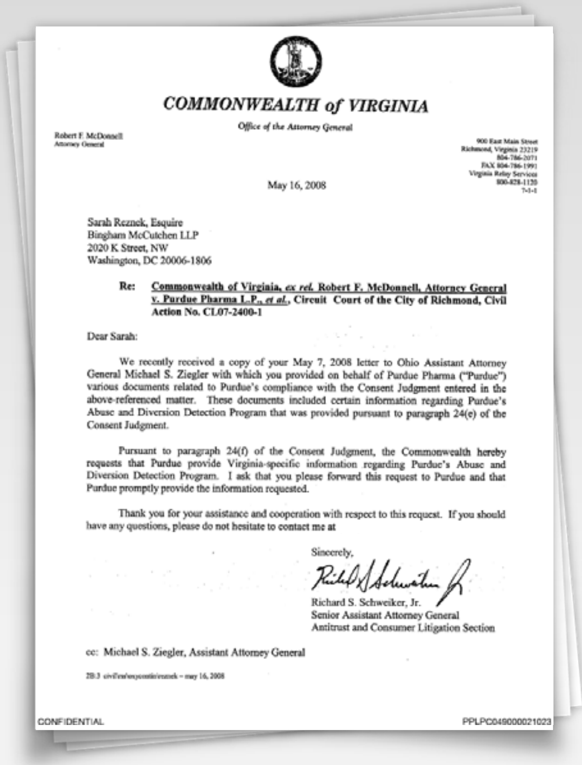
13

Kentucky Consent Judgment ¶24(f)

Purdue Provided AGs State-Specific Information On Request Per Consent Judgments



COMMONWEALTH of VIRGINIA

Office of the Attorney General

Robert F. McDonnell
Attorney General

900 East Main Street
Richmond, Virginia 23219
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800-828-1120
7-1-1

May 16, 2008

Sarah Reznek, Esquire
Bingham McCutchen LLP
2020 K Street, NW
Washington, DC 20006-1806

Re: Commonwealth of Virginia, *ex rel.* Robert F. McDonnell, Attorney General v. Purdue Pharma L.P., *et al.*, Circuit Court of the City of Richmond, Civil Action No. CL07-2400-1

Dear Sarah:

We recently received a copy of your May 7, 2008 letter to Ohio Assistant Attorney General Michael S. Ziegler with which you provided on behalf of Purdue Pharma ("Purdue") various documents related to Purdue's compliance with the Consent Judgment entered in the above-referenced matter. These documents included certain information regarding Purdue's Abuse and Diversion Detection Program that was provided pursuant to paragraph 24(e) of the Consent Judgment.

Pursuant to paragraph 24(f) of the Consent Judgment, the Commonwealth hereby requests that Purdue provide Virginia-specific information regarding Purdue's Abuse and Diversion Detection Program. I ask that you please forward this request to Purdue and that Purdue promptly provide the information requested.

Thank you for your assistance and cooperation with respect to this request. If you should have any questions, please do not hesitate to contact me at

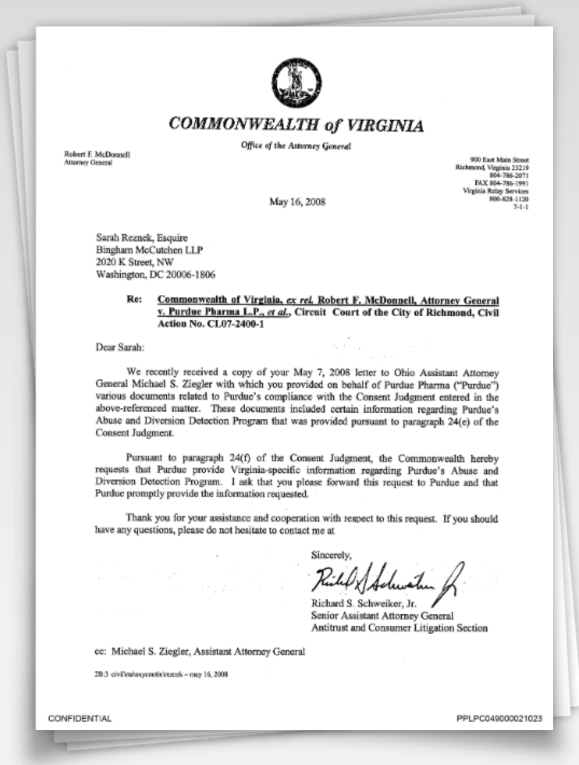
Sincerely,

Richard S. Schweiker, Jr.
Senior Assistant Attorney General
Antitrust and Consumer Litigation Section

cc: Michael S. Ziegler, Assistant Attorney General

CONFIDENTIAL PPLPC049000021023

5/16/08 Letter from Virginia to Purdue Counsel (PPLPC049000021023)



COMMONWEALTH of VIRGINIA

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May 16, 2008

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Dear Sarah:

We recently received a copy of your May 7, 2008 letter to Ohio Assistant Attorney General Michael S. Ziegler with which you provided on behalf of Purdue Pharma ("Purdue") various documents related to Purdue's compliance with the Consent Judgment entered in the above-referenced matter. These documents included certain information regarding Purdue's Abuse and Diversion Detection Program that was provided pursuant to paragraph 24(e) of the Consent Judgment.

Pursuant to paragraph 24(f) of the Consent Judgment, the Commonwealth hereby requests that Purdue provide Virginia-specific information regarding Purdue's Abuse and Diversion Detection Program. I ask that you please forward this request to Purdue and that Purdue promptly provide the information requested.

Thank you for your assistance and cooperation with respect to this request. If you should have any questions, please do not hesitate to contact me at

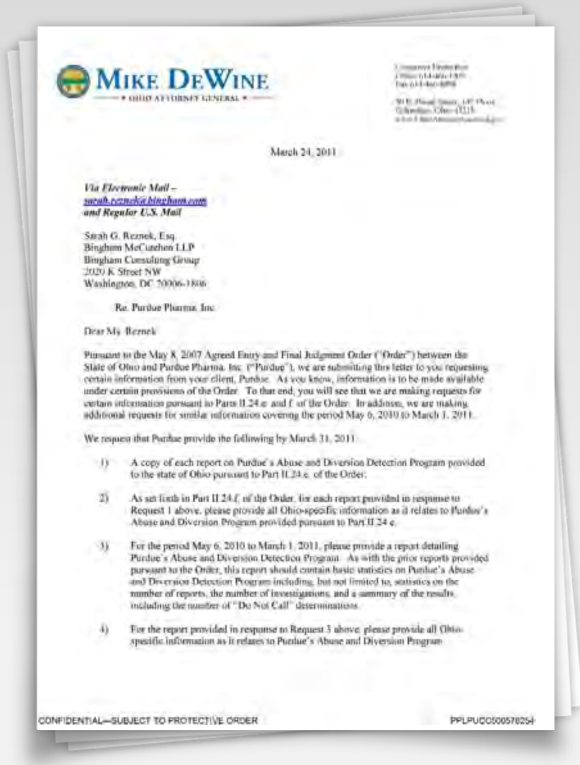
Sincerely,

Richard S. Schweiker, Jr.
Senior Assistant Attorney General
Antitrust and Consumer Litigation Section

cc: Michael S. Ziegler, Assistant Attorney General

CONFIDENTIAL PPLPC049000021023

5/13/10 Letter from Virginia to Purdue Counsel (PPLPD004671883)



MIKE DEWINE
OHIO ATTORNEY GENERAL

March 24, 2011

Via Electronic Mail –
and Regular U.S. Mail

Sarah G. Reznek, Esq.
Bingham McCutchen LLP
Bingham Consulting Group
2020 K Street NW

Re: Purdue Pharma Inc.

Dear Ms. Reznek

Pursuant to the May 8, 2007 Agreed Entry and Final Judgment Order ("Order") between the State of Ohio and Purdue Pharma, Inc. ("Purdue"), we are submitting this letter to you requesting certain information from your client, Purdue. As you know, information is to be made available under certain provisions of the Order. To that end, you will see that we are making requests for certain information pursuant to Parts II.24.e. and f. of the Order. In addition, we are making additional requests for similar information covering the period May 6, 2010 to March 1, 2011.

We request that Purdue provide the following by March 31, 2011

1) A copy of each report on Purdue's Abuse and Diversion Detection Program provided to the state of Ohio pursuant to Part II.24.e. of the Order.

2) As set forth in Part II.24.f. of the Order, for each report provided in response to Request 1 above, please provide all Ohio-specific information as it relates to Purdue's Abuse and Diversion Program provided pursuant to Part II.24.e.

3) For the period May 6, 2010 to March 1, 2011, please provide a report detailing Purdue's Abuse and Diversion Detection Program. As with the prior reports provided pursuant to the Order, this report should contain basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports, the number of investigations, and a summary of the results including the number of "Do Not Call" determinations.

4) For the report provided in response to Request 3 above, please provide all Ohio-specific information as it relates to Purdue's Abuse and Diversion Program.

CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER PPLPUCC500578254

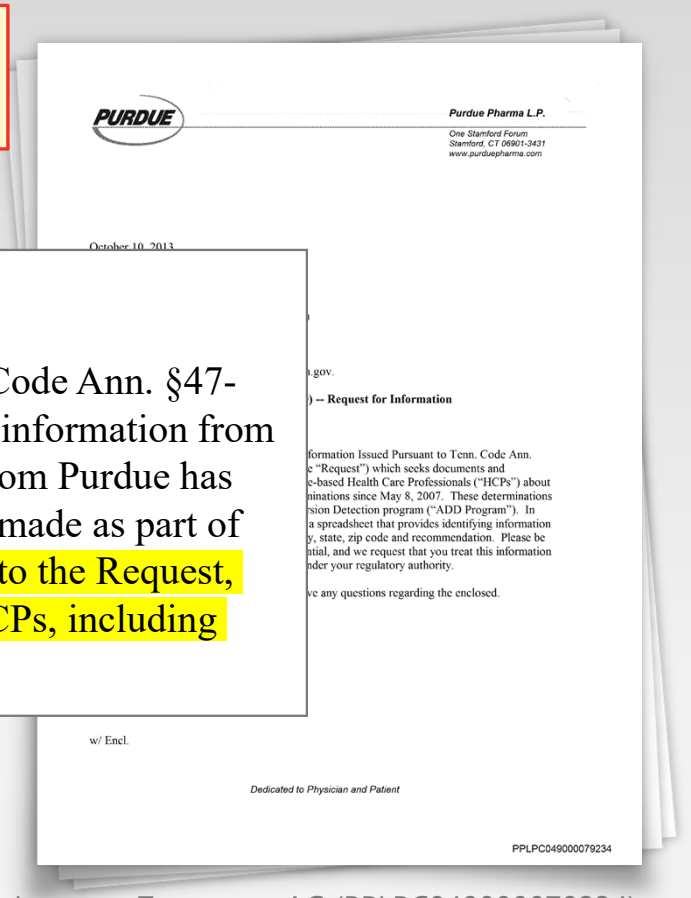
3/24/11 Letter from Ohio to Purdue Counsel (PPLPUCC500578254)

Purdue Provided AGs State-Specific Information On Request Per Consent Judgments

- In October 2013, Purdue sent the Tennessee AG's Office a list of 75 Tennessee HCPs on its "Do Not Call" list.

Dear Ms. Peacock:

I am writing in response to the Request for Information Issued Pursuant to Tenn. Code Ann. §47-18-101 et seq. dated October 8, 2013 (the "Request") which seeks documents and information from Purdue relating to Tennessee-based Health Care Professionals ("HCPs") about whom Purdue has made "Do Not Call" determinations since May 8, 2007. These determinations are made as part of Purdue's Abuse and Diversion Detection program ("ADD Program"). In response to the Request, enclosed please find a spreadsheet that provides identifying information for 75 HCPs, including first and last name, city, state, zip code and recommendation.



10/10/13 Purdue Letter to Tennessee AG (PPLPC049000079234)

Purdue Referred HCPs to the DEA

- **Between 2002 and 2018, Purdue referred 222 HCPs to the DEA**
- **In April 2011, alone, Purdue provided DEA the names of 82 Region Zero HCPs**

From: Crowley, Jack
To: Abrams, Robin
Sent: Fri Apr 29 15:02:36 2011
Subject: FW: Request for oxycodone API sample

Hello Robin:

I spoke with Barbara Boockholdt, and they loved the information (82 doctors) we referred to them.

They are now anxious to receive our pharmacy referrals. I told her that we would send them out – or at least the first batch, next week.

PPLPC053000051213

From: Crowley, Jack
Sent: Tuesday, April 12, 2011 8:31 PM
To: Rosen, Burt; Geraci, Mark; Must, Alan; Hester, Ted
Subject: FW: What happened at DEA?

We did make a referral of 82 doctors via thumb drive (Oxycontin TRx Changes May 2010-Jan2011) - this included 2 tabs one with the addresses and details hidden so they can see the summarized information and one with the addresses and details showing. Robin explained our methodology for referring these particular prescribers, and DEA received the information in a positive fashion.

PPLPC053000051213

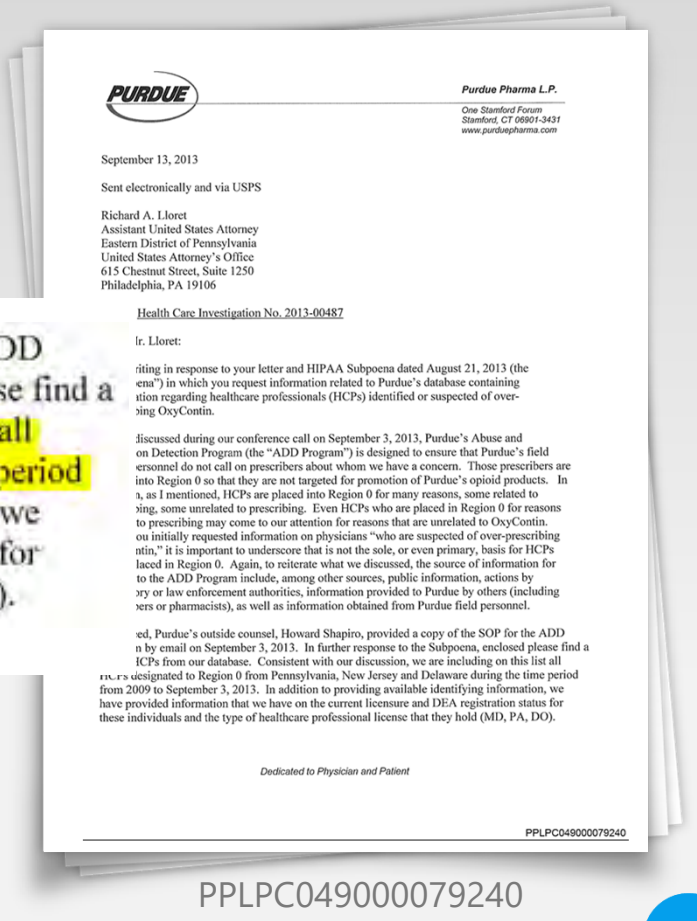
PPLPC053000051170 / PPLPC05300005121

PPLPUCC9007416689

Purdue Provided Region Zero Information to the U.S. Attorney for the Eastern District of Pennsylvania

In 2013, Purdue sent the names of Region Zero HCPs in Pennsylvania, New Jersey, and Delaware to the U.S. Attorney for the Eastern District of Pennsylvania

As agreed, Purdue's outside counsel, Howard Shapiro, provided a copy of the SOP for the ADD Program by email on September 3, 2013. In further response to the Subpoena, enclosed please find a list of HCPs from our database. Consistent with our discussion, we are including on this list all HCPs designated to Region 0 from Pennsylvania, New Jersey and Delaware during the time period from 2009 to September 3, 2013. In addition to providing available identifying information, we have provided information that we have on the current licensure and DEA registration status for these individuals and the type of healthcare professional license that they hold (MD, PA, DO).



PURDUE

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431
www.purduepharma.com

September 13, 2013

Sent electronically and via USPS

Richard A. Lloret
Assistant United States Attorney
Eastern District of Pennsylvania
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

Health Care Investigation No. 2013-00487

lr. Lloret:

riting in response to your letter and HIPAA Subpoena dated August 21, 2013 (the ena") in which you request information related to Purdue's database containing tion regarding healthcare professionals (HCPs) identified or suspected of over- bing OxyContin.

discussed during our conference call on September 3, 2013, Purdue's Abuse and on Detection Program (the "ADD Program") is designed to ensure that Purdue's field ersonnel do not call on prescribers about whom we have a concern. Those prescribers are into Region 0 so that they are not targeted for promotion of Purdue's opioid products. In n, as I mentioned, HCPs are placed into Region 0 for many reasons, some related to bing, some unrelated to prescribing. Even HCPs who are placed in Region 0 for reasons to prescribing may come to our attention for reasons that are unrelated to OxyContin. ou initially requested information on physicians "who are suspected of over-prescribing ntin," it is important to underscore that is not the sole, or even primary, basis for HCPs laced in Region 0. Again, to reiterate what we discussed, the source of information for to the ADD Program include, among other sources, public information, actions by ory or law enforcement authorities, information provided to Purdue by others (including ers or pharmacists), as well as information obtained from Purdue field personnel.

ed, Purdue's outside counsel, Howard Shapiro, provided a copy of the SOP for the ADD n by email on September 3, 2013. In further response to the Subpoena, enclosed please find a ICPs from our database. Consistent with our discussion, we are including on this list all HCPs designated to Region 0 from Pennsylvania, New Jersey and Delaware during the time period from 2009 to September 3, 2013. In addition to providing available identifying information, we have provided information that we have on the current licensure and DEA registration status for these individuals and the type of healthcare professional license that they hold (MD, PA, DO).

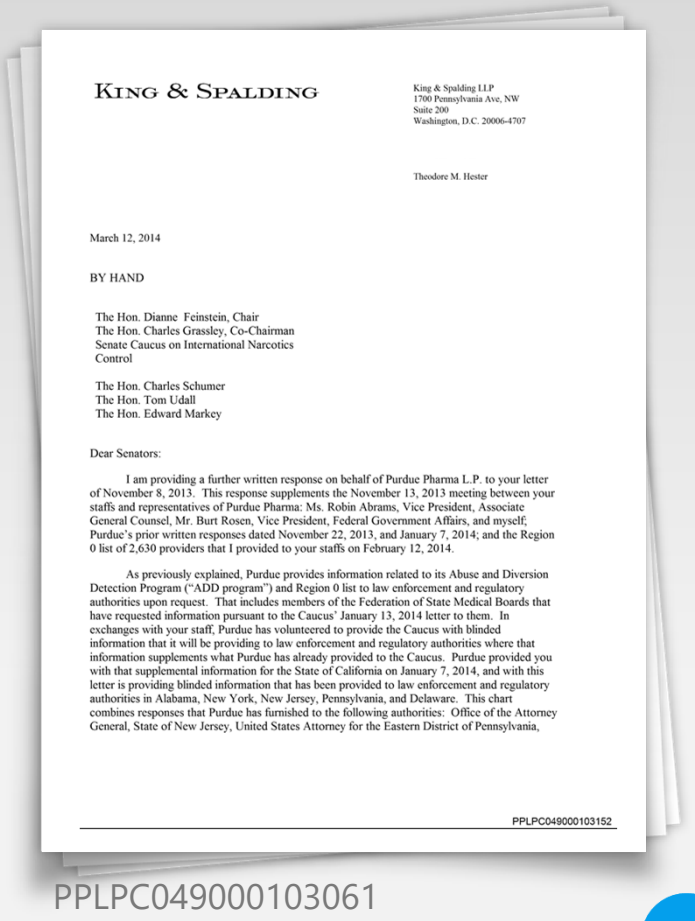
Dedicated to Physician and Patient

PPLPC049000079240

PPLPC049000079240

Purdue Provided Region Zero Information to the U.S. Senate Caucus on International Narcotics Control

As previously explained, Purdue provides information related to its Abuse and Diversion Detection Program ("ADD program") and Region 0 list to law enforcement and regulatory authorities upon request. That includes members of the Federation of State Medical Boards that have requested information pursuant to the Caucus' January 13, 2014 letter to them. In exchanges with your staff, Purdue has volunteered to provide the Caucus with blinded information that it will be providing to law enforcement and regulatory authorities where that information supplements what Purdue has already provided to the Caucus. Purdue provided you with that supplemental information for the State of California on January 7, 2014, and with this letter is providing blinded information that has been provided to law enforcement and regulatory authorities in Alabama, New York, New Jersey, Pennsylvania, and Delaware. This chart combines responses that Purdue has furnished to the following authorities: Office of the Attorney General, State of New Jersey, United States Attorney for the Eastern District of Pennsylvania,



KING & SPALDING

King & Spalding LLP
1700 Pennsylvania Ave, NW
Suite 200
Washington, D.C. 20006-4707

Theodore M. Hester

March 12, 2014

BY HAND

The Hon. Dianne Feinstein, Chair
The Hon. Charles Grassley, Co-Chairman
Senate Caucus on International Narcotics Control

The Hon. Charles Schumer
The Hon. Tom Udall
The Hon. Edward Markey

Dear Senators:

I am providing a further written response on behalf of Purdue Pharma L.P. to your letter of November 8, 2013. This response supplements the November 13, 2013 meeting between your staffs and representatives of Purdue Pharma: Ms. Robin Abrams, Vice President, Associate General Counsel, Mr. Burt Rosen, Vice President, Federal Government Affairs, and myself; Purdue's prior written responses dated November 22, 2013, and January 7, 2014; and the Region 0 list of 2,630 providers that I provided to your staffs on February 12, 2014.

As previously explained, Purdue provides information related to its Abuse and Diversion Detection Program ("ADD program") and Region 0 list to law enforcement and regulatory authorities upon request. That includes members of the Federation of State Medical Boards that have requested information pursuant to the Caucus' January 13, 2014 letter to them. In exchanges with your staff, Purdue has volunteered to provide the Caucus with blinded information that it will be providing to law enforcement and regulatory authorities where that information supplements what Purdue has already provided to the Caucus. Purdue provided you with that supplemental information for the State of California on January 7, 2014, and with this letter is providing blinded information that has been provided to law enforcement and regulatory authorities in Alabama, New York, New Jersey, Pennsylvania, and Delaware. This chart combines responses that Purdue has furnished to the following authorities: Office of the Attorney General, State of New Jersey, United States Attorney for the Eastern District of Pennsylvania,

PPLPC049000103152

PPLPC049000103061

Purdue Provided Region Zero Information To 25 Agencies 17 States

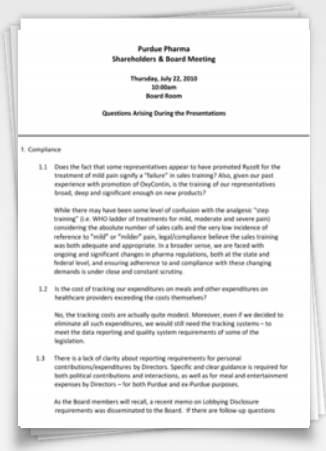
State	Agencies
Nevada	Nevada State Board of Medical Examiners (April 27, 2013), (August 11, 2015) Nevada State Board of Pharmacy (September 3, 2013) Nevada State Board of Osteopathic Medicine (September 25, 2013)
California	Medical Board of California (September 11, 2013), (September 25, 2013) Dental Board of California (September 12, 2013) Board of Registered Nursing of California (September 25, 2013) Osteopathic Medical Board of California (September 25, 2013) Physician Assistant Board of California (September 26, 2013) Board of Podiatric Medicine of California (September 26, 2013)
Tennessee	Office of Tennessee Attorney General (October 15, 2013)
New Jersey	Office of the Attorney General (November 8, 2013)
Illinois	Illinois Department of Financial and Professional Regulation (February 12, 2014)
Virginia	Virginia Department of Health Professions (February 19, 2014)
Wisconsin	Wisconsin Department of Safety and Professional Services (February 25, 2014), (April 28, 2014)

State	Agencies
Wyoming	Wyoming Board of Medicine (February 26, 2014)
Georgia	Georgia Composite Medical Board (February 27, 2014)
West Virginia	West Virginia Board of Medicine (February 27, 2014) West Virginia Board of Osteopathic Medicine (February 27, 2014)
Arizona	AZ Board of Osteopathic Examiners in Medicine and Surgery (February 28, 2014)
Pennsylvania	Pennsylvania Department of State, Bureau of Professional and Occupational Affairs (February 28, 2014)
Kansas	Kansas State Board of Healing Arts (March 4, 2014)
North Dakota	ND State Board of Medical Examiners (March 7, 2014)
Alabama	Alabama State Board of Medical Examiners (March 11, 2014)
Rhode Island	Board of Medical Licensure & Discipline, State of Rhode Island Department of Health (March 11, 2014)
Oregon	Oregon Medical Board (May 20, 2014)

PPLPC049000076533; PPLPC049000079271; PPLPC049000079268; PPLPC05100189775; PPLP004437593; PPLP004437542; PPLPC05100018973; PPLPC051000189745; PPLPUCC9011507902; PPLP004438085; PPLP004437814; PPLP004437654; PPLP004438105; PPLP004438118; PPLP004438157; PPLP004437620; PPLP004438134; PPLP004438138; PPLP004437482; PPLP004437994; PPLP004437673; PPLP004437795; PPLP004437472; PPLP004438019; PPLP004438113; PPLPUCC9011455002; PPLPUCC9011507906; PPLPC049000103152; PPLPUCC9011507904; PPLPUCC9011512808; PPLPC019000877747

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **DOJ alleges that:** "In or around August 2010, the Named Sacklers, received a Board package that included Region Zero sales data, including the names of Region Zero prescribers" (Addendum A ¶61)
- **Nothing in the Board package invited Board input in Region Zero determinations**
- **The Board package was sent in response to Board questions responsibly monitoring anti-diversion activities** *("Do we track IMS scripts for region '0'? What is the rate of 'no call' MD's and if rising, what is the driver?")*
- **The first part of the Board package was a memo answering the Board's questions and describing the robust steps Purdue was taking to identify suspect prescribers** (PPLPC012000283163)
- **The second part was a spreadsheet listing Region Zero prescribers giving the Board a snapshot of Region Zero** (PPLPC012000283169-70)
- **Nothing in the package raised concerns or invited action**


Purdue Pharma
Shareholders & Board Meeting
Thursday, July 22, 2010
10:00am
Board Room
Questions Arising During the Presentations
1. Compliance
1.1 Does the fact that some representatives appear to have promoted Butrans for the treatment of mild pain signify a "failure" in sales training? Also, given our past experience with promotion of OxyContin, is the training of our representatives broad, deep and significant enough on new products?
While there may have been some level of confusion with the analgesic "step training" (i.e. WHO ladder of treatments for mild, moderate and severe pain) considering the absolute number of sales calls and the very low incidence of reference to "mild" or "milder" pain, legal/compliance believe the sales training was both adequate and appropriate. In a broader sense, we are faced with ongoing and significant changes in pharma regulations, both at the state and federal level, and ensuring adherence to and compliance with these changing demands is under close and constant scrutiny.
1.2 Is the cost of tracking our expenditures on meals and other expenditures on healthcare providers exceeding the costs themselves?
No, the tracking costs are actually quite modest. Moreover, even if we decided to eliminate all such expenditures, we would still need the tracking systems – to meet the data reporting and quality system requirements of some of the legislation.
1.3 There is a lack of clarity about reporting requirements for personal contributions/expenditures by Directors. Specific and clear guidance is required for both political contributions and interactions, as well as for meal and entertainment expenses by Directors – for both Purdue and ex-Purdue purposes.
As the Board members will recall, a recent memo on Lobbying Disclosure requirements was disseminated to the Board. If there are follow-up questions

PPLPC012000283163

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **DOJ alleges that:** "Purdue had detailed information (down to the number of prescriptions written, product, and dosage) of Purdue products prescribed by Region Zero doctors and knew that Purdue had been making a considerable profit from these prescriptions." (Addendum A ¶59)
- **The Board never saw any of this information apart from the snapshot it received in August 2010**
- **Purdue could not stop Region Zero doctors from prescribing OxyContin**
- **The Board was not consulted on Region Zero determinations**
- **DOJ admits that:** "After prescribers were referred to ADD, an ADD review team comprised of Purdue employees reviewed information concerning the prescribers to determine whether Purdue should continue to market its opioids to them. The Named Sacklers did not sit on the ADD review team." (Addendum A ¶123)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **DOJ alleges that** "the Named Sacklers knew, or should have known, that abuse and diversion appeared concentrated among a cohort of high-volume prescribers" (Addendum A ¶71)
- **The 2011 presentation that DOJ cites for this:**
  - **Nowhere suggests that this is a continuing issue**
  - **Reports that 1900 prescribers have been placed in Region Zero**
  - **Shows that the abuse-deterrent formulation succeeded in reducing prescriptions by Region Zero prescribers**
  - **Stresses that the ADD Program is "[d]esigned to ensure that the company <u>does not promote</u> Purdue's products … where there is a concern about potential abuse or diversion"** (Addendum A ¶70; PURDUE-COR-00032186 (emphasis in original))

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **DOJ alleges:**

"126. Purdue sales representatives were trained to report prescribers suspected of abuse and diversion to ADD, and some sales representatives did so. However, many high-volume prescribers, despite having indicia of abuse and diversion, were not reported. Further, even after they were reported to ADD, Purdue continued to detail and generate prescriptions from high volume prescribers that were prescribing opioids that were not for a medically accepted indication; were unsafe, ineffective, and medically unnecessary; and that were often diverted for uses that lacked a legitimate medical purpose. The following are two examples of high-volume prescribers that Purdue detailed during E2E." (Addendum A ¶126)

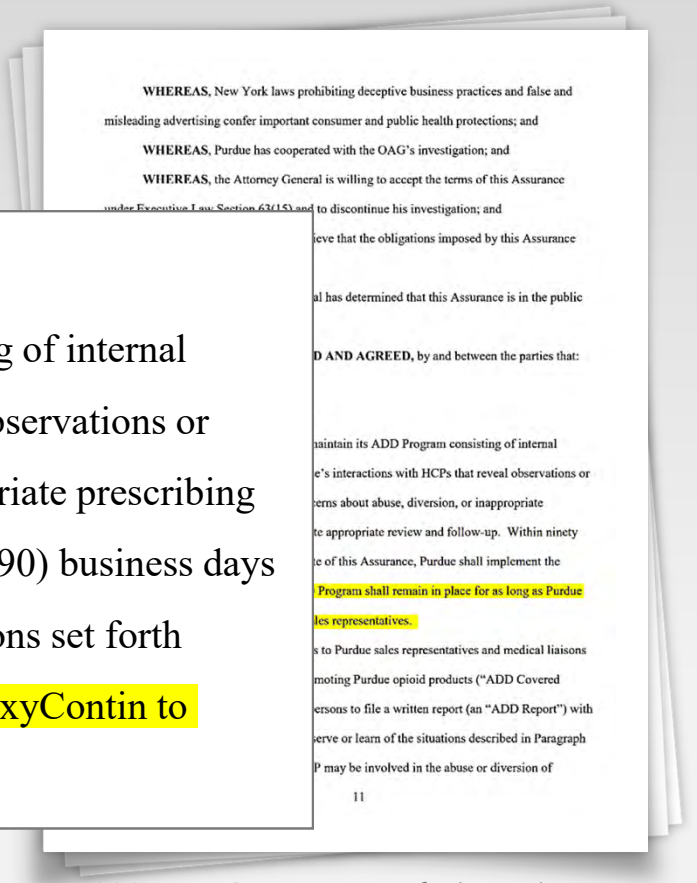
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **There is no evidence that any of this information was ever presented to the Board**
- The Directors were not provided data as to specific prescribers that were suggested for review, were under review, or should be under review — or what prescriptions any of them wrote
- DOJ admits the Directors did not sit on the ADD review team that received prescriber-specific information and decided whether to continue to place them in Region Zero (Addendum A ¶123)
- The Directors understood that Purdue conscientiously implemented the ADD Program, and this was confirmed by an auditor approved by the New York Attorney General

NYAG Investigated Purdue from 2013-15, Settled for $75,000 and Required That Purdue Maintain the ADD Program and Region Zero

A. Maintenance of ADD Program

28. Purdue shall continue to maintain its ADD Program consisting of internal procedures designed to ensure that Purdue's interactions with HCPs that reveal observations or circumstances that suggest potential concerns about abuse, diversion, or inappropriate prescribing of opioid medications generate appropriate review and follow-up. Within ninety (90) business days after the Effective Date of this Assurance, Purdue shall implement the modifications set forth below. The ADD Program shall remain in place for as long as Purdue promotes OxyContin to HCPs through sales representatives.


WHEREAS, New York laws prohibiting deceptive business practices and false and misleading advertising confer important consumer and public health protections; and

WHEREAS, Purdue has cooperated with the OAG's investigation; and

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; and

ieve that the obligations imposed by this Assurance

al has determined that this Assurance is in the public

D AND AGREED, by and between the parties that:

aintain its ADD Program consisting of internal
e's interactions with HCPs that reveal observations or
erns about abuse, diversion, or inappropriate
te appropriate review and follow-up. Within ninety
e of this Assurance, Purdue shall implement the
Program shall remain in place for as long as Purdue
les representatives.
s to Purdue sales representatives and medical liaisons
moting Purdue opioid products ("ADD Covered
ersons to file a written report (an "ADD Report") with
erve or learn of the situations described in Paragraph
P may be involved in the abuse or diversion of

11

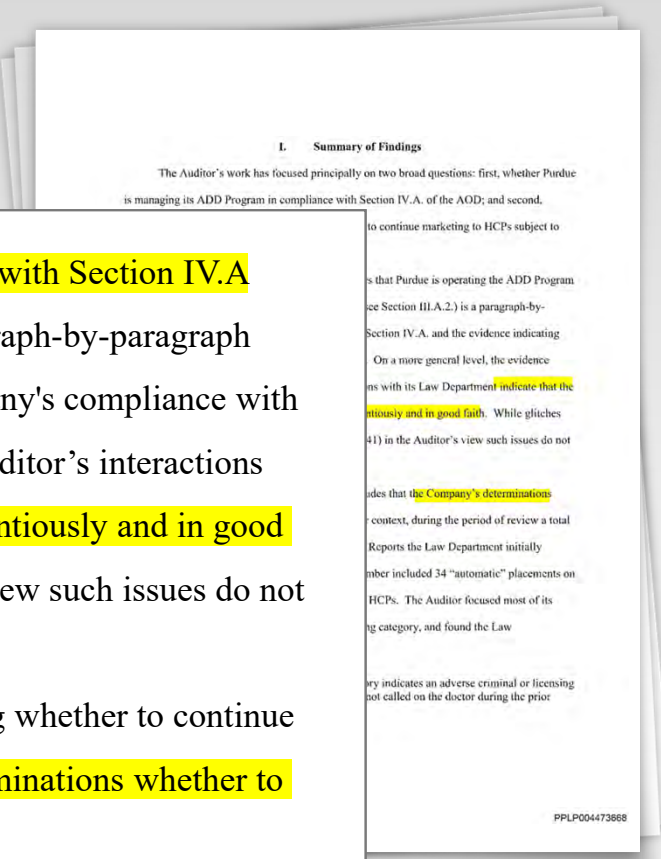
2015 NYAG Assurance of Discontinuance

An Auditor Approved by NYAG Endorsed Purdue's Implementation of Region Zero in 2016, 2017 and 2018

- Purdue acted "conscientiously and in good faith"
- Its "determinations whether to continue marketing were reasonable"

[T]he Auditor concludes that Purdue is operating the ADD Program in compliance with Section IV.A [which sets for ADD Program requirements]. Set forth below (see Section III.A.2.) is a paragraph-by-paragraph description of the requirements posed by Section IV.A. and the evidence indicating the Company's compliance with those requirements. On a more general level, the evidence reviewed by the Auditor and the Auditor's interactions with its Law Department indicate that the Company is approaching the ADD Program conscientiously and in good faith. While glitches have occurred (see for example discussion below at 4) in the Auditor's view such issues do not result from a lack of commitment to the Program.

As to the second question [the reasonableness of Purdue's determinations regarding whether to continue marketing to HCPs subject to ADD Reports], the Auditor concludes that the Company's determinations whether to continue marketing were reasonable.


I. Summary of Findings

The Auditor's work has focused principally on two broad questions: first, whether Purdue is managing its ADD Program in compliance with Section IV.A. of the AOD; and second, to continue marketing to HCPs subject to

s that Purdue is operating the ADD Program
ee Section III.A.2.) is a paragraph-by-
Section IV.A. and the evidence indicating
On a more general level, the evidence
ns with its Law Department indicate that the
ntiously and in good faith. While glitches
41) in the Auditor's view such issues do not

ades that the Company's determinations
context, during the period of review a total
Reports the Law Department initially
mber included 34 "automatic" placements on
HCPs. The Auditor focused most of its
g category, and found the Law

ory indicates an adverse criminal or licensing
not called on the doctor during the prior

PPLP004473668

(2016 Auditor's Rept: PPLP004473667)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **The Board relied on management reports that Purdue was vigorously implementing the ADD Program**

ADD Program

- Based on SOP developed in 2002
- Identifies criteria that require field-based personnel to report certain circumstances to Law Department (i.e., aberrant prescribing, long lines of patients, high cash pay patients, out of state patients)
- More than 3200 inquiries conducted since 2002
- If determine sales force shall not promote Purdue products to particular prescriber, put in Region 0
- Approximately 1900 prescribers in Region 0

Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion?

Oct. 25, 2011 Presentation (PPLPC042000024694)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- The Board relied on District Managers' monitoring of sales rep adherence to the ADD Program and management's review of the District Managers' reports
- District Managers personally observed each sales rep's interactions with prescribers several days each year to ensure sales rep compliance with Purdue policies, and reported on:

  (i) sales reps' knowledge of indicators of diversion set forth in the ADD Program and

  (ii) sales reps' filing Reports of Concern and ADD Reports

  7/30/09 Period 2 IRO Rept. on Systems Engagement at PPLP004433834-38; 9/25/09 2nd Ann. Purdue Rept. to OIG w/exhibits at PDF p. 323 of 627; PPLP03342689, PPLP003430131, PPLP003578717; PPLP004434750-51

- District Managers documented their observations in Field Contact Reports *(Id.)*

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Compliance Section of PMP Forms

Compliance to Policies and Procedures		For OIG Demonstration only
Legal Guidelines for Product Promotion	5	For OIG Demonstration only
Healthcare Law Compliance (HCLC) Policies	5	For OIG Demonstration only
Code of Business Ethics	5	For OIG Demonstration only
Indicators of Possible Diversion	5	For OIG Demonstration only
Expense Reporting/Attribution	5	For OIG Demonstration only
Call Reporting	1	For OIG Demonstration only
AE Reporting/Product Complaints	5	For OIG Demonstration only
Reports Of Concern (ROCs)	5	For OIG Demonstration only
Sampling (PDMA)	5	For OIG Demonstration only
Professional Conduct	5	For OIG Demonstration only
Requests for Off-Label Information	5	For OIG Demonstration only
Grants	5	For OIG Demonstration only

Compliance Section of Field Contact Reports


Corporate Compliance Quarterly Report to Board of Directors 3Q10

November 3, 2010
Bert Weinstein
Vice President, Corporate Compliance

3Q 2010 Quarterly Compliance Report at PPLP004405484

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

CIA- Sales Promotion Monitoring – 2Q10

Purdue's CIA requires Corporate Compliance to review Field Contact Reports (FCRs) with a compliance category rating of "1," indicating less than 100% compliance with Sales SOPs

- 637 FCRs were prepared during 2Q10
  - 73 FCRs had a Compliance Rating of "1" – 18 required Compliance investigation; 17 resulted in discipline
    - 13 representatives recorded call note(s) that: contained language which was unclear about indication or proper use of Ryzolt; did not clearly show they corrected a Health Care Provider's misconception about Ryzolt's Indication; or contained a concerning "Next Call Objective"
    - 1 new representative terminated for multiple violations, including, poor overall performance, failure to perform administrative tasks, and compliance-related activities
    - 3 representatives in possession of discontinued materials

PURDUE

4

Management Review of Field Contact Reports As Reported To The Board


Corporate Compliance
Quarterly Report to
Board of Directors
2Q10

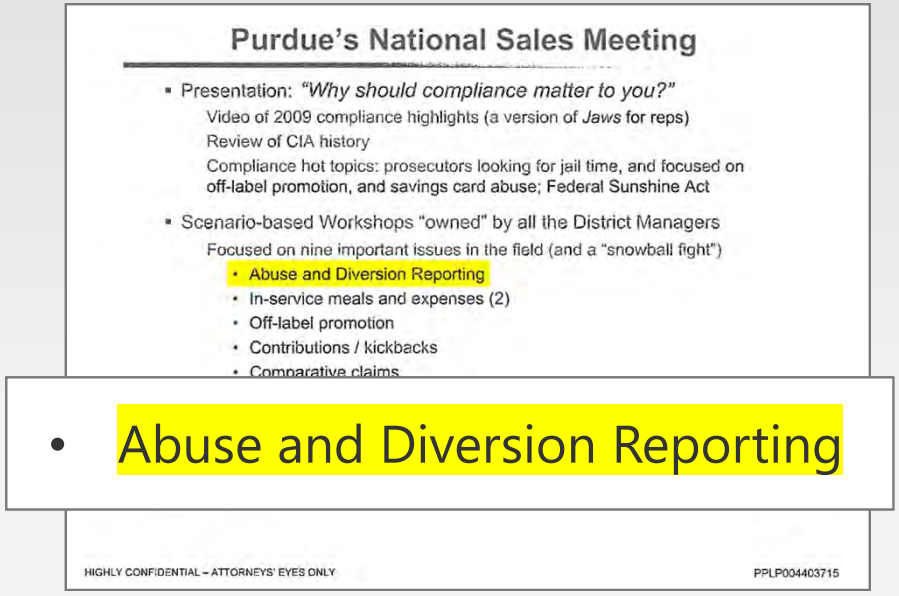
July 22, 2010
Bert Weinstein
Vice President, Corporate Compliance

PURDUE

2Q 2010 Quarterly Compliance Report at PPLP004404554

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- **Management regularly reported that Sales Reps and District Managers were trained on the ADD Program**



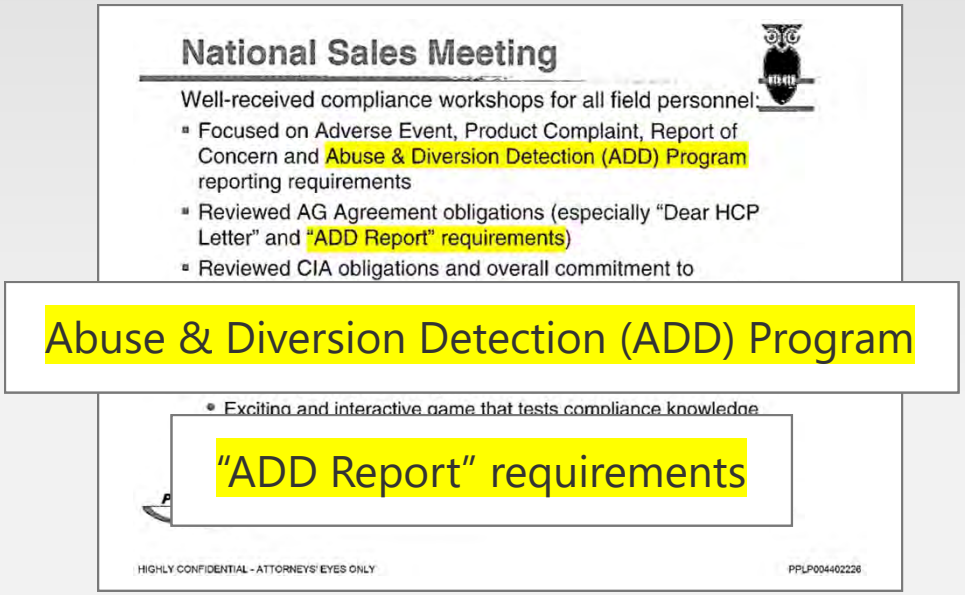
Purdue's National Sales Meeting

- Presentation: *"Why should compliance matter to you?"*
  - Video of 2009 compliance highlights (a version of *Jaws* for reps)
  - Review of CIA history
  - Compliance hot topics: prosecutors looking for jail time, and focused on off-label promotion, and savings card abuse; Federal Sunshine Act
- Scenario-based Workshops "owned" by all the District Managers
  - Focused on nine important issues in the field (and a "snowball fight")
    - Abuse and Diversion Reporting
    - In-service meals and expenses (2)
    - Off-label promotion
    - Contributions / kickbacks
    - Comparative claims

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004403715

- Abuse and Diversion Reporting

Q4 2009 Quarterly Compliance Report at 9 (PPLP004403661)



National Sales Meeting

Well-received compliance workshops for all field personnel:

- Focused on Adverse Event, Product Complaint, Report of Concern and Abuse & Diversion Detection (ADD) Program reporting requirements
- Reviewed AG Agreement obligations (especially "Dear HCP Letter" and "ADD Report" requirements)
- Reviewed CIA obligations and overall commitment to
- Exciting and interactive game that tests compliance knowledge

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY PPLP004402226

Abuse & Diversion Detection (ADD) Program

"ADD Report" requirements

4Q 2008 Quarterly Compliance Report at 22 (PPLP004402205)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Sept. 23, 2010 Board Report:

Office of the General Counsel

- Serve as an affiant/deponent in various legal actions
  - Defended our opioid-agonist/sequestered-antagonist patents in deposition
  - Identified and assisted with retention of expert witnesses
- Invited to consult with Order Monitoring System Committee
  - Now a member of the committee.
  - Assist with policy development and implementation (eg, the new DEA requirements regarding response to "suspicious orders")
- Collaborating with Robin Abrams and Risk Management & Epidemiology
  - Developing model to attempt identification of suspicious prescribing patterns that warrant further investigation (Polaris/Principled Strategies/Wolters Kluwer)

Sept. 23, 2010 Board Slides at 59 (PWG004349936)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

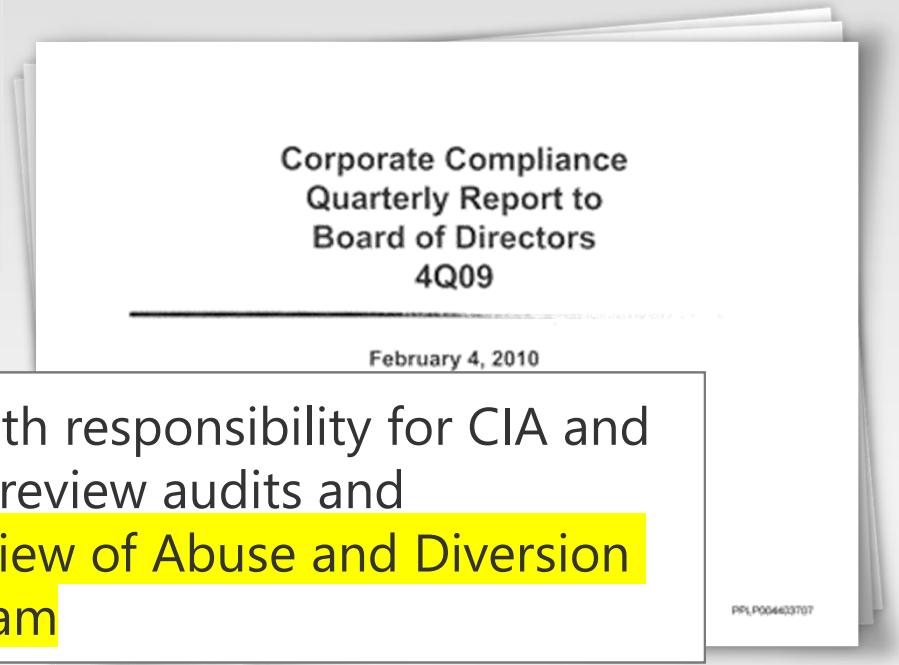
- The Board was advised that Purdue's Compliance Council reviewed the ADD Program

Major Compliance Oversight Activities

- Compliance Council – senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality program
- Reportable Events Committee – senior medical, Legal, regulatory and compliance execs meet monthly- review all pending compliance and other matters
- Sales and Marketing Compliance Committee – senior Sales and Marketing and Compliance execs meet every six weeks
- Sales Discipline Committee – Sales, Legal, HR and Compliance

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004403724

- Compliance Council – senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality Program


Corporate Compliance
Quarterly Report to
Board of Directors
4Q09

February 4, 2010

4Q 2009 Quarterly Compliance Report (PPLP004403661)

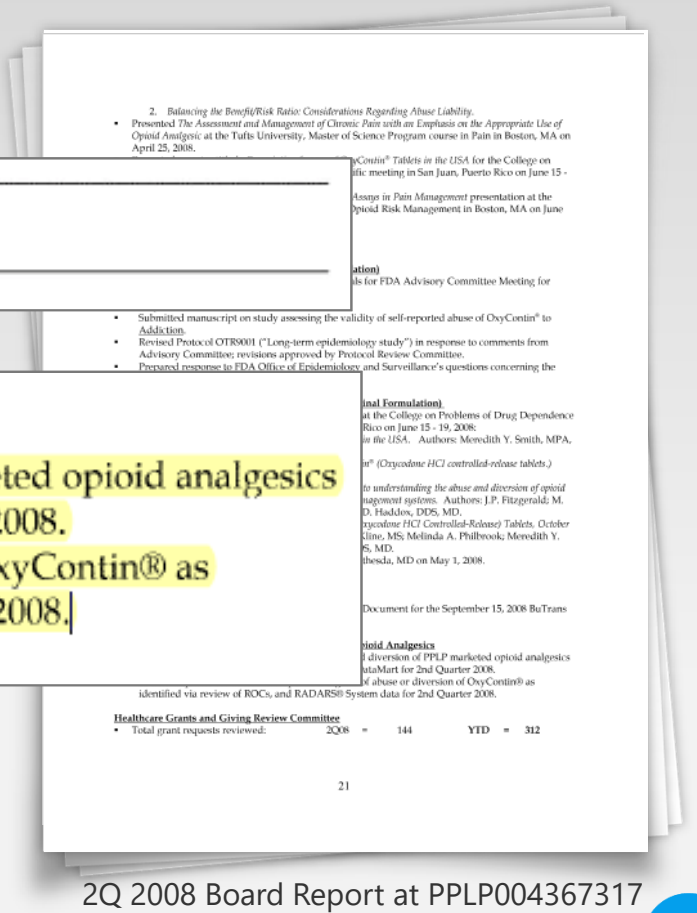
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- The Board was advised that Purdue's Risk Management Department was monitoring Diversion

RISK MANAGEMENT & HEALTH POLICY

Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics

- 890 Repots of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics reviewed and entered into the Risk Management DataMart for 2nd Quarter 2008.
- 25 field inquiries conducted in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data for 2nd Quarter 2008.



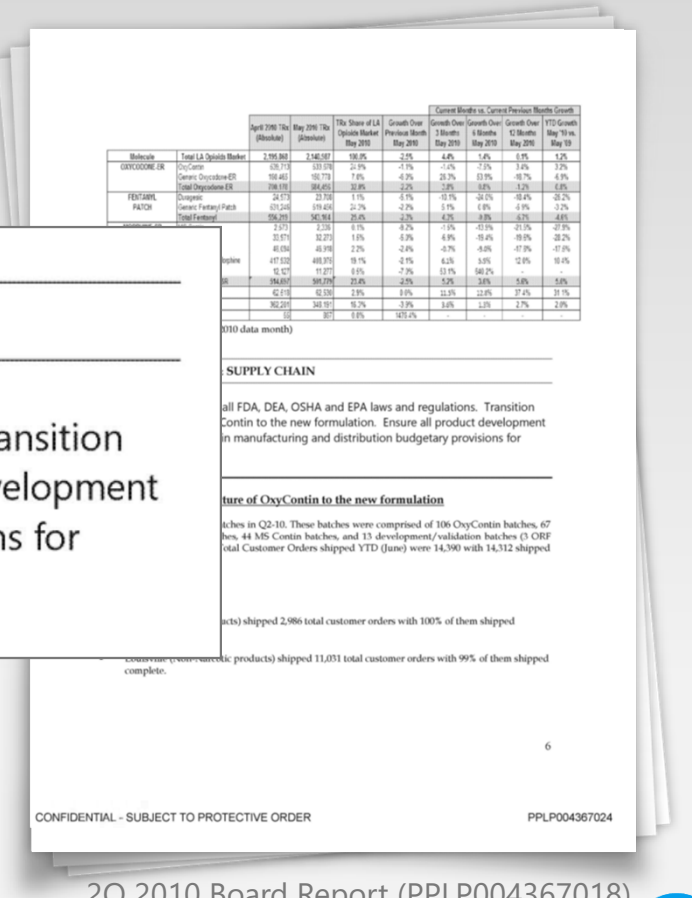
2Q 2008 Board Report at PPLP004367317

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- The Board was advised that Purdue's Manufacturing & Supply Chain Department was ensuring compliance with DEA requirements

MANUFACTURING & SUPPLY CHAIN

Assure compliance with all FDA, DEA, OSHA and EPA laws and regulations. Transition the manufacture of OxyContin to the new formulation. Ensure all product development targets are met. Maintain manufacturing and distribution budgetary provisions for 2010.



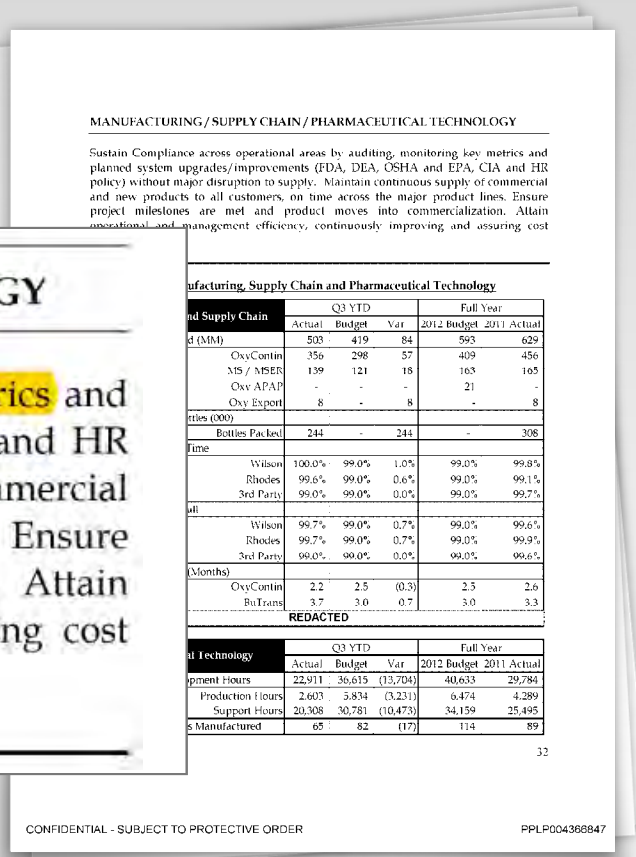
2Q 2010 Board Report (PPLP004367018)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

- The Board was advised that Purdue's Manufacturing, Supply Chain and Pharmaceutical Technology Dept. monitored compliance across all operational areas

MANUFACTURING / SUPPLY CHAIN / PHARMACEUTICAL TECHNOLOGY

Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major product lines. Ensure project milestones are met and product moves into commercialization. Attain operational and management efficiency, continuously improving and assuring cost effectiveness.



MANUFACTURING / SUPPLY CHAIN / PHARMACEUTICAL TECHNOLOGY

Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major product lines. Ensure project milestones are met and product moves into commercialization. Attain operational and management efficiency, continuously improving and assuring cost

ufacturing, Supply Chain and Pharmaceutical Technology

nd Supply Chain	Q3 YTD Actual	Q3 YTD Budget	Q3 YTD Var	Full Year 2012 Budget	Full Year 2011 Actual
d (MM)	503	419	84	593	629
OxyContin	356	298	57	409	456
MS / MSER	139	121	18	163	165
Oxy APAP	-	-	-	21	-
Oxy Export	8	-	8	-	8
ttles (000)					
Bottles Packed	244	-	244	-	308
Time					
Wilson	100.0%	99.0%	1.0%	99.0%	99.8%
Rhodes	99.6%	99.0%	0.6%	99.0%	99.1%
3rd Party	99.0%	99.0%	0.0%	99.0%	99.7%
ull					
Wilson	99.7%	99.0%	0.7%	99.0%	99.6%
Rhodes	99.7%	99.0%	0.7%	99.0%	99.9%
3rd Party	99.0%	99.0%	0.0%	99.0%	99.6%
(Months)					
OxyContin	2.2	2.5	(0.3)	2.5	2.6
BuTrans	3.7	3.0	0.7	3.0	3.3

REDACTED

l Technology	Q3 YTD Actual	Q3 YTD Budget	Q3 YTD Var	Full Year 2012 Budget	Full Year 2011 Actual
pment Hours	22,911	36,615	(13,704)	40,633	29,784
Production Hours	2,603	5,834	(3,231)	6,474	4,289
Support Hours	20,308	30,781	(10,473)	34,159	25,495
s Manufactured	65	82	(17)	114	89

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004366847

3Q 2012 Board Report at PPLP004366847

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Hotline and Other Inquires Q2 2007

- We handled a total of 101 inquiries in Q2 2007, of which 17 had compliance implications:
  - 3 Policy Matters – e.g., expensing gift to MD: insider trading
  - 11 Sales & Marketing Matters – e.g., gifts/meals to HCPs; competitor's promotional activities; alleged representative misconduct; AE reporting
  - 2 Abuse, Diversion Matters – e.g., sales representative reports pursuant to RSOP 1.7.1
  - 1 Other Matter – e.g., grant request issues
  - Note: Call Log maintained; available for review

PURDUE

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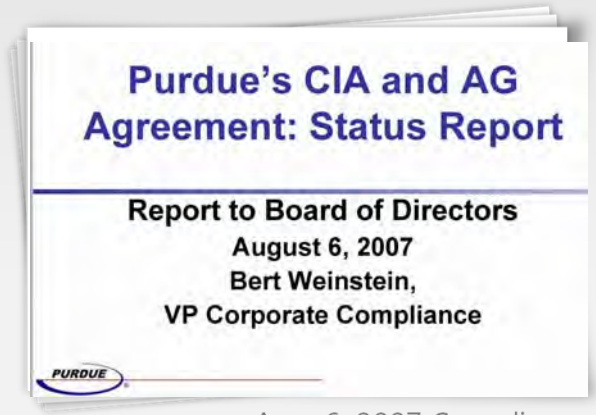

Aug. 6, 2007 Compliance Report at PLP004399968

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Q2 2007 Compliance Inquiries

2007 Distribution of Inquiries

PURDUE

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Purdue's CIA and AG Agreement: Status Report

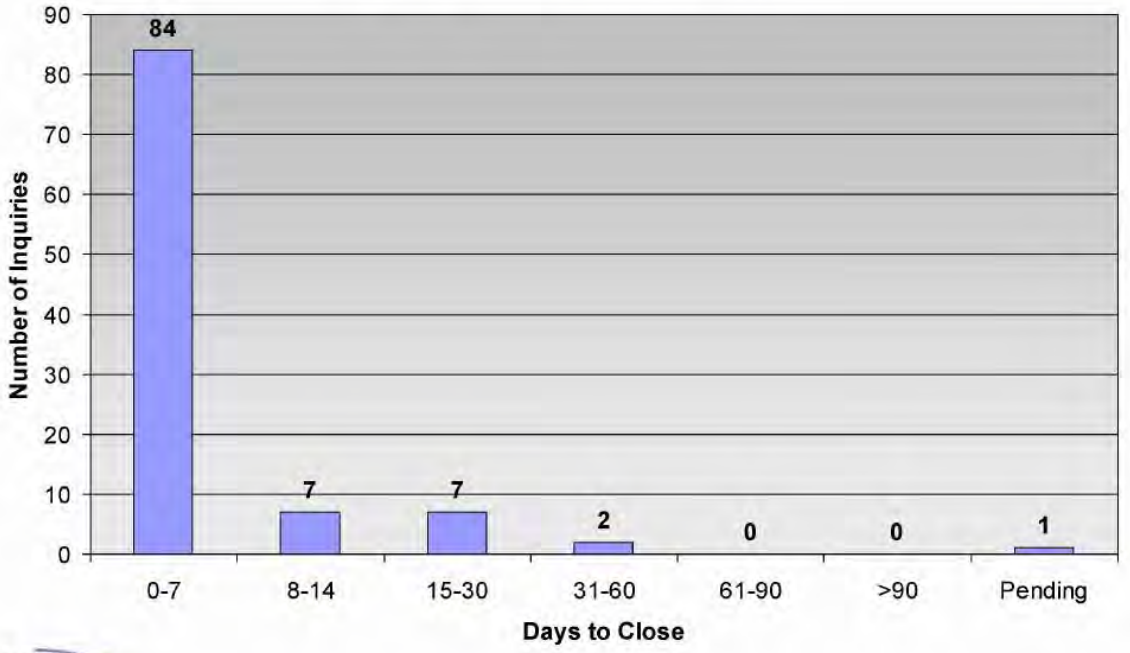
Report to Board of Directors
August 6, 2007
Bert Weinstein,
VP Corporate Compliance

PURDUE

Aug. 6, 2007 Compliance Report at PLP004399970

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time (Q2 2007)



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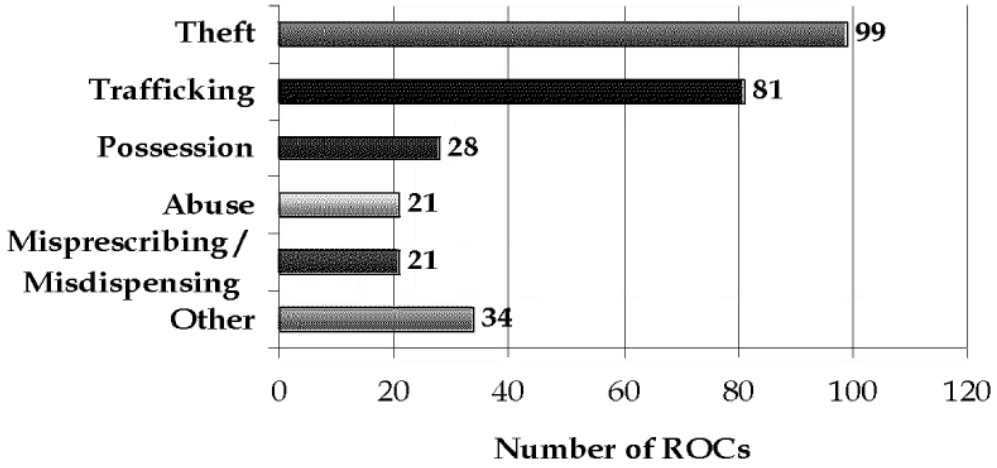
Purdue's CIA and AG Agreement: Status Report

Report to Board of Directors
August 6, 2007
Bert Weinstein,
VP Corporate Compliance

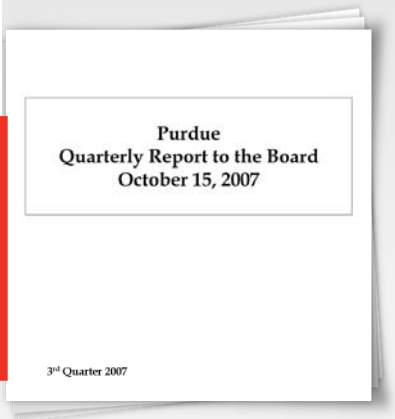
PURDUE

Aug. 6, 2007 Compliance Report at PLP004399971

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

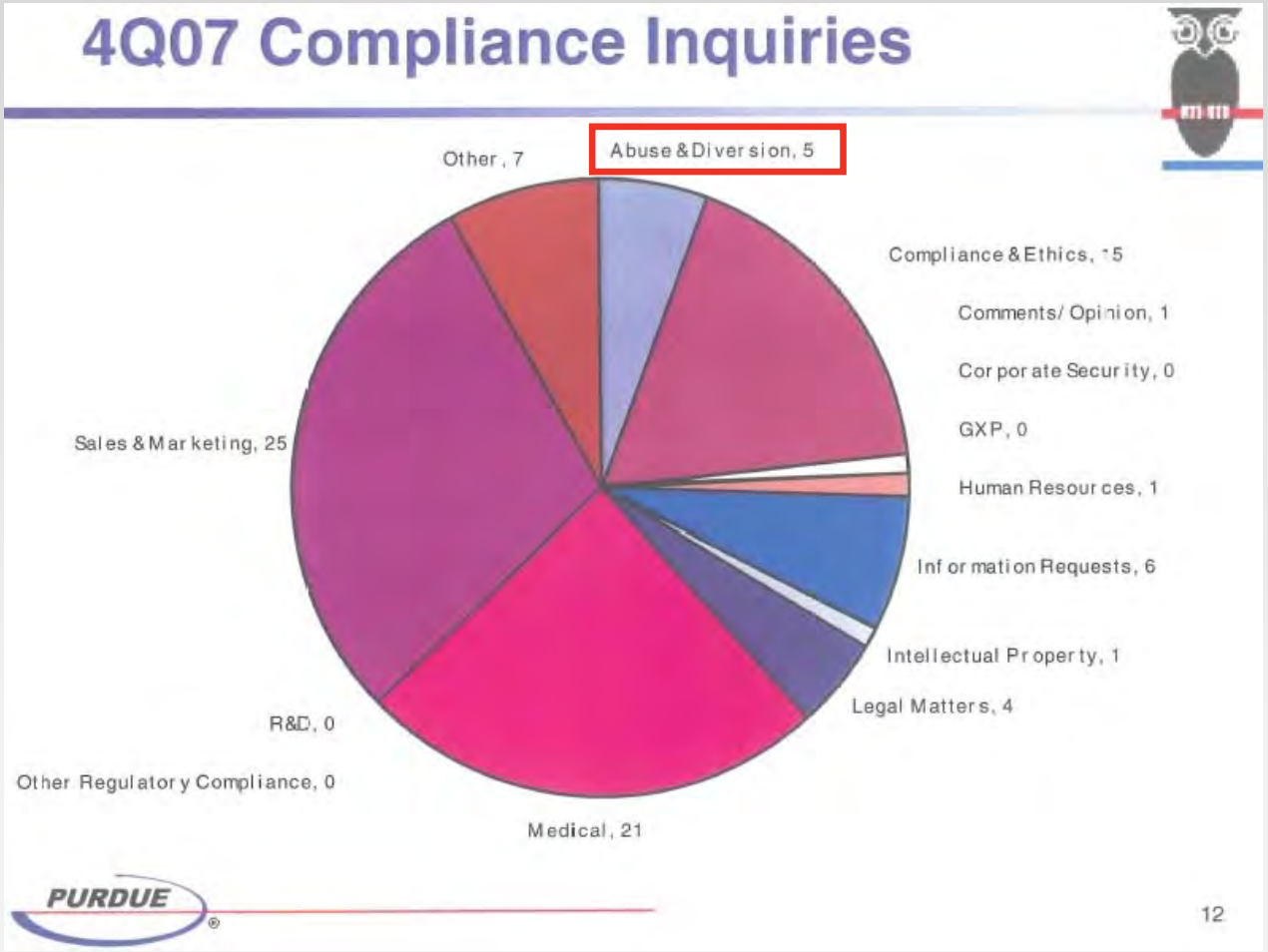


- **Figure 1:** 284 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics reviewed and entered into the Risk Management DataMart for 3rd Quarter 2007
- 46 field inquiries conducted in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data


Purdue
Quarterly Report to the Board
October 15, 2007
3rd Quarter 2007

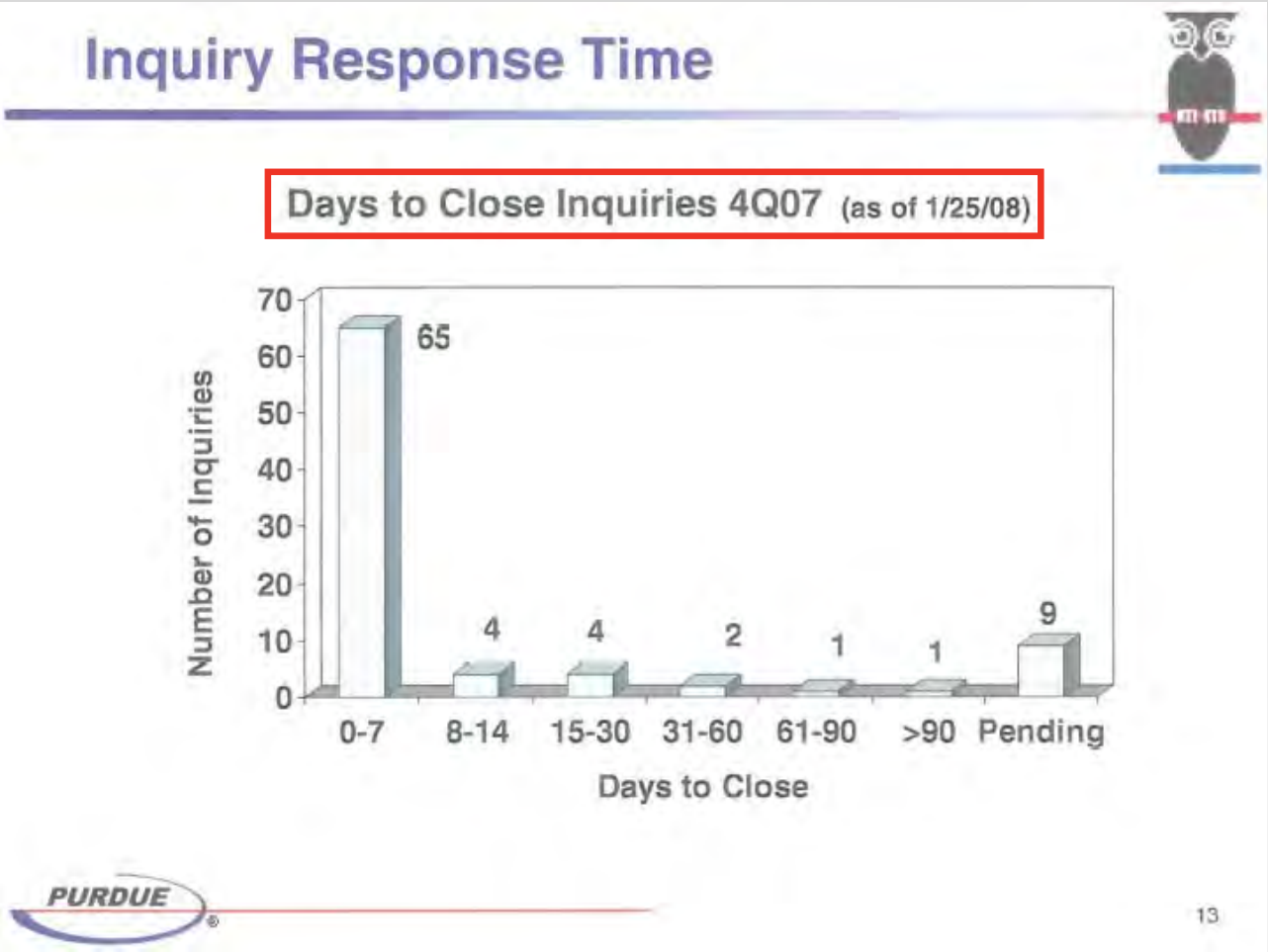
3Q 2007 Report to Board at PPLPC012000157437

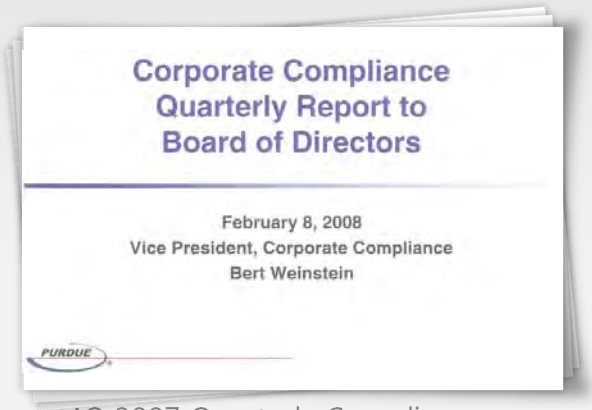
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



4Q 2007 Quarterly Compliance Report (PPLPC019000195607)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts





4Q 2007 Quarterly Compliance Report (PPLPC019000195607)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

CIA and AG Agreement Status

- CIA Implementation Report
  - Submitted to OIG on 11/28/07
  - Questions received 4/7 - answered 4/10
  - OIG approval of implementation 5/2
- OIG notice of exclusion of individuals - 3/31 letter
  - Purdue responded 4/14 re proposed consulting
  - OIG approval of consulting arrangement – 5/5 letter
- IRO Work plan submitted 1/08
- Preparing for IRO review - summer
- Annual Report Submission to OIG – Due 9/29/08

- Purdue in compliance with AG Agreements
  - Abuse & Diversion Detection (ADD) training - current
  - HCP letter process - current

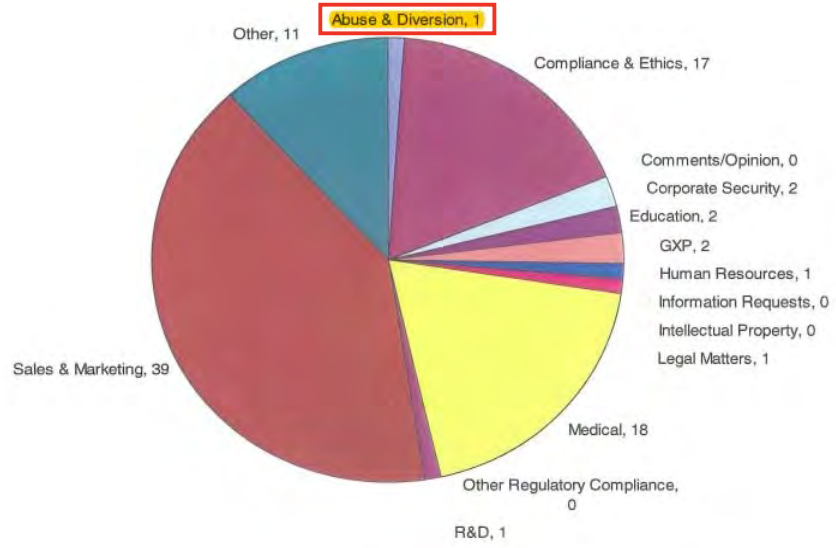
PURDUE

3

1Q 2008 Quarterly Compliance Report at PPLP004401171

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

1Q08 Compliance Incidents



PURDUE

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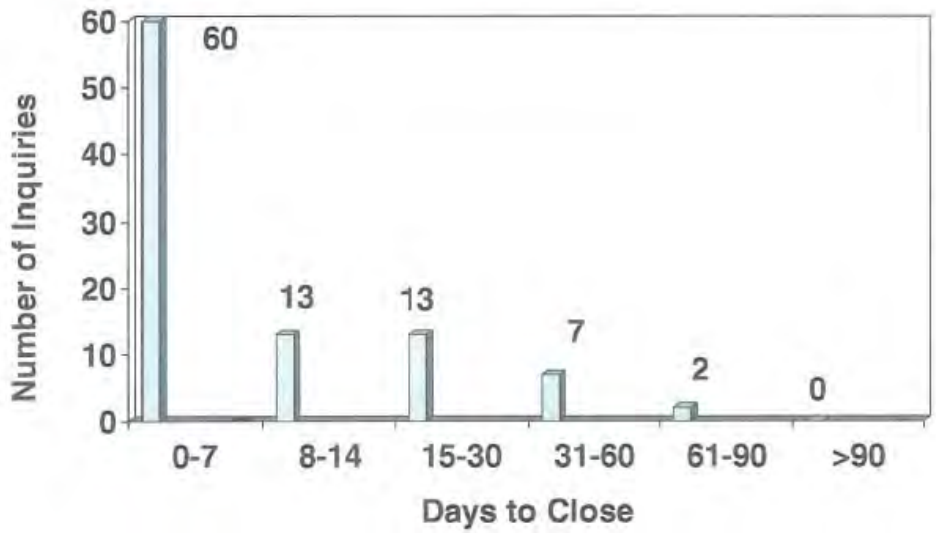
1Q 2008 Quarterly Compliance Report at PPLP004401186

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 1Q08 (as of 05/07/2008)



PURDUE

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1Q 2008 Quarterly Compliance Report at PPLP004401187

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

CIA Highlights

All transactions this quarter with OIG / Monitor Keshia Thompson have had successful results. Recap:

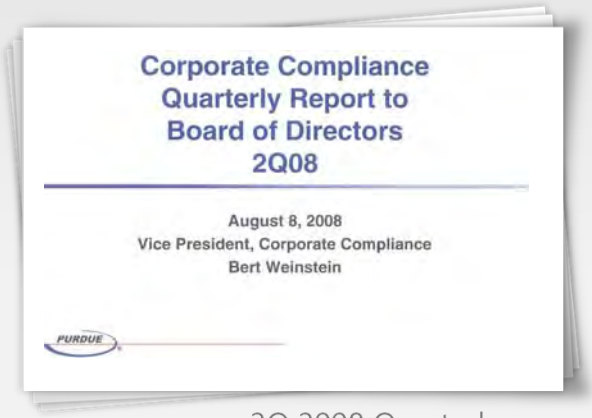
- CIA Implementation Report – approved by OIG 5/2
- OIG notice of exclusion of individuals - 3/31
  - But OIG approved consulting arrangement – 5/5
- OIG affirms Par not 'covered' in Rhodes arrangement -6/5

Purdue is also in full compliance with its AG Agreements

- Abuse & Diversion Detection (ADD) training - current
- HCP letter process – current / monitored monthly via Sales

PURDUE

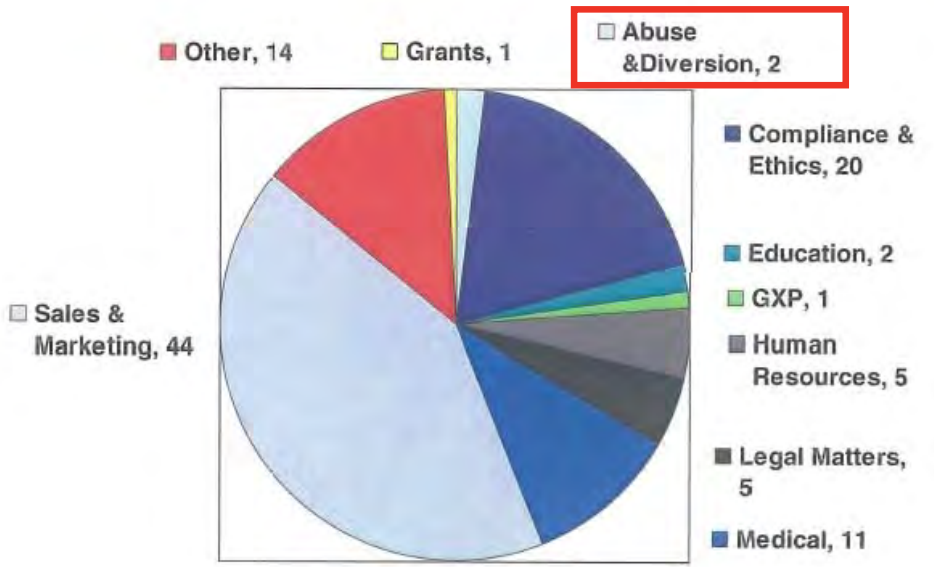
3



2Q 2008 Quarterly Compliance Report at PPLP004401344

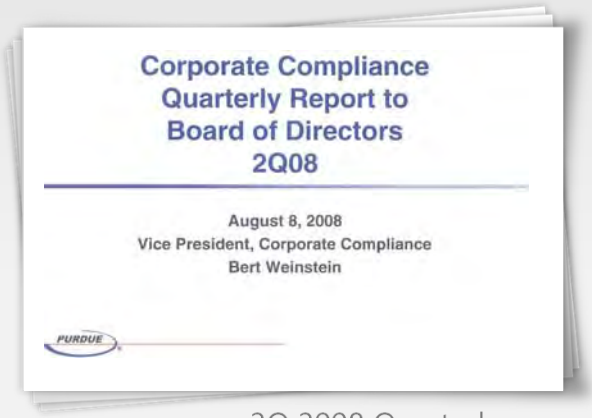
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

2Q08 Compliance Incidents



PURDUE

19

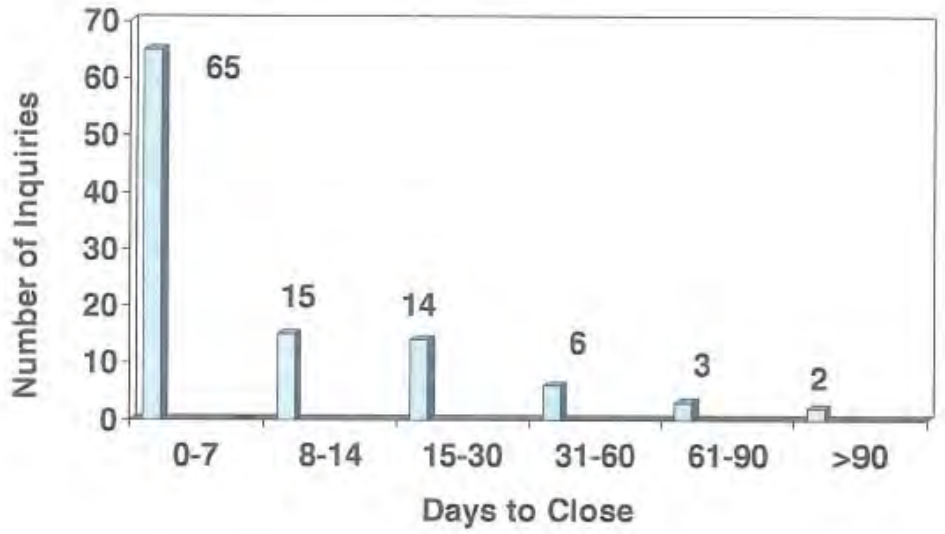


2Q 2008 Quarterly Compliance Report at PPLP004401360

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 2Q08 (as of 07/28/2008)



PURDUE

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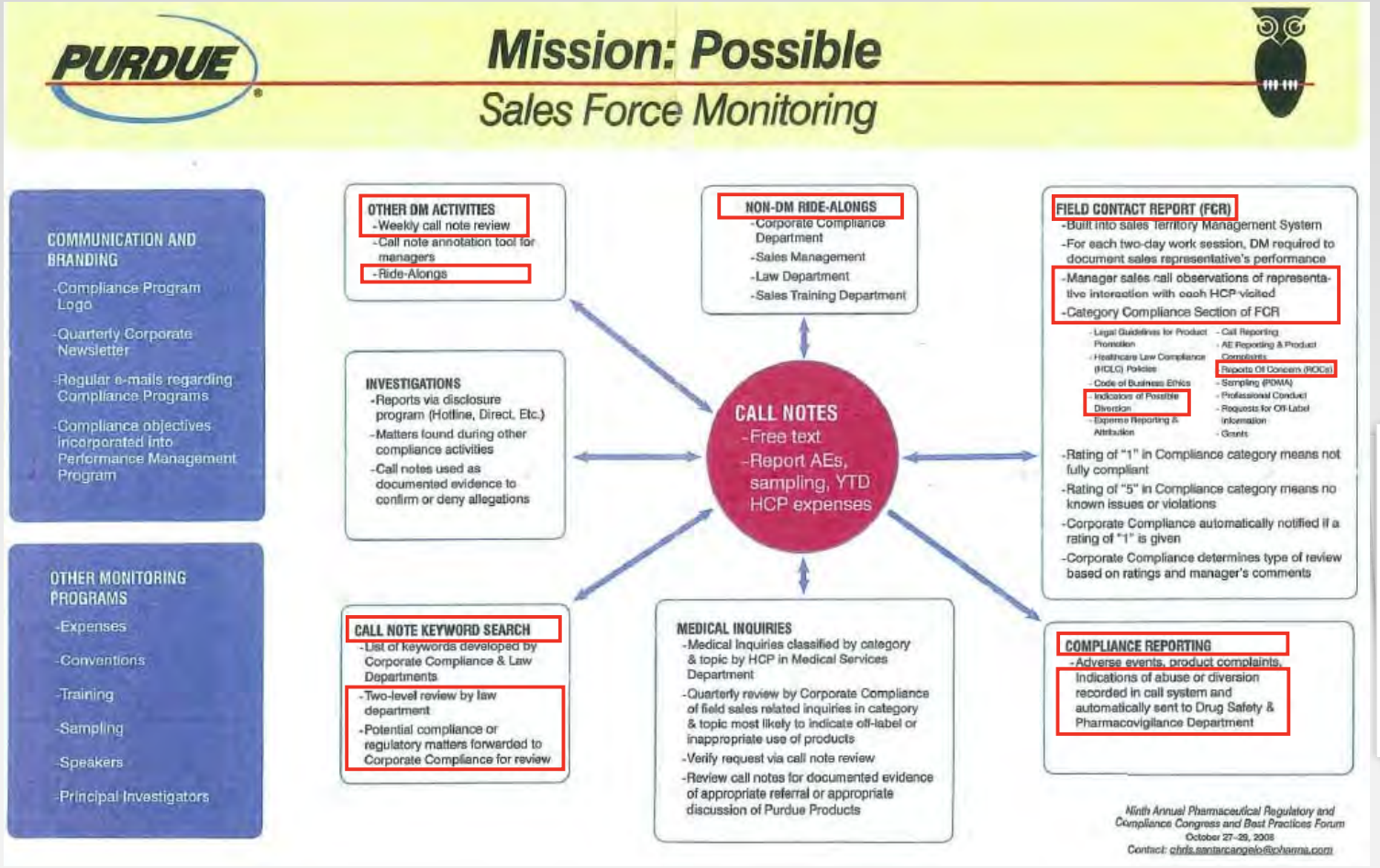
2Q 2008 Quarterly Compliance Report at PPLP004401361

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



Anti-diversion-related aspects of compliance program boxed in red

3Q 2008 Quarterly Compliance Report at PPLP004402086

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Purdue CIA Highlights

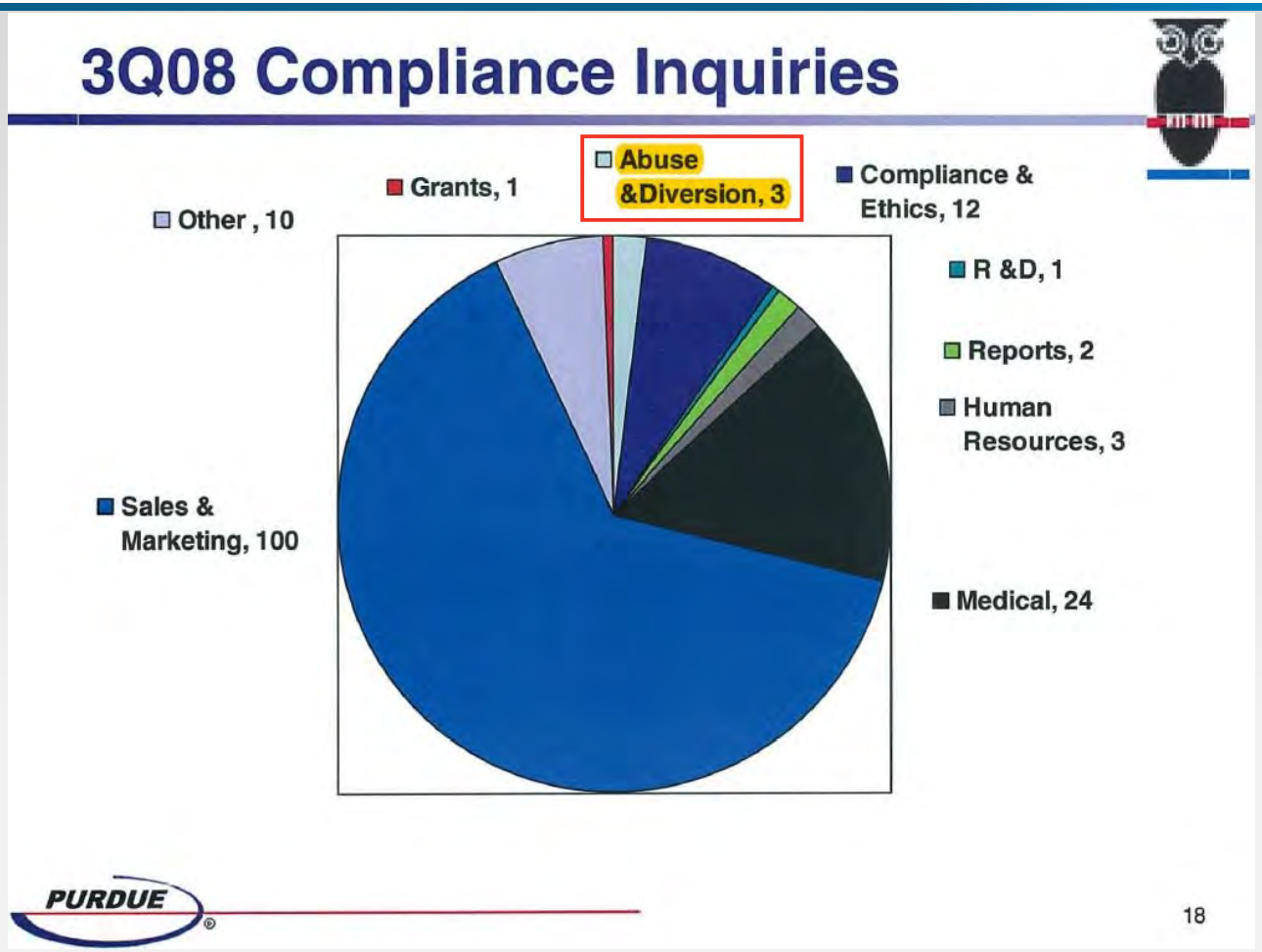
- First Annual Report to OIG submitted 9/25/08, certifies to all CIA requirements, including:
  - Updated policies and procedures
  - Code and other training
  - Disclosure Log information
  - Screening for Excluded Individuals
  - Investigations and Legal Proceedings
  - Material Review Documents
- A copy of the Report (without voluminous attachments) follows these slides
- Purdue is also in full compliance with its AG Agreements
  - Abuse & Diversion Detection (ADD) training - current
  - HCP letter process – current / monitored monthly via Sales

PURDUE

5

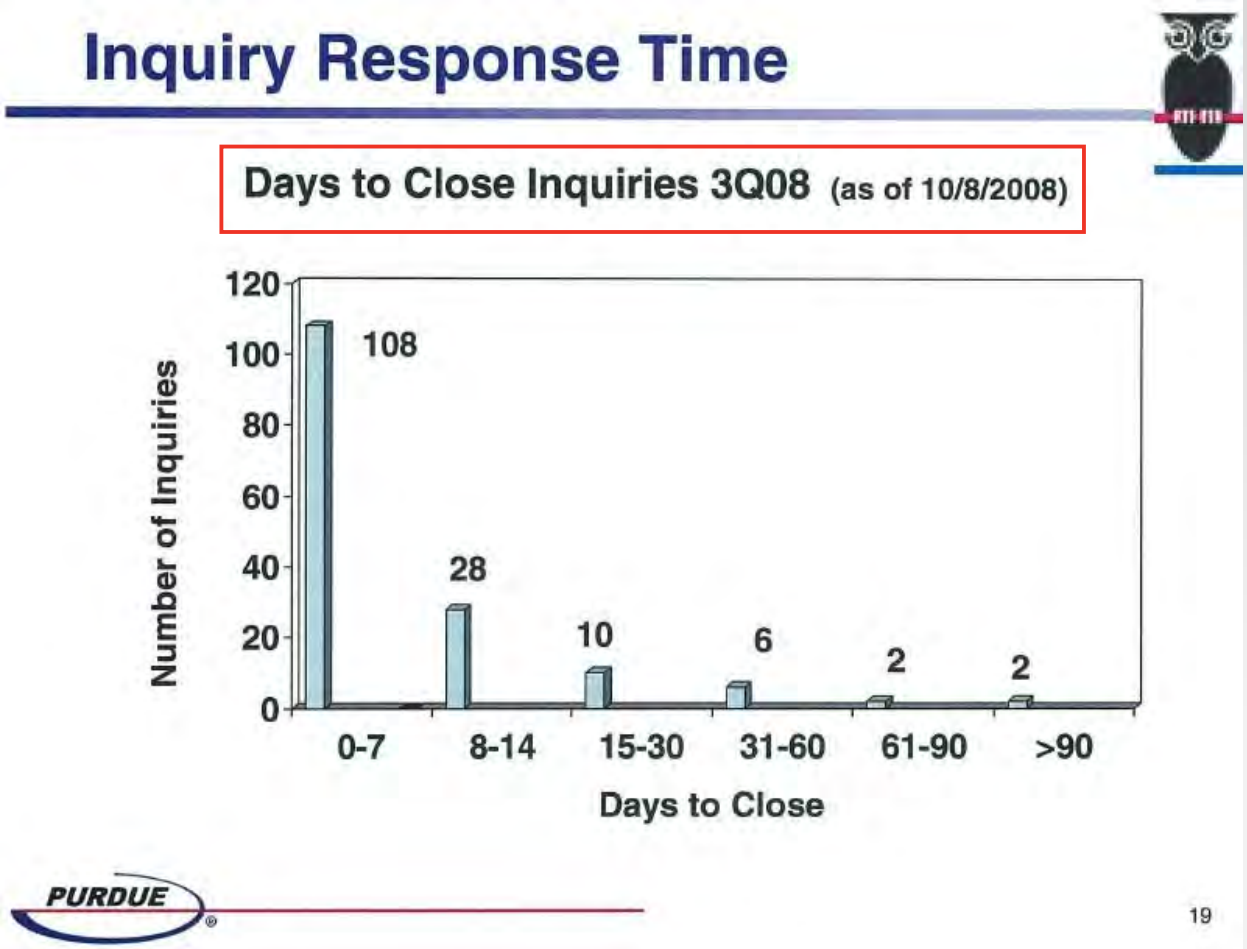
3Q 2008 Quarterly Compliance Report at PPLP004402036

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



3Q 2008 Quarterly Compliance Report at PPLP004402049

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



3Q 2008 Quarterly Compliance Report at PPLP004402050

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

National Sales Meeting

Well-received compliance workshops for all field personnel:

- Focused on Adverse Event, Product Complaint, Report of Concern and Abuse & Diversion Detection (ADD) Program reporting requirements
- Reviewed AG Agreement obligations (especially "Dear HCP Letter" and "ADD Report" requirements)
- Reviewed CIA obligations and overall commitment to compliance with laws, regulations and policies and procedures
- Emphasized appropriate messaging around OxyContin Visual Aid
- *"Be a Compliance Star!"* game
  - Exciting and interactive game that tests compliance knowledge
  - Rewarded strong knowledge of compliance concepts
  - Developed in-house

PURDUE

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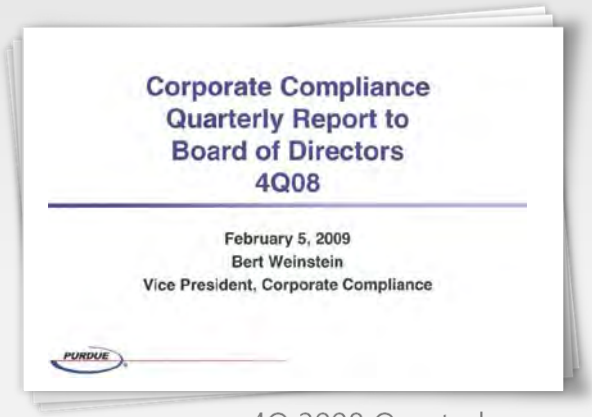
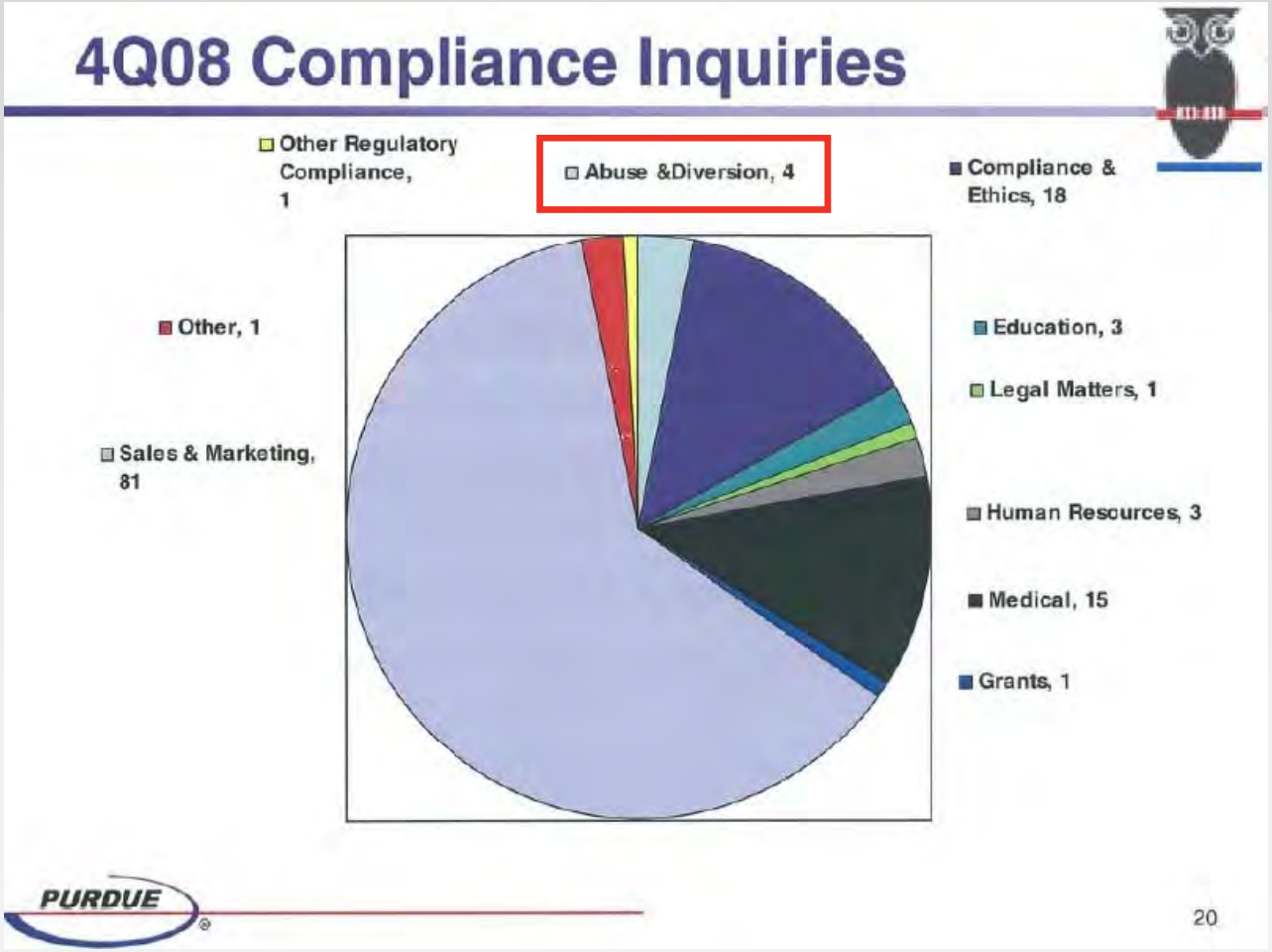


4Q 2008 Quarterly Compliance Report at PPLP004402226

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

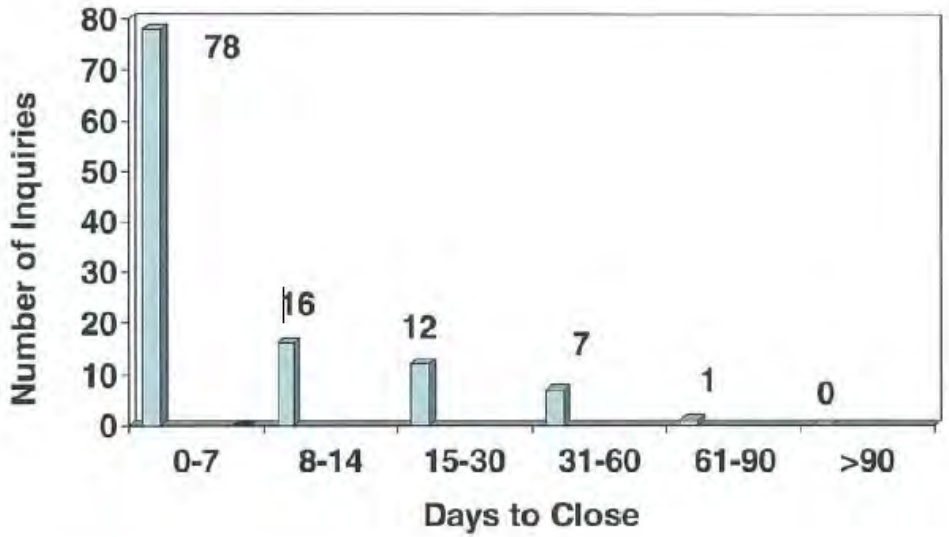


4Q 2008 Quarterly Compliance Report at PPLP004402224

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 4Q08



PURDUE

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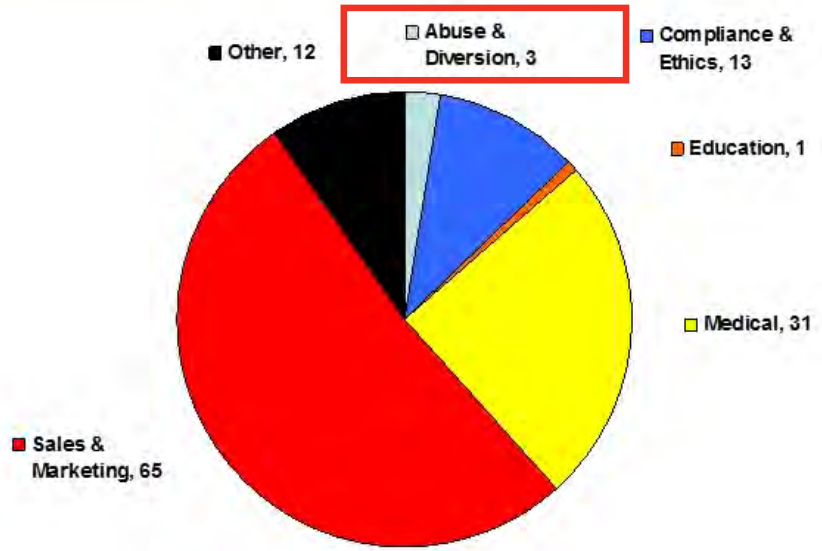
4Q 2008 Quarterly Compliance Report at PPLP004402225

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

1Q09 Compliance Inquiries



PURDUE

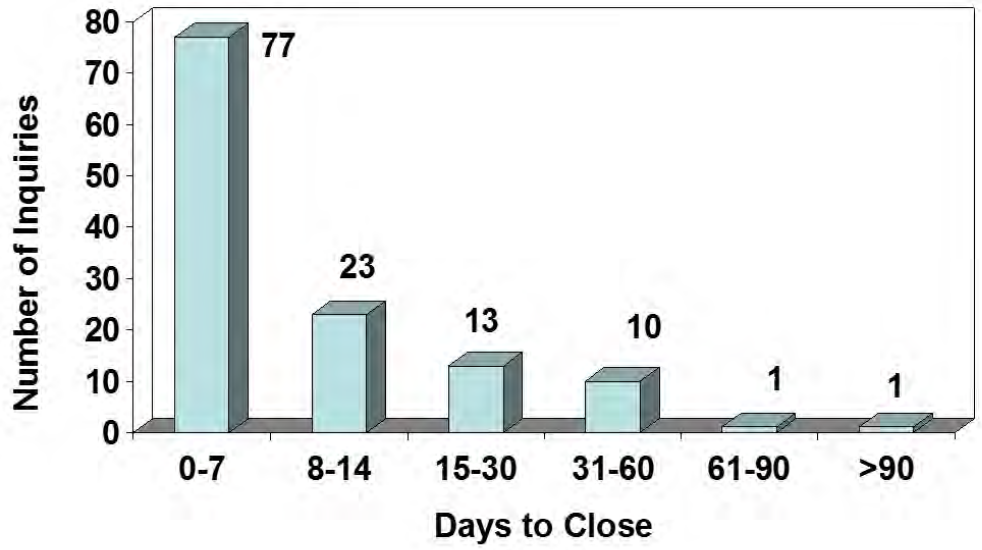
20

1Q 2009 Quarterly Compliance Report at PPLP004402670

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 1Q09 (as of 4/29/09)



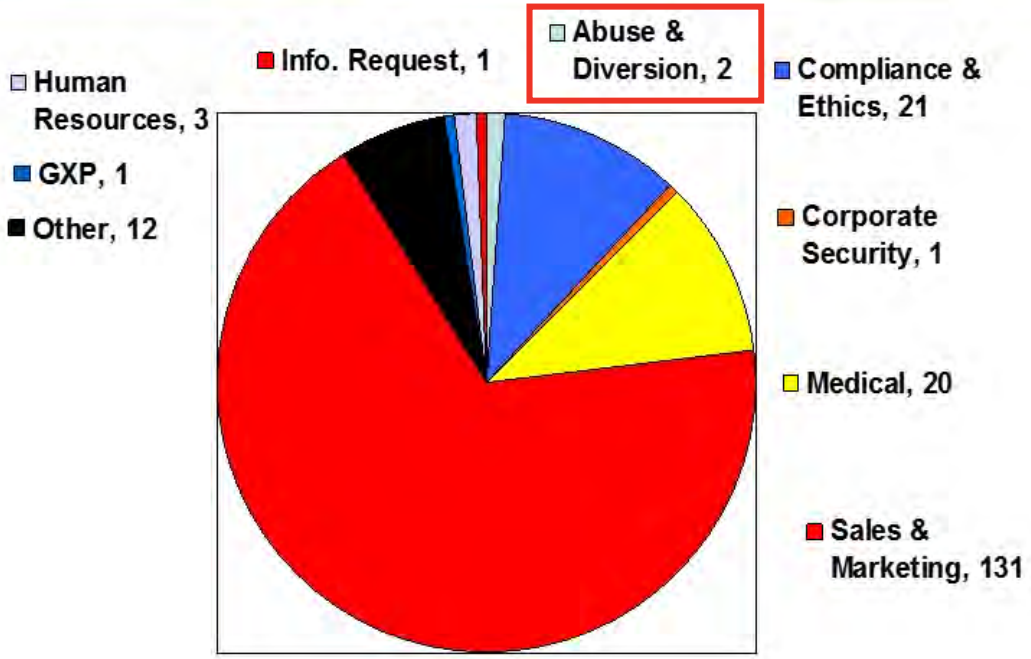
PURDUE

21

1Q 2009 Quarterly Compliance Report at PPLP004402671

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

2Q09 Compliance Inquiries



PURDUE

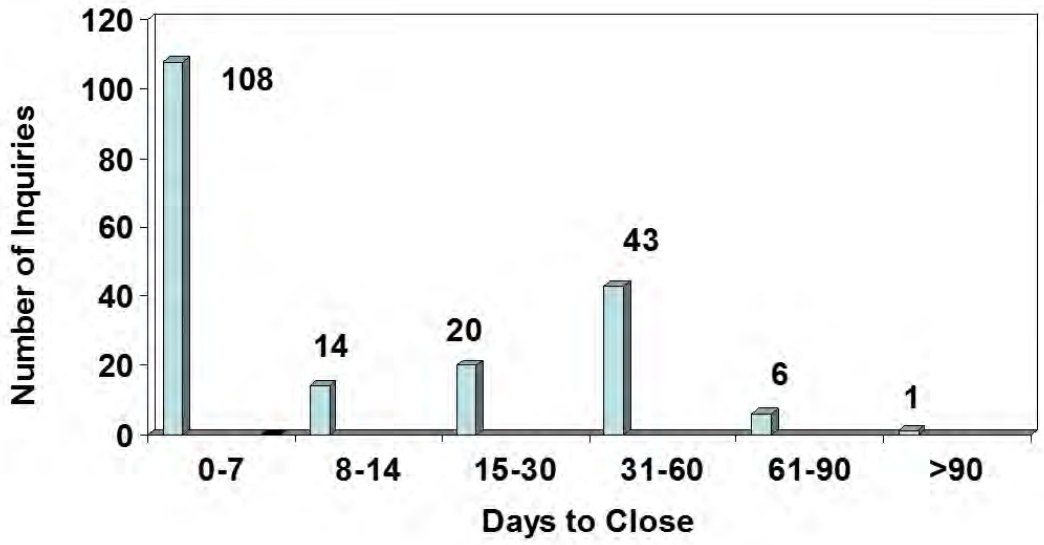
18

2Q 2009 Quarterly Compliance Report at 18 (PPLPC012000236639)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 2Q09 (as of 8/3/09)

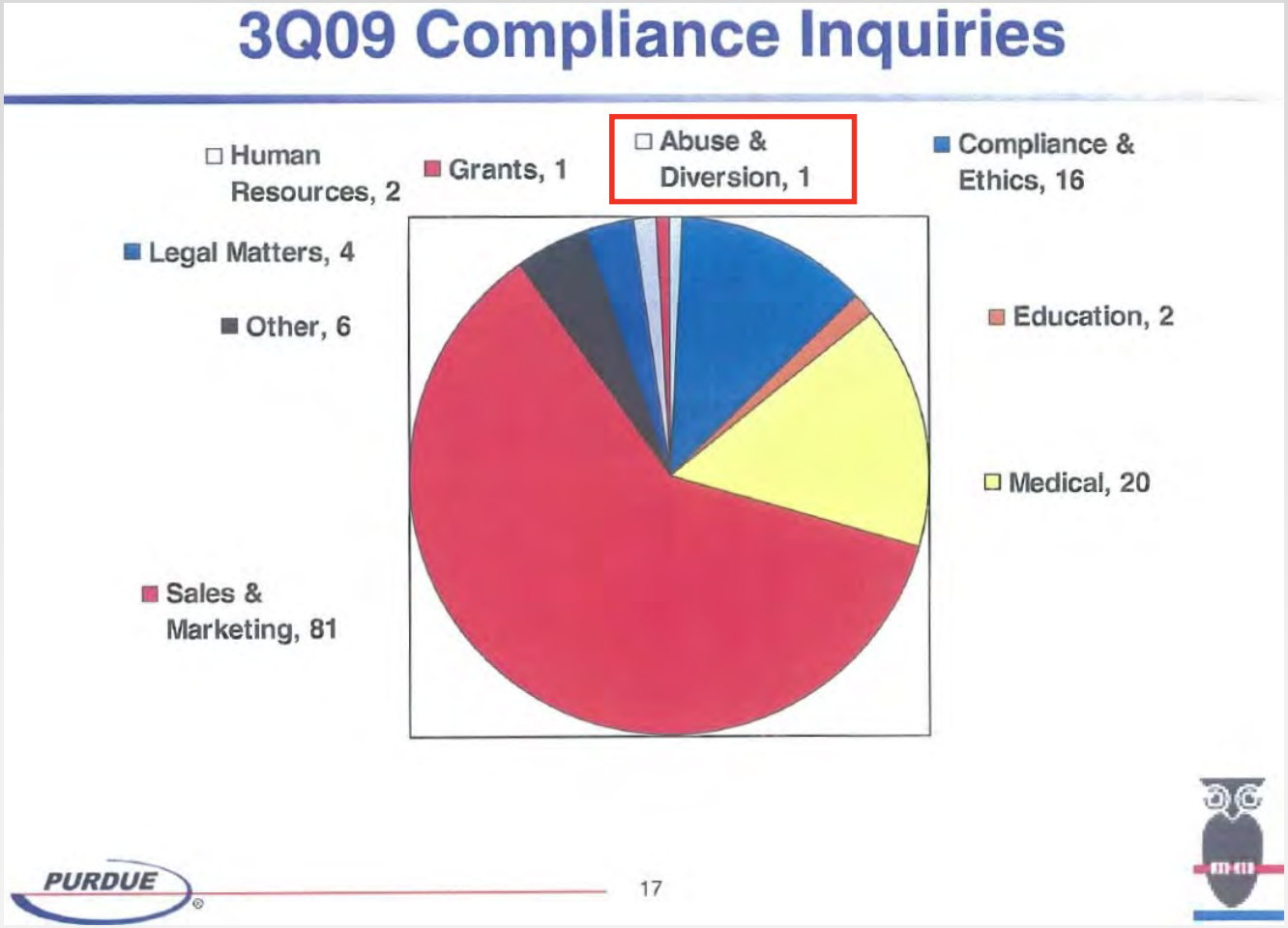


PURDUE

19

2Q 2009 Quarterly Compliance Report at 18 (PPLPC012000236639)

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

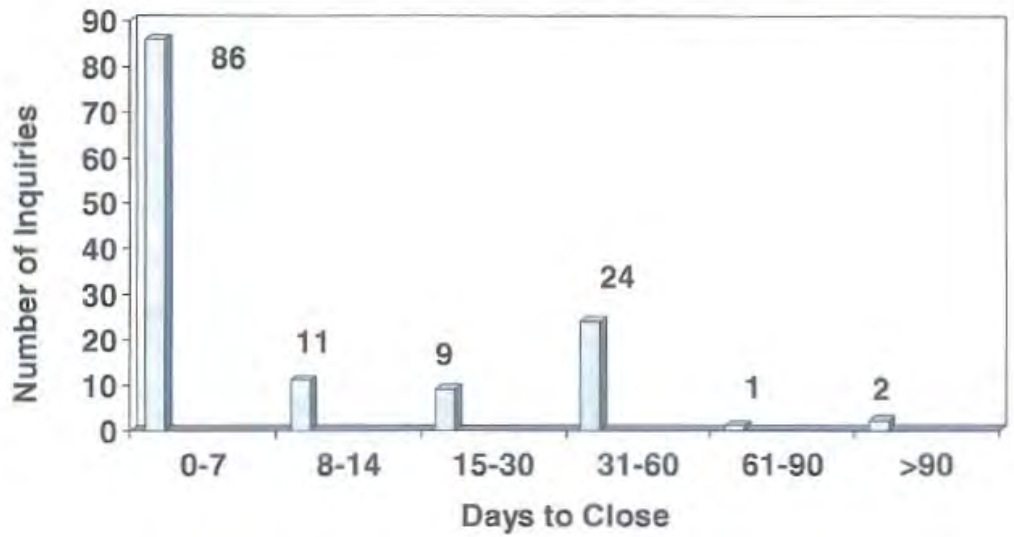


3Q 2009 Quarterly Compliance Report at PPLP004402998

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 3Q09 (as of 10/7/09)



PURDUE

18

3Q 2009 Quarterly Compliance Report at PPLP004402999

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Second Annual Report to OIG

- Purdue's Second Annual Report to the OIG dated 9/25/09 certifies to our compliance with all CIA requirements, including:
  - Updated policies and procedures
  - Code and other CIA training of employees, Board, etc.
  - Disclosure Log information
  - Screening for Excluded Individuals
  - Investigations and Legal Proceedings
  - Material Review Documents
- A copy of the Report (without voluminous attachments) follows these slides – it is FYI only
- Purdue is also in full compliance with its AG Agreements
  - Abuse & Diversion Detection (ADD) training - current
  - HCP letter process – current, monitored quarterly

PURDUE

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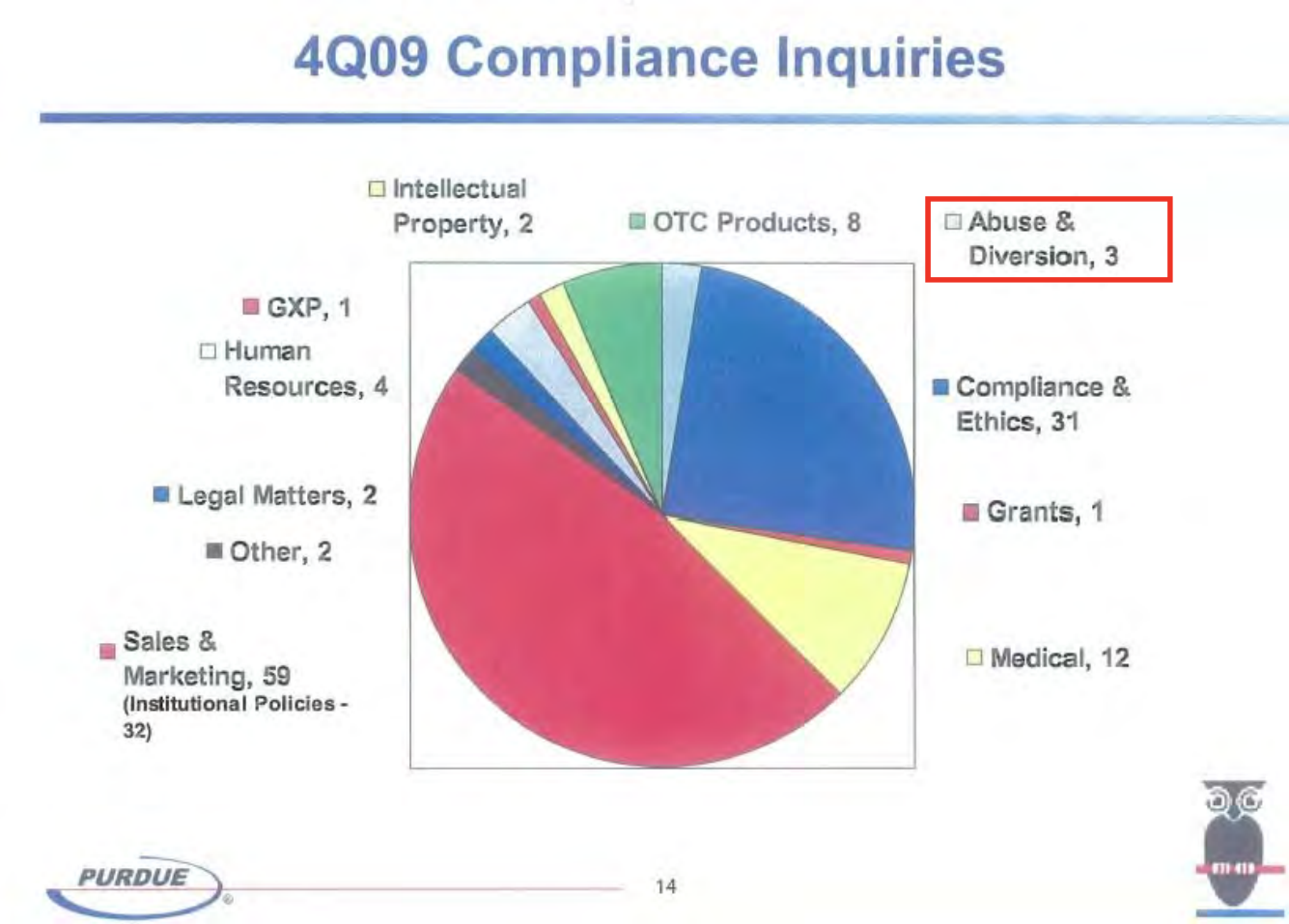
3Q 2009 Quarterly Compliance Report at PPLP004402986

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

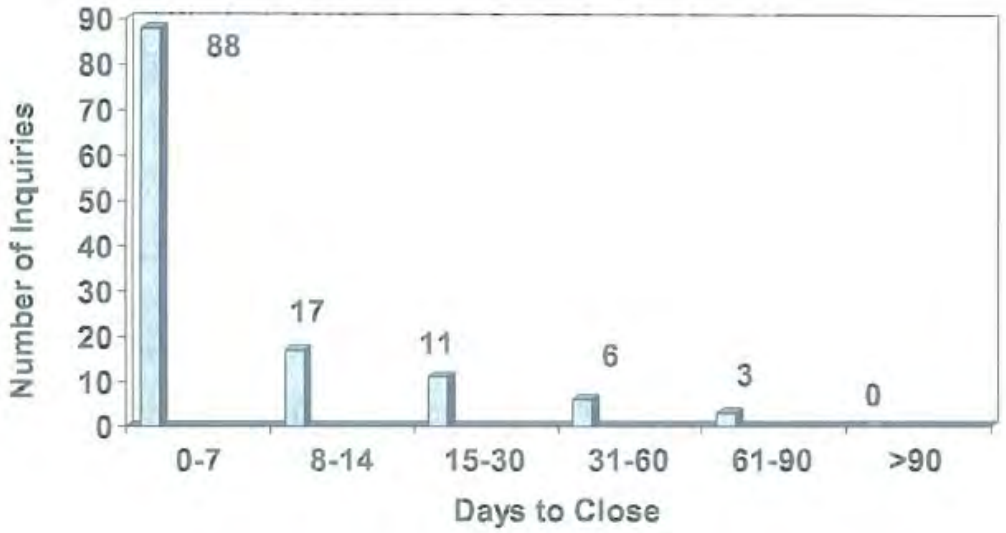


4Q 2009 Quarterly Compliance Report at PPLP004403720

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 4Q09 (as of 1/19/10)



PURDUE

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4Q 2009 Quarterly Compliance Report at PPLP004403721

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Purdue's National Sales Meeting

- Presentation: *"Why should compliance matter to you?"*
  - Video of 2009 compliance highlights (a version of *Jaws* for reps)
  - Review of CIA history
  - Compliance hot topics: prosecutors looking for jail time, and focused on off-label promotion, and savings card abuse; Federal Sunshine Act
- Scenario-based Workshops "owned" by all the District Managers
  - Focused on nine important issues in the field (and a "snowball fight")
    - Abuse and Diversion Reporting
    - In-service meals and expenses (2)
    - Off-label promotion
    - Contributions / kickbacks
    - Comparative claims
    - Use of discontinued materials
    - Call notes
    - Savings cards

PURDUE 9

4Q 2009 Quarterly Compliance Report at PPLP004403715

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Major Compliance Oversight Activities

- Compliance Council – senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality program
- Reportable Events Committee – senior medical, Legal, regulatory and compliance execs meet monthly- review all pending compliance and other matters
- Sales and Marketing Compliance Committee – senior Sales and Marketing and Compliance execs meet every six weeks
- Sales Discipline Committee – Sales, Legal, HR and Compliance meet weekly to discuss open matters and decide discipline
- R&D compliance – Compliance Manager focusing on this area

PURDUE 18

4Q 2009 Quarterly Compliance Report at PPLP004403724

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Supply Chain Security Program 2009 Accomplishments

- Losses in Transit – 0
  - (Purdue to Customers/Wholesalers)
- Supply Chain Loss
  - McKesson – Memphis, Tennessee
  - OxyContin left outside a secured area over the weekend
  - Crime Stopper Reward $10,000
  - No arrest made to date
  - Follow-up with McKesson with appropriate recommendations for improvement
- US Government Supply Chain Security Compliance Programs
  - US Customs Trade Partnership against Terrorism (C-TPAT)
  - U.S. Transportation Security Administration (TSA) – "Certified Cargo Screening Program" (CCSP)
- Pharmaceutical Cargo Security Coalition (PCSC)
  - Value of goods recovered $76,000,000 in 2009 vs. $16,000,000 in 2008

Brand Protection / Investigations Program 2009 Accomplishments

- Counterfeiting
  - Internet Monitoring
  - Law Enforcement Assistance
    - RFID
    - Chemical Lab & Analysis
- Diversion (all Products)
  - Doctor Shopping / False Rx
- Product Complaints/Tampering
  - e.g. "Skittles"
- Bottle Tracking
  - Approvals in 6 states (Washington, Oregon, New Mexico, Ohio, Georgia, Florida)
  - Deployed – 29 stores – State of Washington
  - 6 Individuals Arrested (Washington)

Physical Security Program 2009 Accomplishments

- DEA "Inspections/Audits"
  Wilson and Coventry - no deficiencies
- Totowa Transition – no significant security related incidents

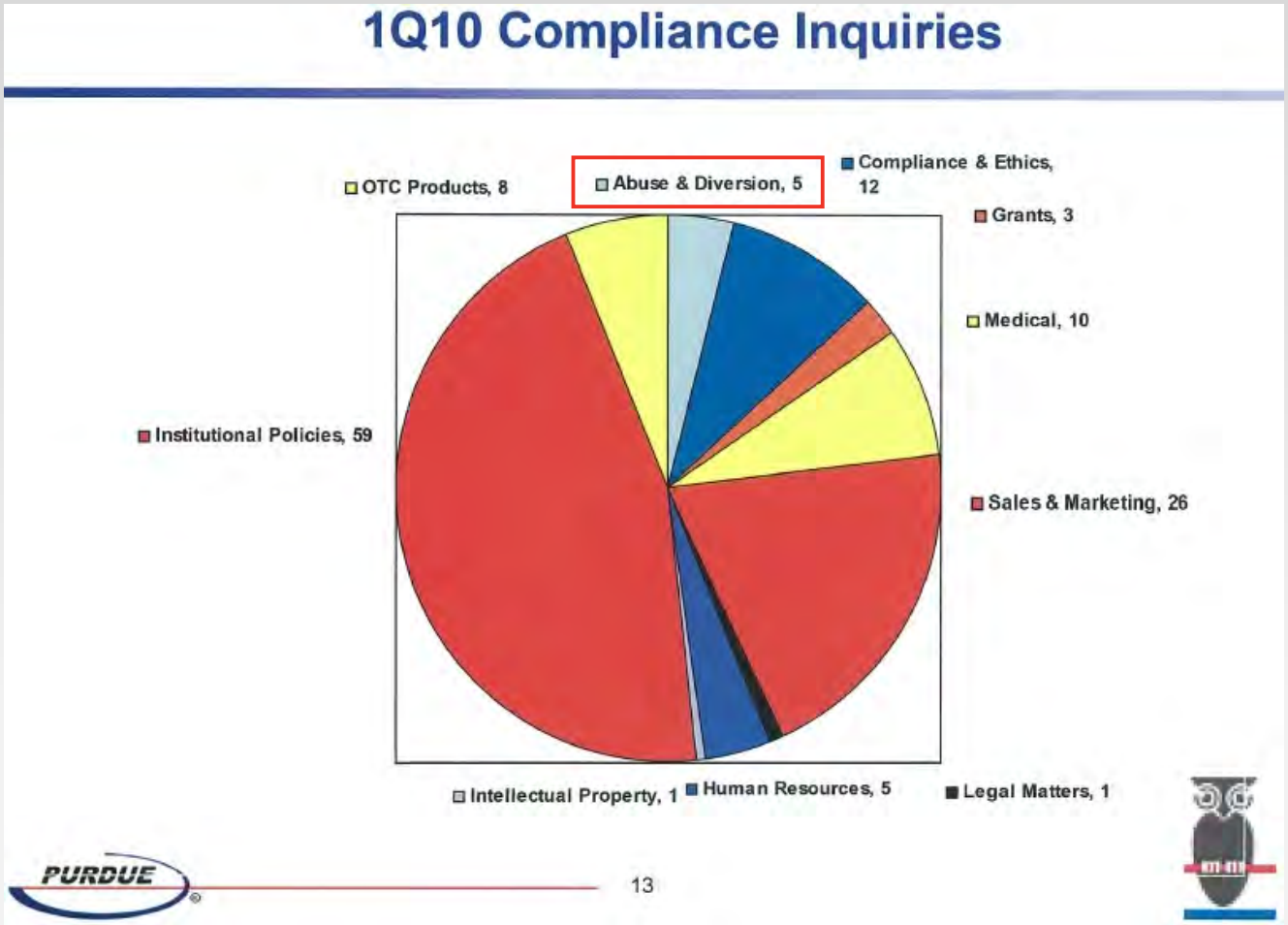
4Q 2009 Corporate Security Dept. Report at 4-6
(Jan. 21, 2010 Board Agenda at PPLPC044000024003-005)


Purdue Pharma
Corporate Security Department

OVERVIEW

- Law Enforcement Liaison and Education Program (LELE)
- RxPatrol / Crime Stoppers Program
- Supply Chain Security Program
- Physical Security Program
- Brand Protection & Investigations Program

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

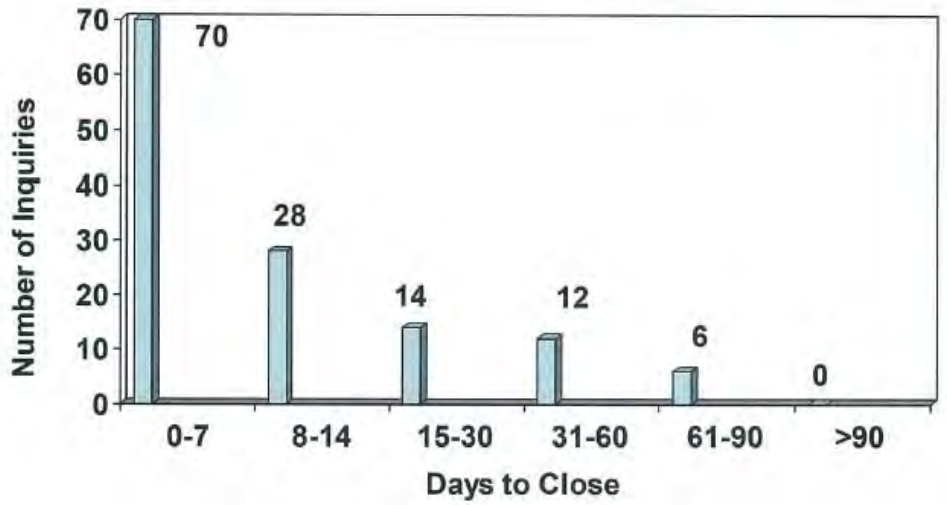


1Q 2010 Quarterly Compliance Report at PPLP004404114

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 1Q10 (as of 4/27/10)



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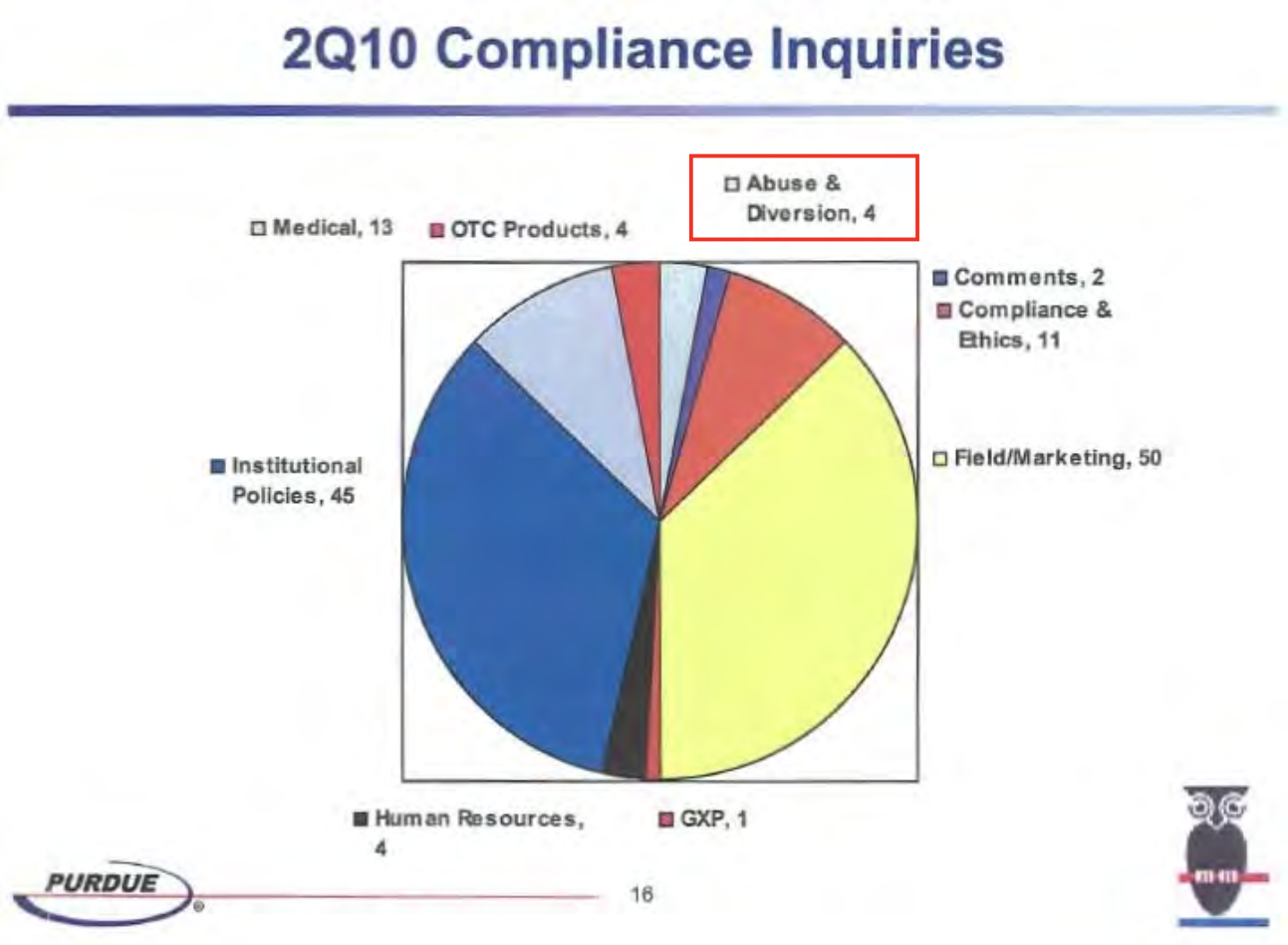
1Q 2010 Quarterly Compliance Report at PPLP004404115

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

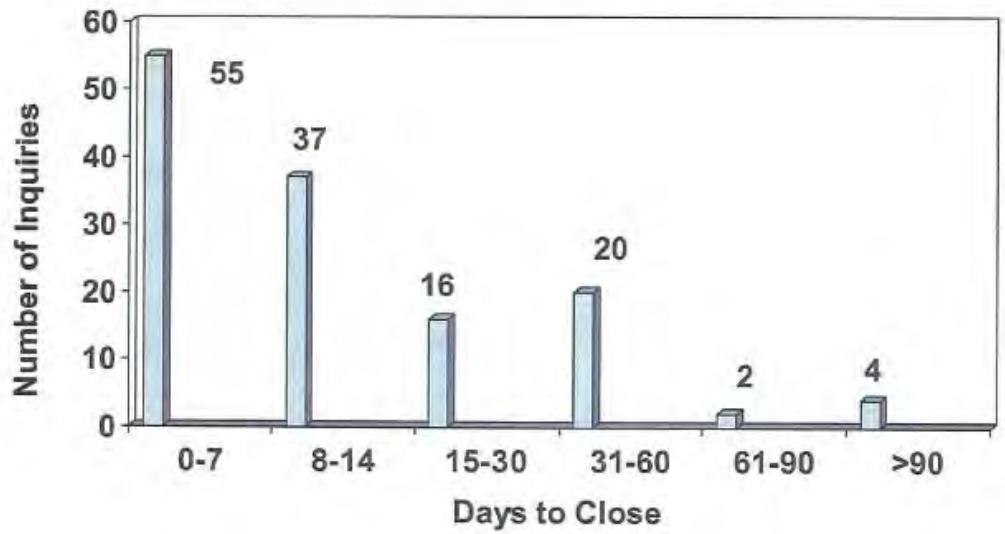


2Q 2010 Quarterly Compliance Report at PPLP004404566

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 2Q10 (as of 7/6/10)



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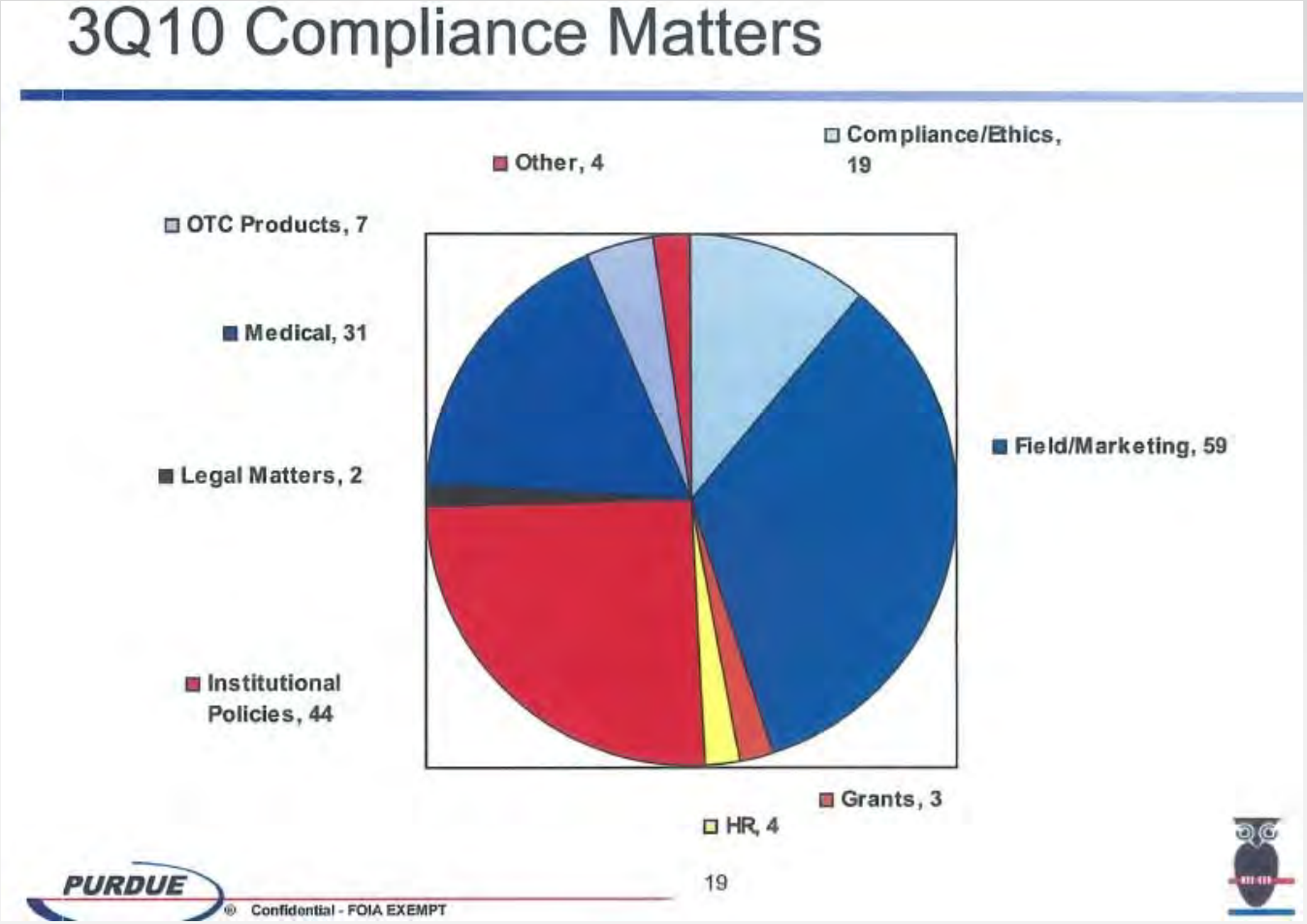
2Q 2010 Quarterly Compliance Report at PPLP004404567

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



Abuse and Diversion, 0

3Q 2010 Quarterly Compliance Report at PPLP004405478

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

2010 Audit Schedule Snapshot

Purdue
Corporate Compliance
Audits & Risk Assessments
October 8, 2010

COMPLETED

#	Year	Type	Description
1	2009	Audit	Healthcare Grants - Completed audit to confirm compliance to current operating procedures.
2	2009	Audit	Field Contact Reports - Completed audit to determine compliance to SOP requirements for District Managers. The audit included a review of metrics for expense submissi

#	Year	Type	Description
1	2010	Audit	Contracts Database - To review the database for Legal to assess input accuracy. Completed Q3 of 2010.
2	2010	Audit	PCR Analysis - Based on our original audit and subsequent changes to our policies and procedures, we would like to revisit in order to measure the anticipated improvement areas. This audit was completed in Q3 of 2010.
1	2010	Risk Assessment	HIPAA Information - A request was made by Finance to review the company's HIPAA procedures. The main concern centers around protecting the health information of c There are certain groups who have access to background screens, medical information and other highly confidential data. What safeguards are in place to protect or inform downstream? Completed Q1 of 2010.

IN-PROGRESS

#	Year	Type	Description
1	2010	Audit	In-service Sign Sheets – Maggie, based on the memo that was sent out in September and our initial review, we would like to revisit this risk assessment during the 3rd or 4th to measure the expected improvement. Anticipated completion – Q4 of 2010.
2	2010	Risk Assessment	Sales Force/Manager Training - A request was made by Sales Management to review some of the non-compliance training sessions. The goal of this review is to ensure that are approved, not revised from the approved version, the trainer stays on-topic, etc.

#	Year	Type	Description
1	2010	Audit	ADD Audit - To review current policies, procedures, and SOPs
2	2010	Audit	Consulting Agreements - To review and audit of the current Cabell consultancy agreements
3	2010	Audit	HR - To review the Human Resource Information Management System. Before any work begins, Bert will review with David Long first
1	2010	Risk Assessment	CSA Audit Reports - A request was made by Finance to review the CSA audit reports. The main concern centers around tracking and accounting for controlled substances
2	2010	Risk Assessment	HCP Contracts - A request was made by finance to review HCP contracts. The main question was which HCPs are Purdue paying and do we have any contracts with them?
3	2010	Risk Assessment	Sr. Office & Board Expense Reports - A request was made by Finance to review Sr. Officer and Board expense reports. The main concern centered around checking for any meals/entertainment/gift spend used on HCPs
4	2010	Risk Assessment	District Meeting - A request was made by Sales Management to review a District Meeting. The goal would be to assure that content and materials are being delivered as pla
5	2010	Risk Assessment	IPAP Program - A request was made by Finance to review the IPAP program. The main concern centered around the utilization of the program.
6	2010	Risk Assessment	Sampling - A request was made by Finance to review the sampling program. The main concern centers around the current procedures of the program and the level of risk in distributing product for free.

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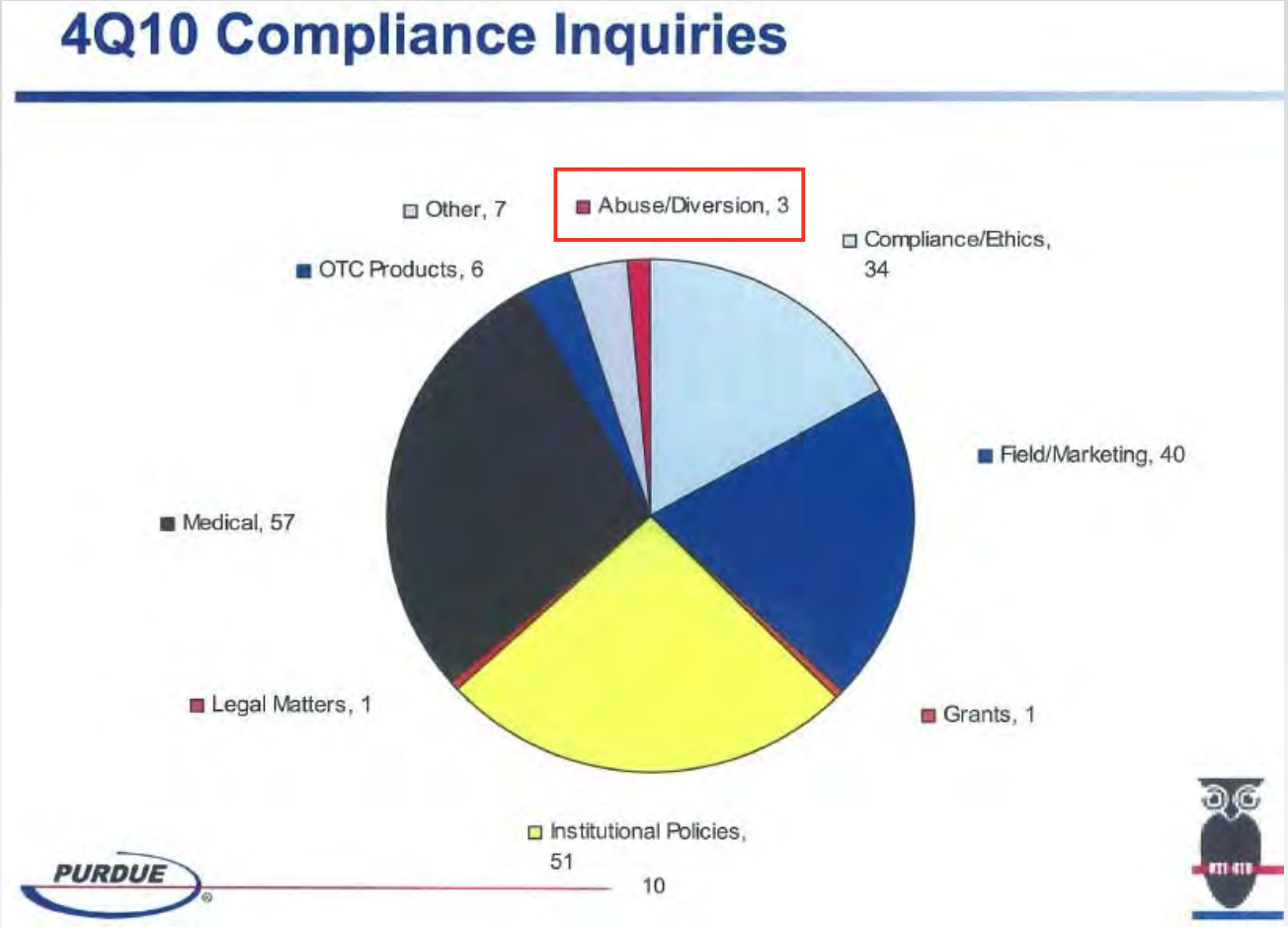
#	Year	Type	Description
1	2010	Audit	ADD Audit – To review current policies, procedures and SOPs

3Q 2010 Quarterly Compliance Report at PPLP004405482

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

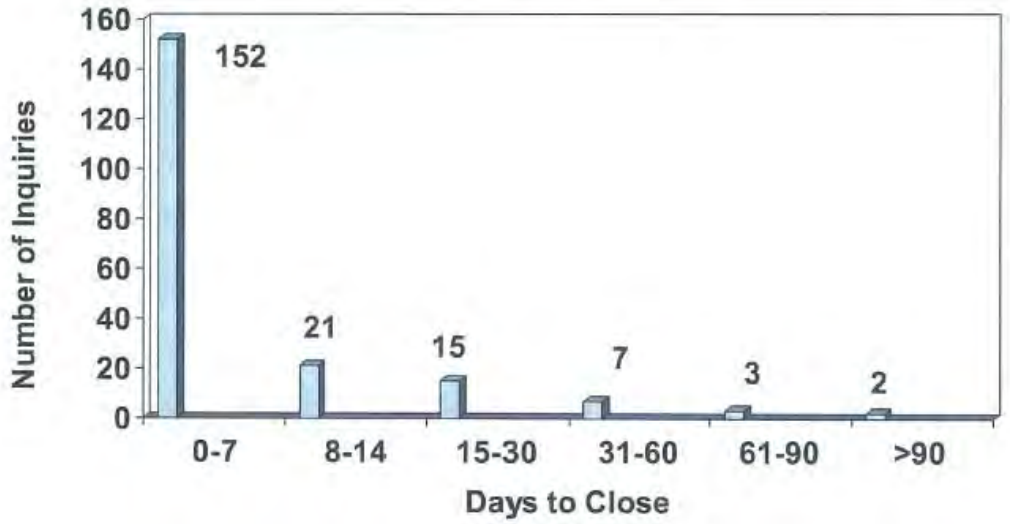


4Q 2010 Quarterly Compliance Report at PPLP004405718

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 4Q10 as of 1/14/11)



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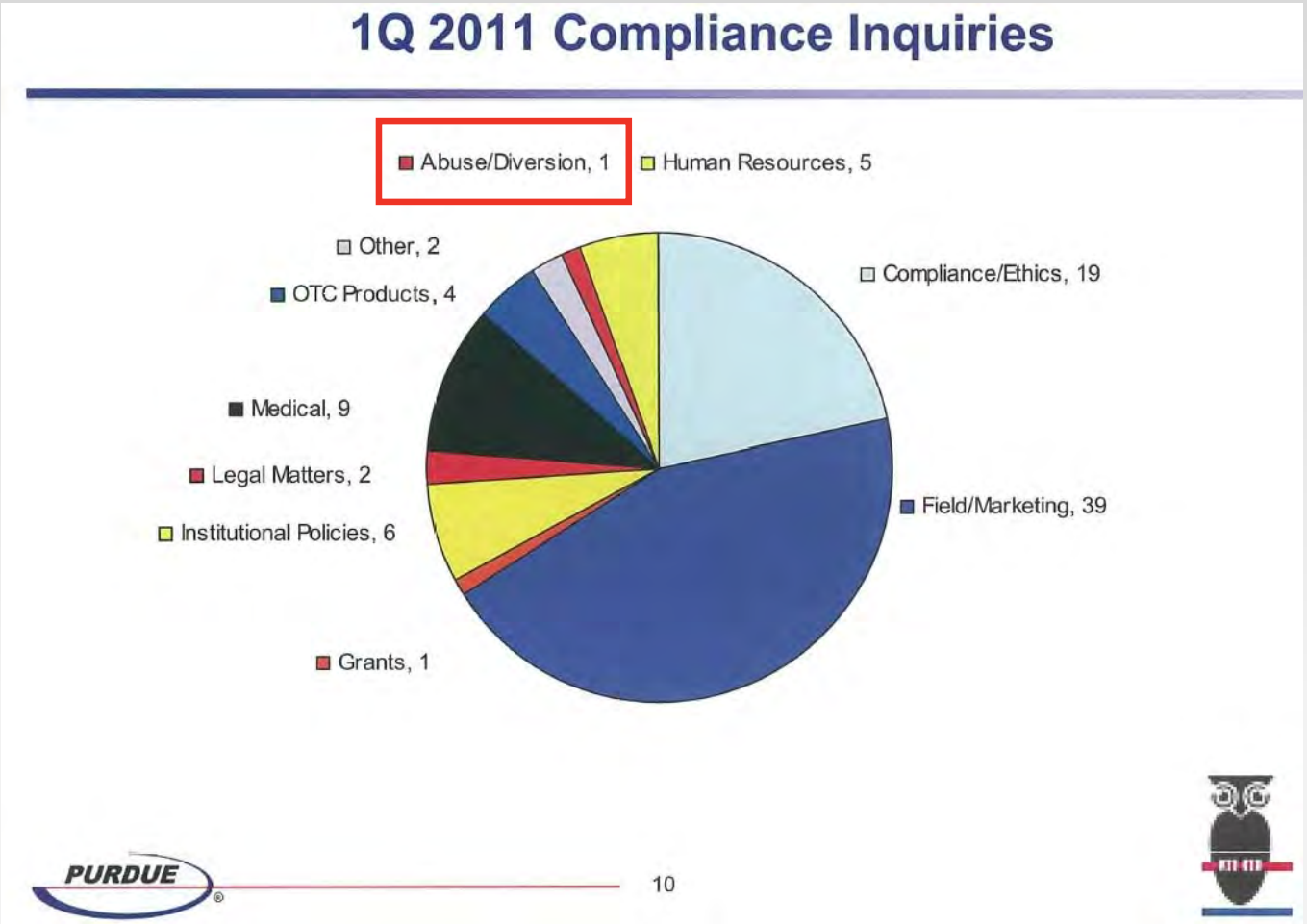
4Q 2010 Quarterly Compliance Report at PPLP004405719

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

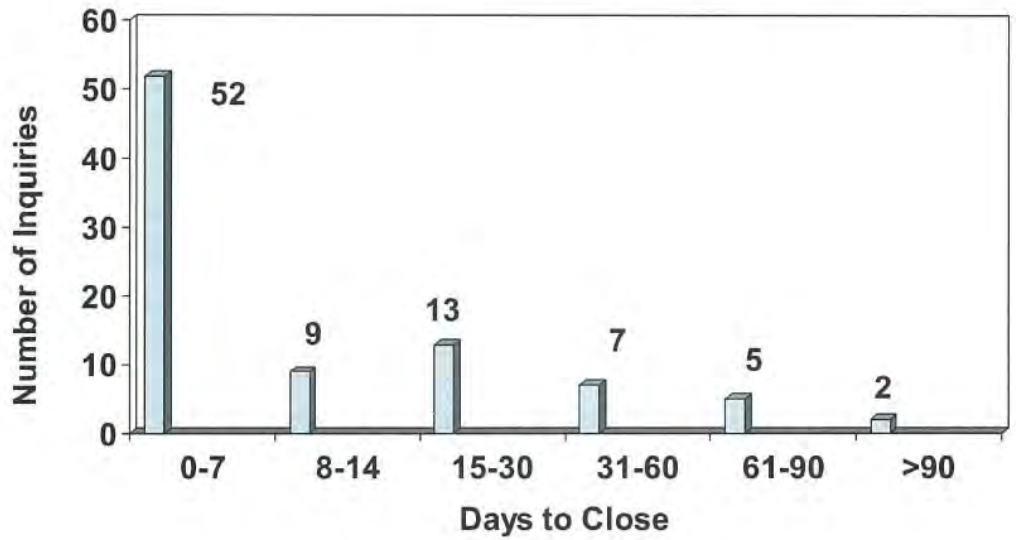


1Q 2011 Quarterly Compliance Report at PPLP004406041

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Inquiry Response Time

Days to Close Inquiries 1Q11 as of 4/4/11)



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1Q 2011 Quarterly Compliance Report at PPLP004406042

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Sales and Marketing

"Risk Area"	Activity
▪ Proper promotion	▪ Policies, training, monitoring
▪ CIA and Sales SOP Standards	▪ Focused actions, monitoring
▪ Material Review and use	▪ New electronic system
▪ Fee for service arrangements	▪ Meeting OIG Safe Harbor fully
▪ Speaker programs	▪ Training, monitoring
▪ Direct to consumer advertising	▪ Material review, monitoring
▪ E-marketing	▪ Material review, monitoring
▪ Sales force training	▪ Audit, monitoring
▪ Pricing	▪ Law & Finance oversight, audits
▪ Coupons / Value Cards	▪ Call note review, auditing
▪ Suspect prescribers	▪ "ADD" program, Law oversight

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2Q 2011 Quarterly Compliance Report at PPLP004406472

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Sales Force Monitoring

- *PLUS:*
  - Adverse Event Reporting
  - Medical Information Requests
  - Product Complaints
  - Abuse, Diversion Detection Reporting
  - Expense Reporting
  - Speaker Program monitoring
  - Live Training / Sales meetings
  - Hotline matters
  - Direct contacts to Compliance

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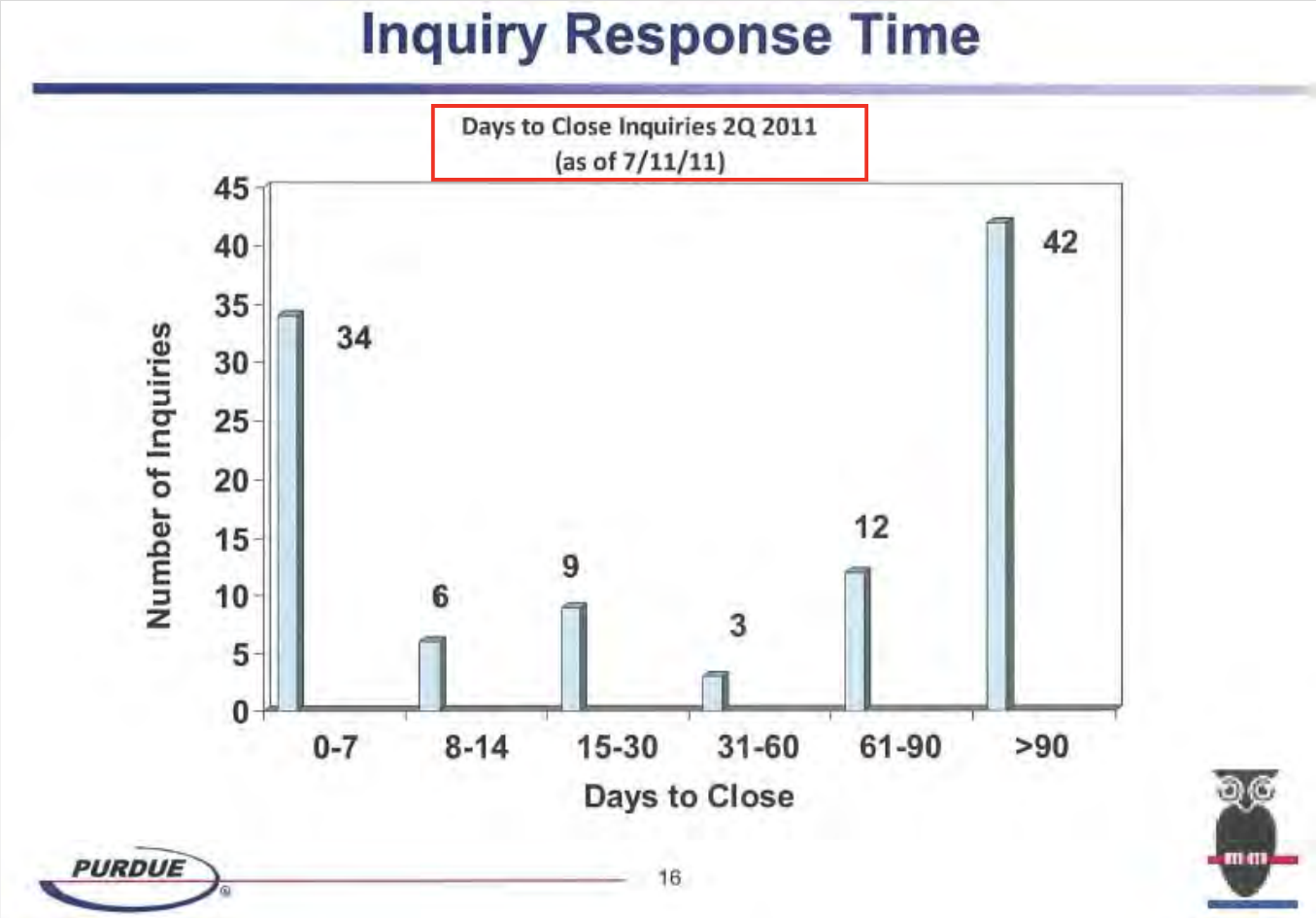
2Q 2011 Quarterly Compliance Report at PPLP004406485

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

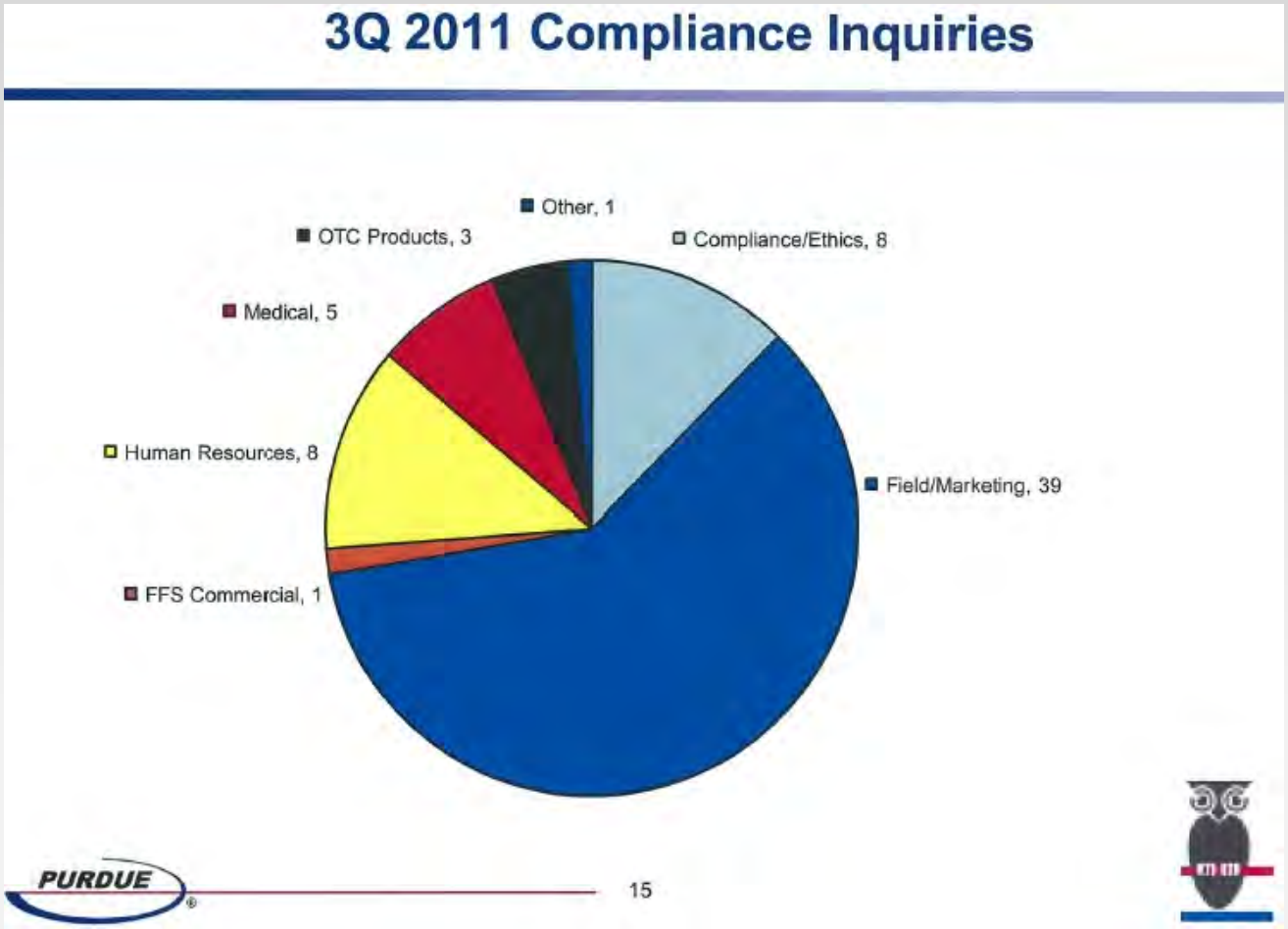
2Q 2011 Quarterly Compliance Report at PPLP004406480

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



2Q 2011 Quarterly Compliance Report at PPLP004406481

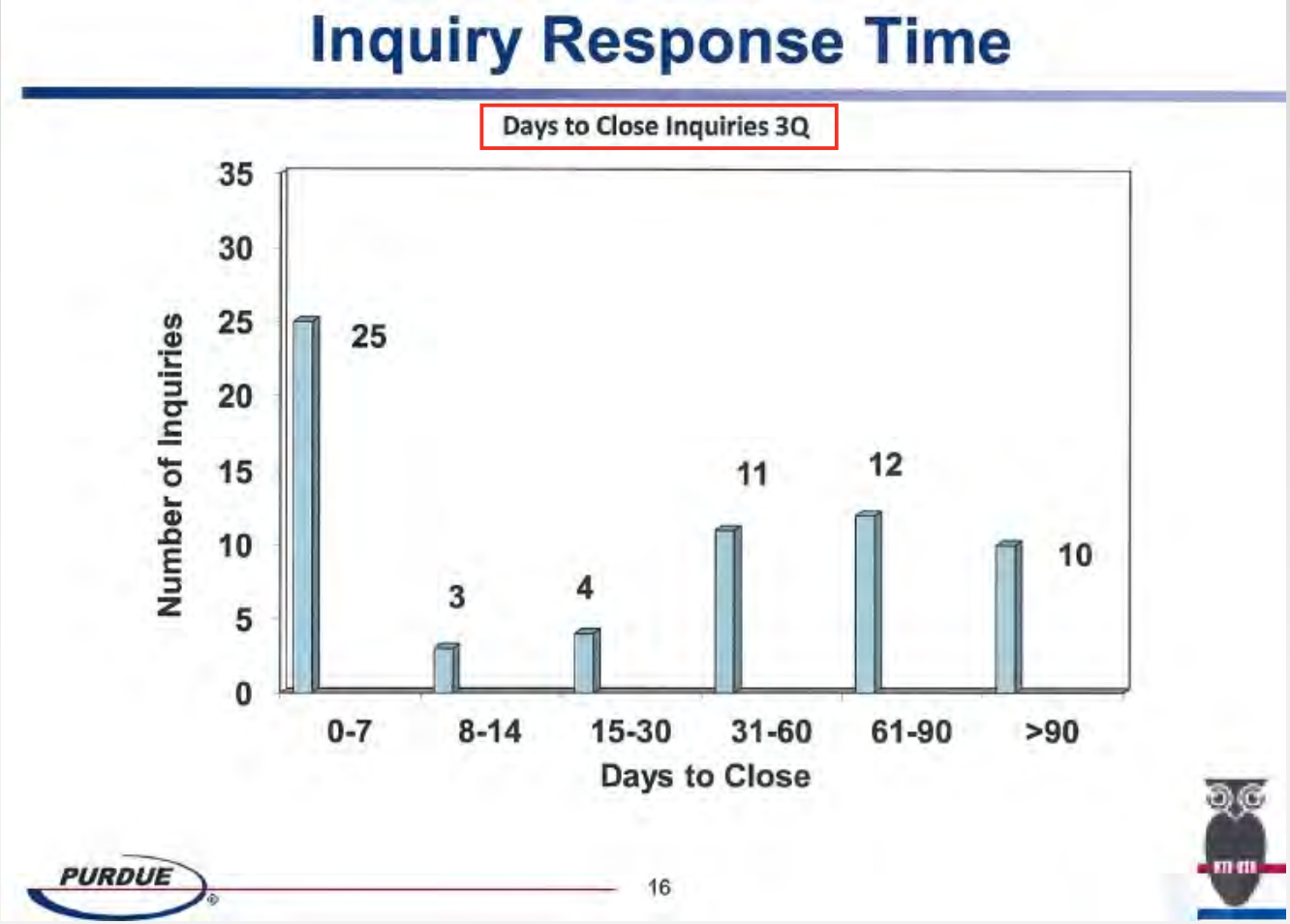
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



Abuse and Diversion, 0

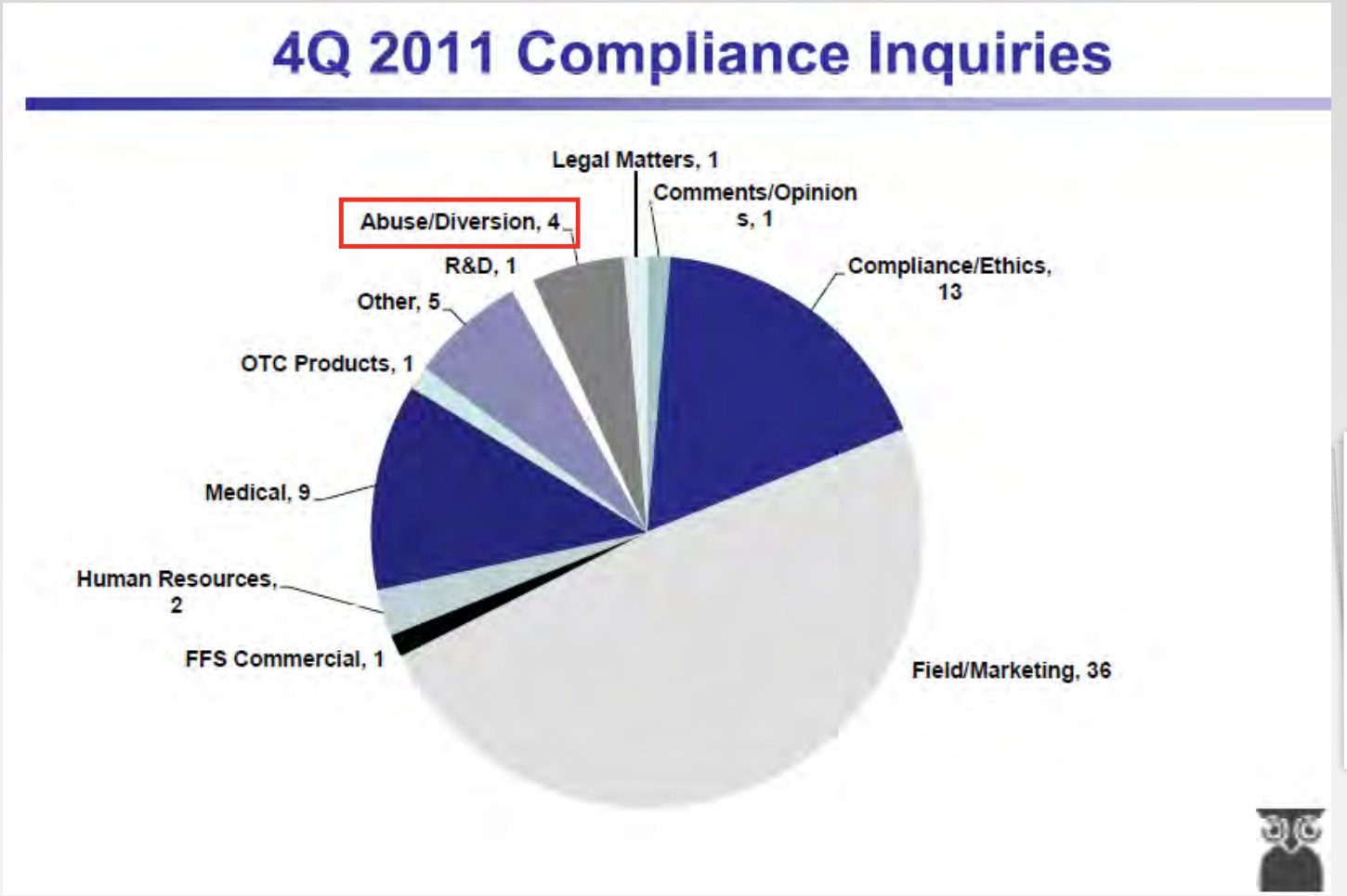
3Q 2011 Quarterly Compliance Report at PPLP004406804

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



3Q 2011 Quarterly Compliance Report at PPLP004406805

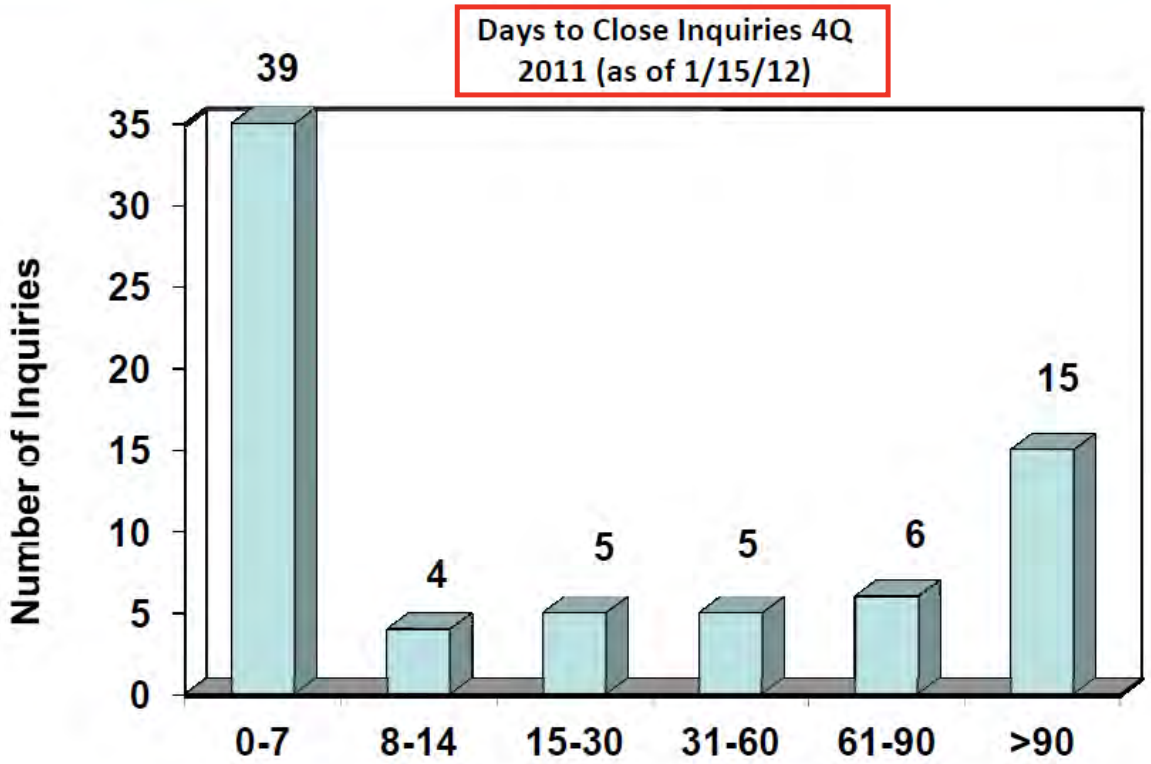
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



4Q 2011 Quarterly Compliance Report at PPLP004407567

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

4Q 2011 Inquiry Response Time




Corporate Compliance Quarterly Report to Board of Directors 4Q2011

January 19, 2012

Bert Weinstein
Vice President, Corporate Compliance

4Q 2011 Quarterly Compliance Report at PPLP004407568

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

Attorneys General Agreement

* 10 year AG Agreement, started in May 2007
* Purdue committed to continue OxyContin Abuse and Diversion Detection Program predicated on RSOP 1.7.1
* Annual reminder and training to employees continues
* Dear HCP Letter and Brochure providing written, non-branded education on abuse and diversion of opioids continues

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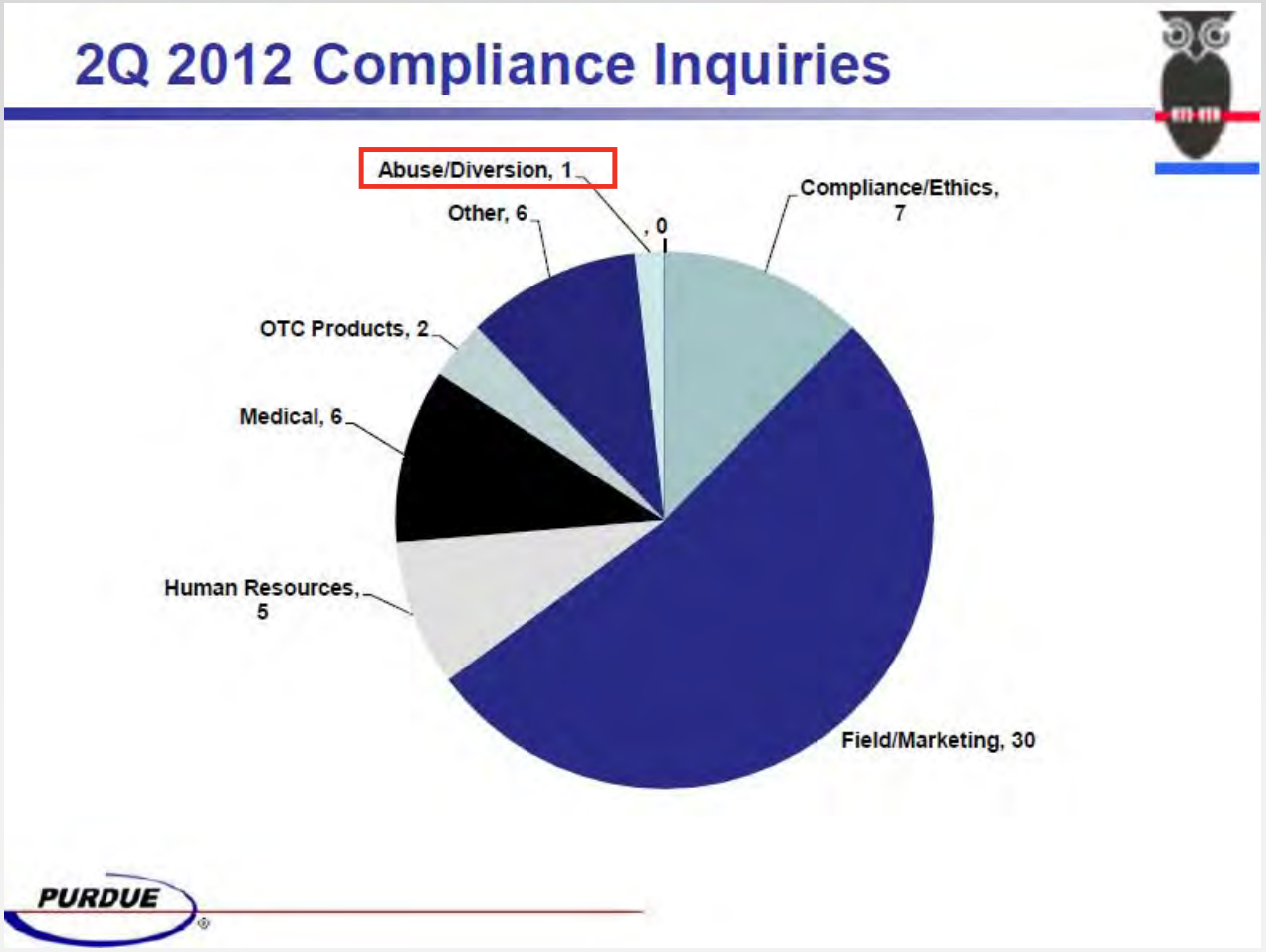
2Q 2012 Quarterly Compliance Report at PPLP004408055

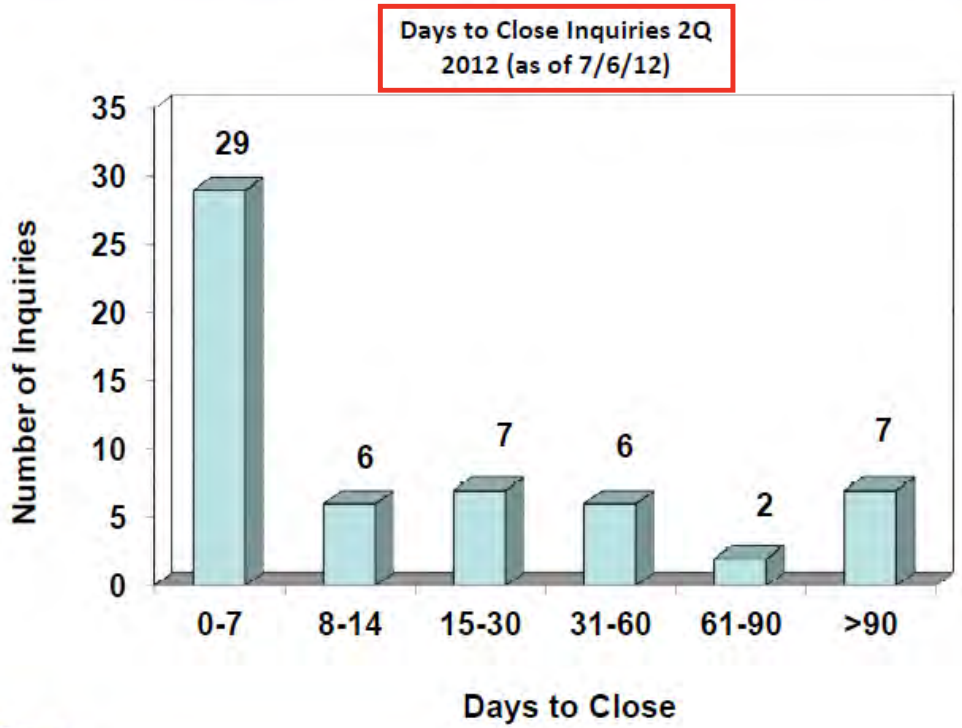
The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



2Q 2012 Quarterly Compliance Report at PPLP004408063

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts

2Q 2012 Inquiry Response Time



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Report to Board of Directors:

Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

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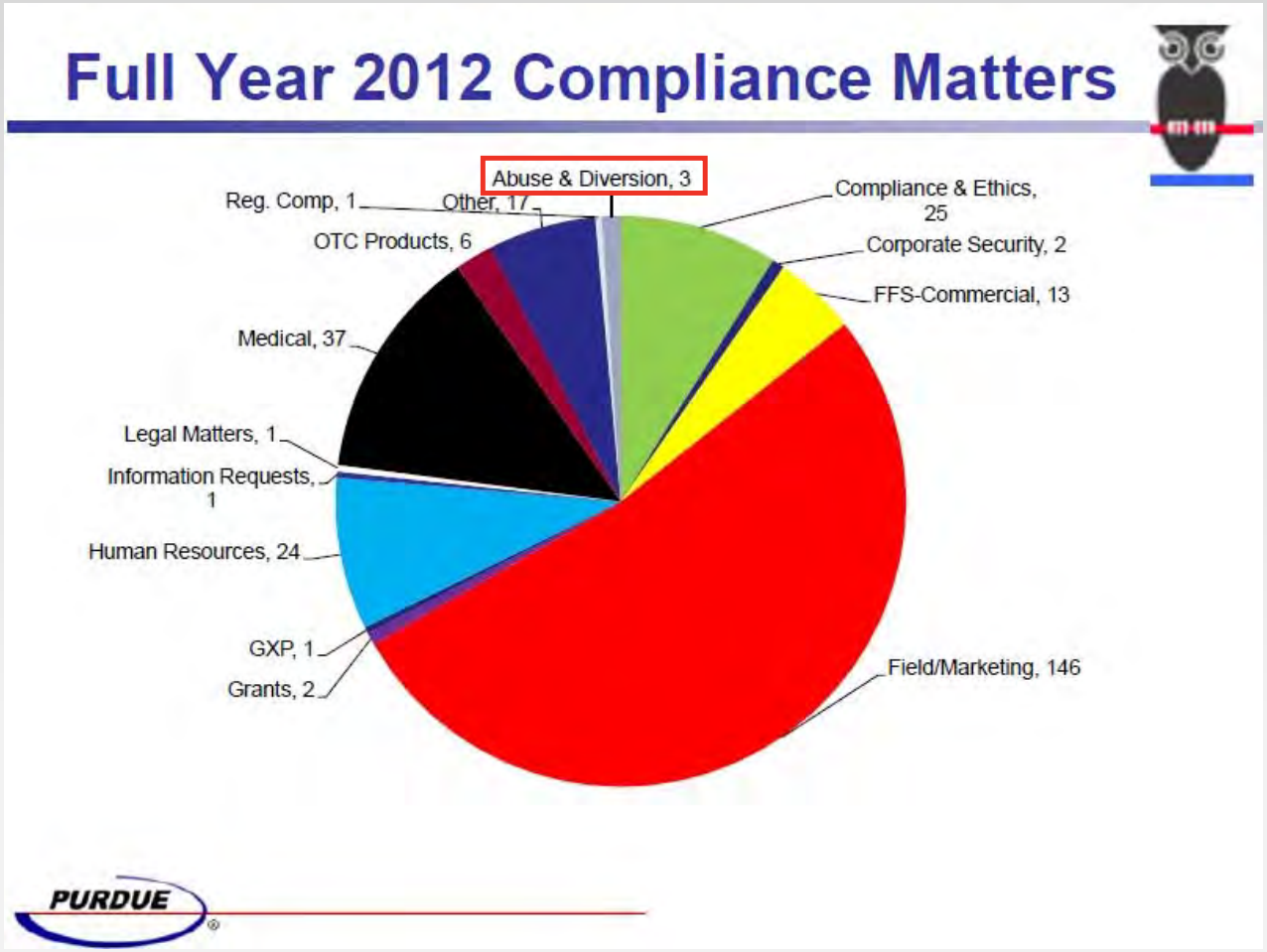
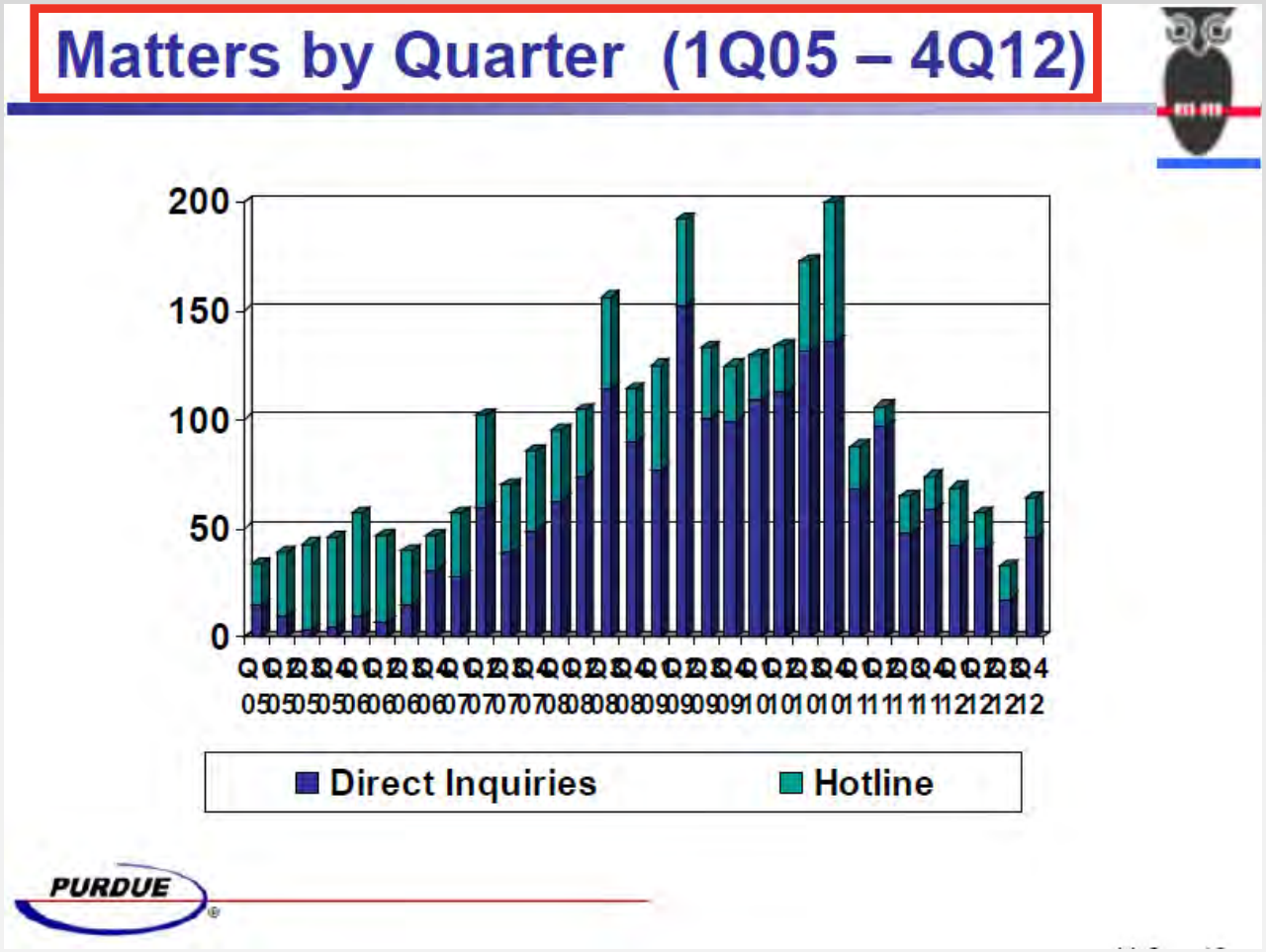
2Q 2012 Quarterly Compliance Report at PPLP004408064

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



4Q 2012 Quarterly Compliance Report at PPLP004409366

The Board Responsibly Monitored But Was Not Involved in Implementation of Purdue's Anti-Diversion Efforts



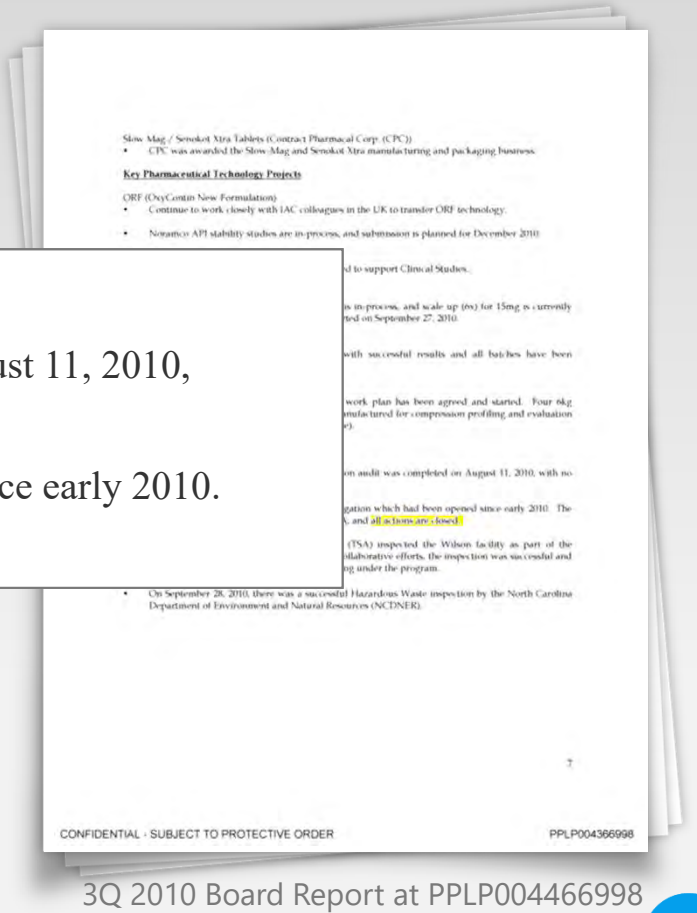
4Q 2012 Quarterly Compliance Report at PPLP004409364

The Board Understood That Purdue's Anti-Diversion Efforts Met DEA Requirements

3Q 2010 Board Report:

DEA / Security / EHS

- Successful DEA Importer / Exporter Registration audit was completed on August 11, 2010, with no observations or findings.
- DEA closed out the product diversion investigation which had been opened since early 2010. The improvement plans were shared with the DEA, and all actions are closed.


Slow Mag / Sensekot Xtra Tablets (Contract Pharmacal Corp. (CPC))
• CPC was awarded the Slow-Mag and Sensekot Xtra manufacturing and packaging business.

Key Pharmaceutical Technology Projects

ORF (OxyContin New Formulation)
• Continue to work closely with IAC colleagues in the UK to transfer ORF technology.
• Noramco API stability studies are in-process, and submission is planned for December 2010.

d to support Clinical Studies.

s in-process, and scale up (6x) for 15mg is currently ted on September 27, 2010.

with successful results and all batches have been

work plan has been agreed and started. Four 6kg nufactured for compression profiling and evaluation e).

on audit was completed on August 11, 2010, with no

gation which had been opened since early 2010. The . and all actions are closed.

(TSA) inspected the Wilson facility as part of the ollaborative efforts, the inspection was successful and ng under the program.

• On September 28, 2010, there was a successful Hazardous Waste inspection by the North Carolina Department of Environment and Natural Resources (NCDNER).

7

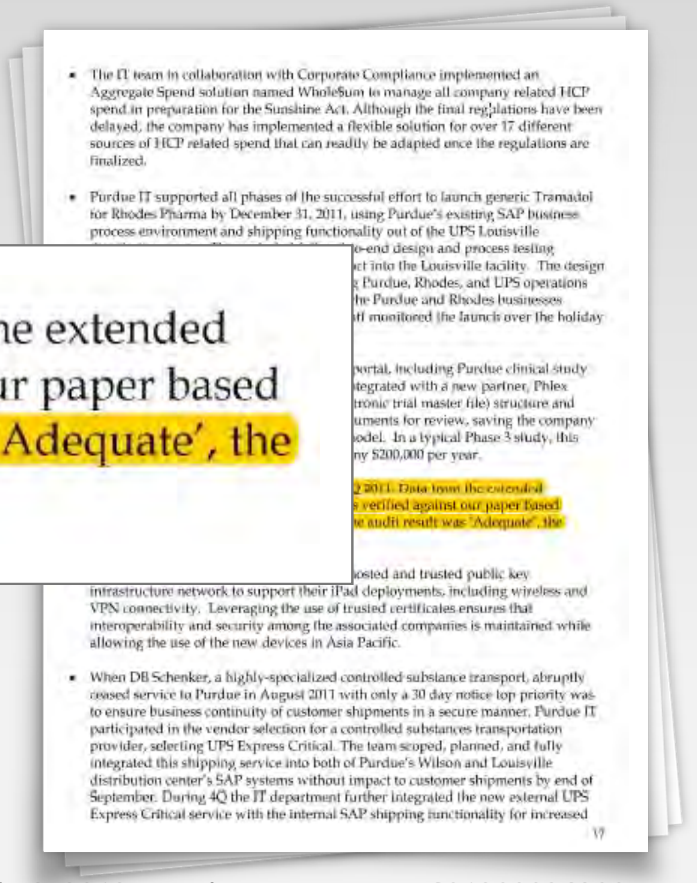
CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004366998

3Q 2010 Board Report at PPLP004466998

The Board Understood That Purdue's Anti-Diversion Efforts Met DEA Requirements

4Q 2011 Board Report:

- The Cranbury site hosted a DEA audit in 4Q 2011. Data from the extended Controlled Substance Inventory System was verified against our paper based inventory and used to support the audit. The audit result was 'Adequate', the highest determination given by the DEA.



- The IT team in collaboration with Corporate Compliance implemented an Aggregate Spend solution named WholeSum to manage all company related HCP spend in preparation for the Sunshine Act. Although the final regulations have been delayed, the company has implemented a flexible solution for over 17 different sources of HCP related spend that can readily be adapted once the regulations are finalized.
- Purdue IT supported all phases of the successful effort to launch generic Tramadol for Rhodes Pharma by December 31, 2011, using Purdue's existing SAP business process environment and shipping functionality out of the UPS Louisville
- ...end design and process testing
- ...ct into the Louisville facility. The design
- ...Purdue, Rhodes, and UPS operations
- ...he Purdue and Rhodes businesses
- ...tl monitored the launch over the holiday
- ...ortal, including Purdue clinical study
- ...tegrated with a new partner, Phlex
- ...tronic trial master file) structure and
- ...uments for review, saving the company
- ...odel. In a typical Phase 3 study, this
- ...ny $200,000 per year.
- ...2011. Data from the extended
- ...verified against our paper based
- ...e audit result was 'Adequate', the
- ...osted and trusted public key infrastructure network to support their iPad deployments, including wireless and VPN connectivity. Leveraging the use of trusted certificates ensures that interoperability and security among the associated companies is maintained while allowing the use of the new devices in Asia Pacific.
- When DB Schenker, a highly-specialized controlled substance transport, abruptly ceased service to Purdue in August 2011 with only a 30 day notice top priority was to ensure business continuity of customer shipments in a secure manner. Purdue IT participated in the vendor selection for a controlled substances transportation provider, selecting UPS Express Critical. The team scoped, planned, and fully integrated this shipping service into both of Purdue's Wilson and Louisville distribution center's SAP systems without impact to customer shipments by end of September. During 4Q the IT department further integrated the new external UPS Express Critical service with the internal SAP shipping functionality for increased

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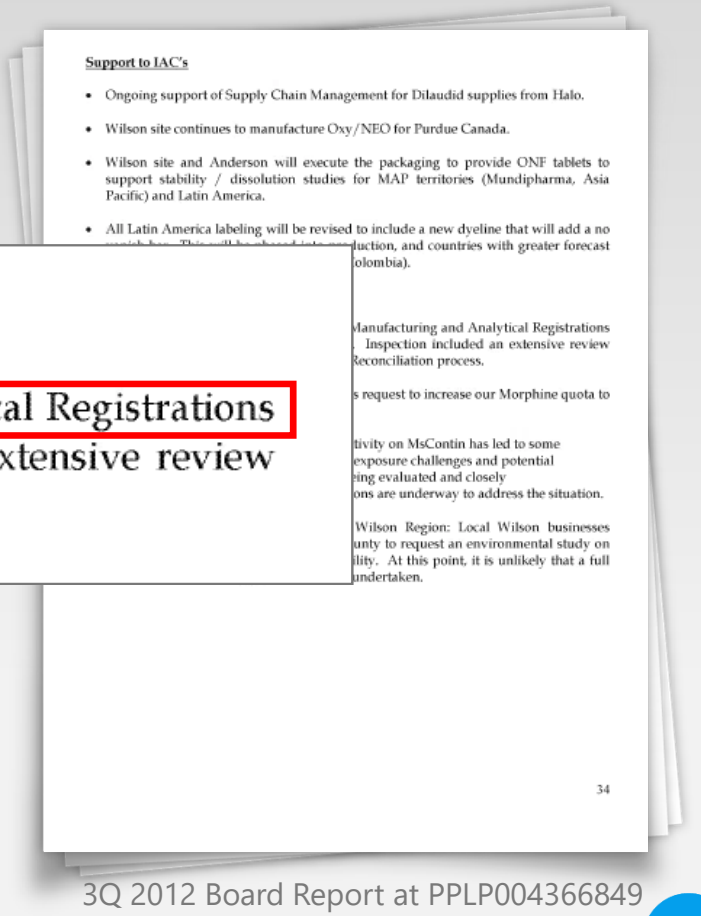
Feb. 2, 2012 Board Report at PPLPC012000362905

The Board Understood That Purdue's Anti-Diversion Efforts Met DEA Requirements

3Q 2012 Board Report:

DEA Requirements / Compliance

- July 2012: Successful DEA Inspection of Manufacturing and Analytical Registrations resulted in no observations or violations. Inspection included an extensive review and approval of the Tablet Counting and Reconciliation process.



Support to IAC's

- Ongoing support of Supply Chain Management for Dilaudid supplies from Halo.
- Wilson site continues to manufacture Oxy/NEO for Purdue Canada.
- Wilson site and Anderson will execute the packaging to provide ONF tablets to support stability / dissolution studies for MAP territories (Mundipharma, Asia Pacific) and Latin America.
- All Latin America labeling will be revised to include a new dyeline that will add a no

olombia).

Manufacturing and Analytical Registrations
Inspection included an extensive review
Reconciliation process.

s request to increase our Morphine quota to

tivity on MsContin has led to some
exposure challenges and potential
ing evaluated and closely
ons are underway to address the situation.

Wilson Region: Local Wilson businesses
unty to request an environmental study on
lity. At this point, it is unlikely that a full
undertaken.

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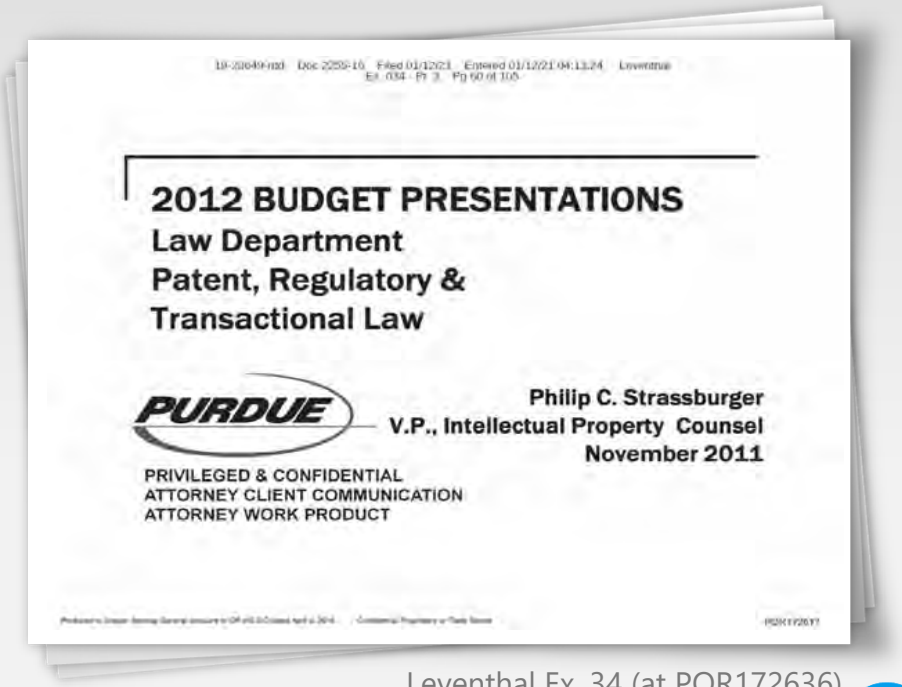
3Q 2012 Board Report at PPLP004366849

The Board Understood That Purdue's Anti-Diversion Efforts Met DEA Requirements

2012 Budget Presentation to Board (Nov. 2011):

Avoiding Risks – Dialogue with DEA regarding ORF

- Sharing data based upon transition to ORF
  - Prescriber data analysis shared in April 2011
  - Pharmacy data analysis shared in October 2011
- DEA feedback on ORF
  - Statements of Barbara Boockholdt, Chief, Regulatory Section, DEA, Office of Diversion Control
    - ORF has made a tremendous difference
    - No longer hear about OxyContin from field offices
    - ORF is saving lives
- Plan presentation on epidemiology study results



2012 BUDGET PRESENTATIONS
Law Department
Patent, Regulatory & Transactional Law

PURDUE

Philip C. Strassburger
V.P., Intellectual Property Counsel
November 2011

PRIVILEGED & CONFIDENTIAL
ATTORNEY CLIENT COMMUNICATION
ATTORNEY WORK PRODUCT

Leventhal Ex. 34 (at POR172636)

The Directors Responsibly Monitored But Did Not Personally Participate in Purdue's Anti-Diversion Efforts And Are Not Liable For Any Failures

- Directors are not liable for the torts of their corporation unless they personally participate in some wrongdoing
  - There is no claim and not evidence that the directors participated in Purdue's anti-diversion activities or took any steps to undermine them
- The directors received continual reports from Purdue management about its vigorous implementation of the anti-diversion programs on which they were entitled to rely
- The Board understood that Purdue's anti-diversion efforts were succeeding based on presentations from management and the findings of the auditor reporting to the New York Attorney General
- The Controlled Substances Act and similar state statutes impose duties on companies, not their directors

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 3: Diversion

April 26, 2021

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 4: Fraudulent Transfer

April 27, 2021

Distributions To The Sackler Families Were Not Fraudulent Transfers

Two Types of Fraudulent Transfer

1. **Actual-intent fraudulent transfer:**

   New York Debtor & Creditor Law ("DCL") §276

   "Every conveyance made and every obligation incurred with actual intent, as distinguished from intent presumed in law, to hinder, delay, or defraud either present or future creditors, is fraudulent as to both present and future creditors."

2. **Constructive fraudulent transfer — Claimant must prove transfers were made without fair consideration while the transferor:**
   - **Was insolvent** (DCL §§271, 273)
   - **Was undercapitalized** (DCL §274), or
   - **Believed or intended to incur debts beyond the transferor's ability to pay as the debts mature** (DCL §275)

Four Insurmountable Problems

1. There was no intent to defraud — Purdue did not in fact perceive a threat from opioid litigation before 2017 and did not face meaningful litigation until 2017

2. When the avalanche of litigation hit in 2017, the Board immediately ceased distributions

3. Purdue was not insolvent when the distributions were made — its sales were in the billions, and the Board left enormous amounts of cash in Purdue every year *after* distributions

4. Purdue's — and other opioid manufacturers' — experience with opioid litigation and access to capital markets shows why Purdue did not anticipate liabilities beyond its ability to pay

Overwhelming Evidence Vitiates Any Claim of Actual Or Constructive Fraudulent Transfer

- Over 2/3 of all distributions — $6.9 of $10.3 billion — were made in 2008-12, when a federal monitor was overseeing Purdue and assuring the Board that Purdue was operating in compliance with its Corporate Integrity Agreement
- The Board kept enormous amounts of cash in Purdue at all times that distributions were made — over $1 billion a year from 2014 on
- Far from stripping Purdue of assets, the Board invested over a billion dollars in Purdue research and development
- Before 2017, management's detailed reports and projections consistently advised the Board that the risk of opioid litigation was low and declining

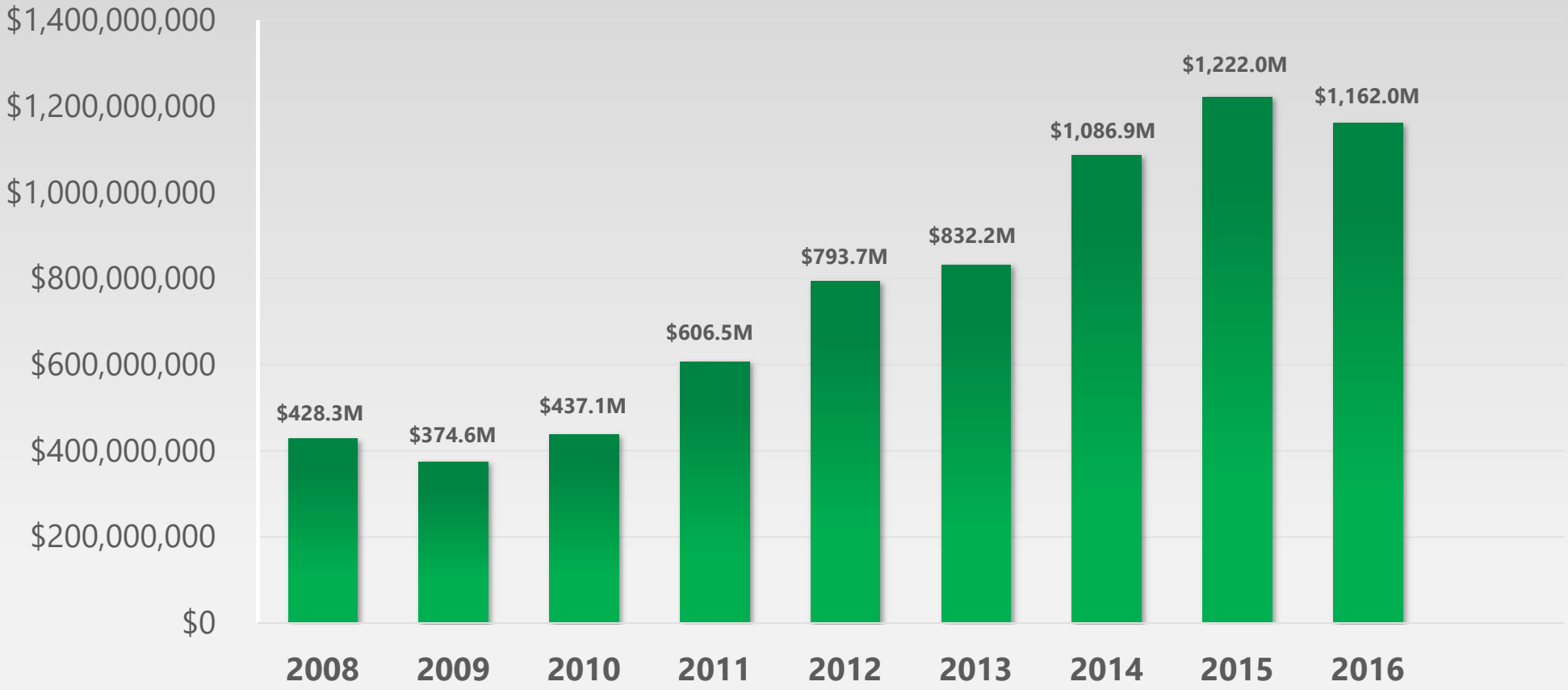
Overwhelming Evidence Vitiates Any Claim of Actual Or Constructive Fraudulent Transfer

- None of the litigations that led to bankruptcy began until 2014; there were only 5 cases before 2017; and distributions ended when hundreds of cases hit in 2017
- Nothing in other opioid manufacturers' litigation experience indicated a litigation risk for Purdue when the distributions were made
- Sophisticated financial parties — JPMorgan in 2014, Moody's and S&P in 2016 — found Purdue creditworthy and did not foresee the avalanche of litigation that descended on Purdue in 2017
- Other opioid manufacturers' access to capital markets confirms that sophisticated financial parties did not see material opioid litigation risk for the industry at the time distributions were made

Overwhelming Evidence Vitiates Any Claim of Actual Or Constructive Fraudulent Transfer

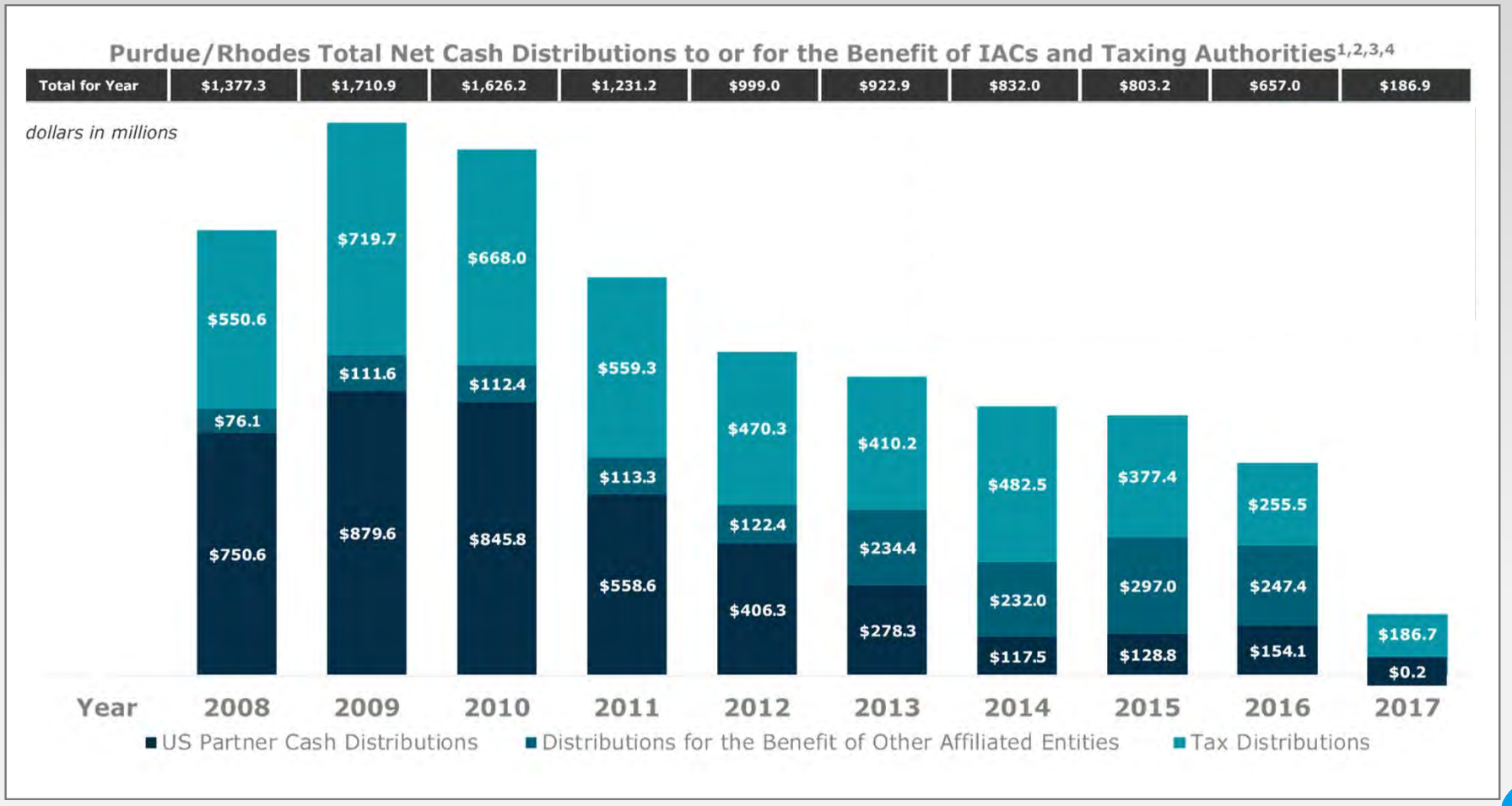
- **The Board was proactive in implementing a strict compliance regimen at Purdue, requiring all 7 elements of an effective compliance program as determined by the OIG of HHS and the Sentencing Guidelines** (Defense Presentation Part 1)
- **The Board monitored Purdue's implementation of all elements of the compliance program** (Defense Presentation Parts 1 and 3)
- **The Board incentivized compliance by incorporating it into bonus calculations** (Defense Presentation Part 1)

The Board Left Enormous Amounts of Unrestricted Cash In Purdue After Distributions



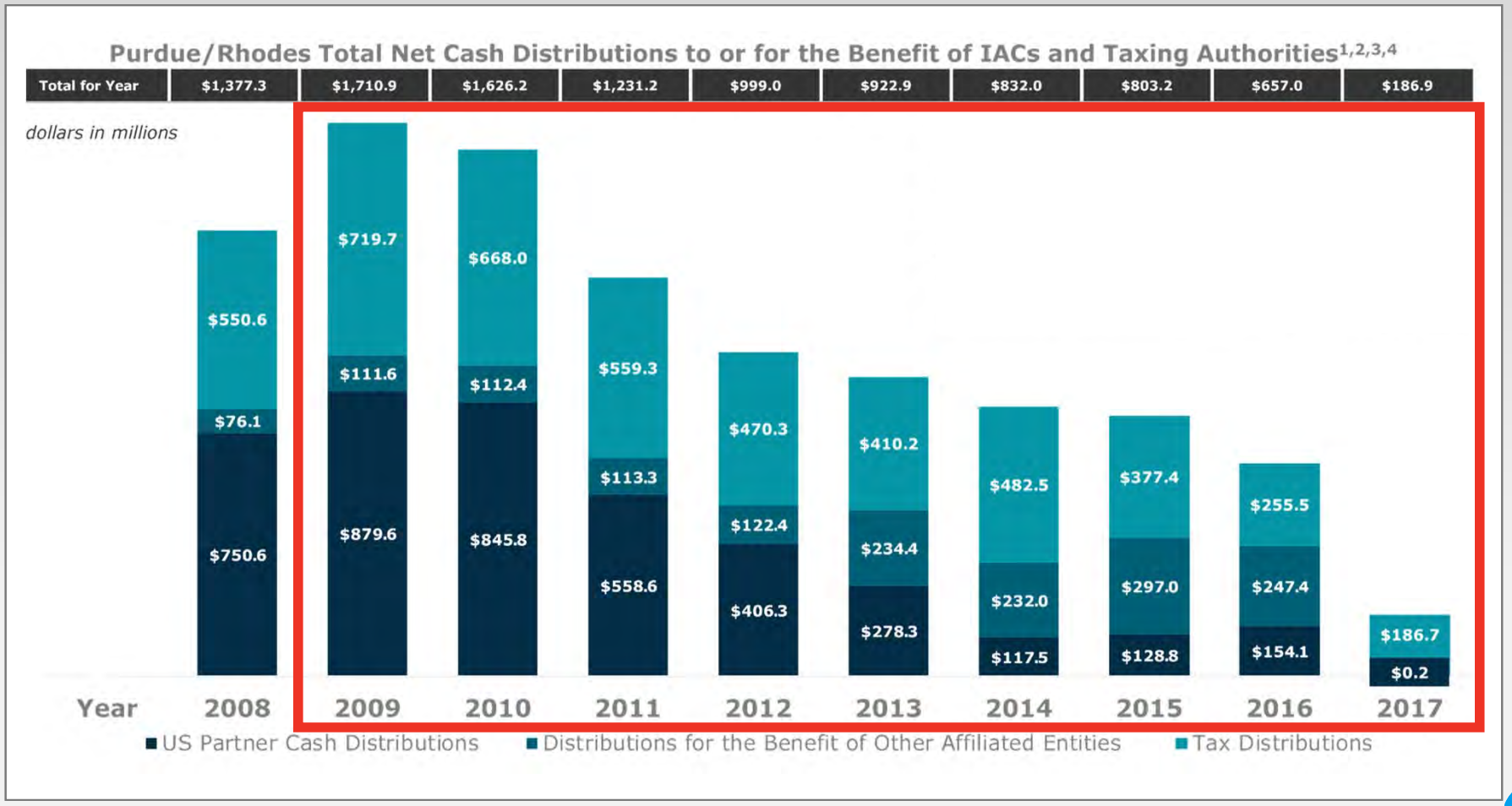
Sources: PPLPC031001244649 (2008-12); PPLPC051000265076 (2013-14); PPLPC045000018249 (2015); PPLPC032000398822 (2016)

The Board Shrank Distributions As It Increased Cash In Purdue



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11 (SDNY (Bankr.) No. 19-23649-rdd Doc 654-1)

The Board Shrank Distributions As It Increased Cash In Purdue



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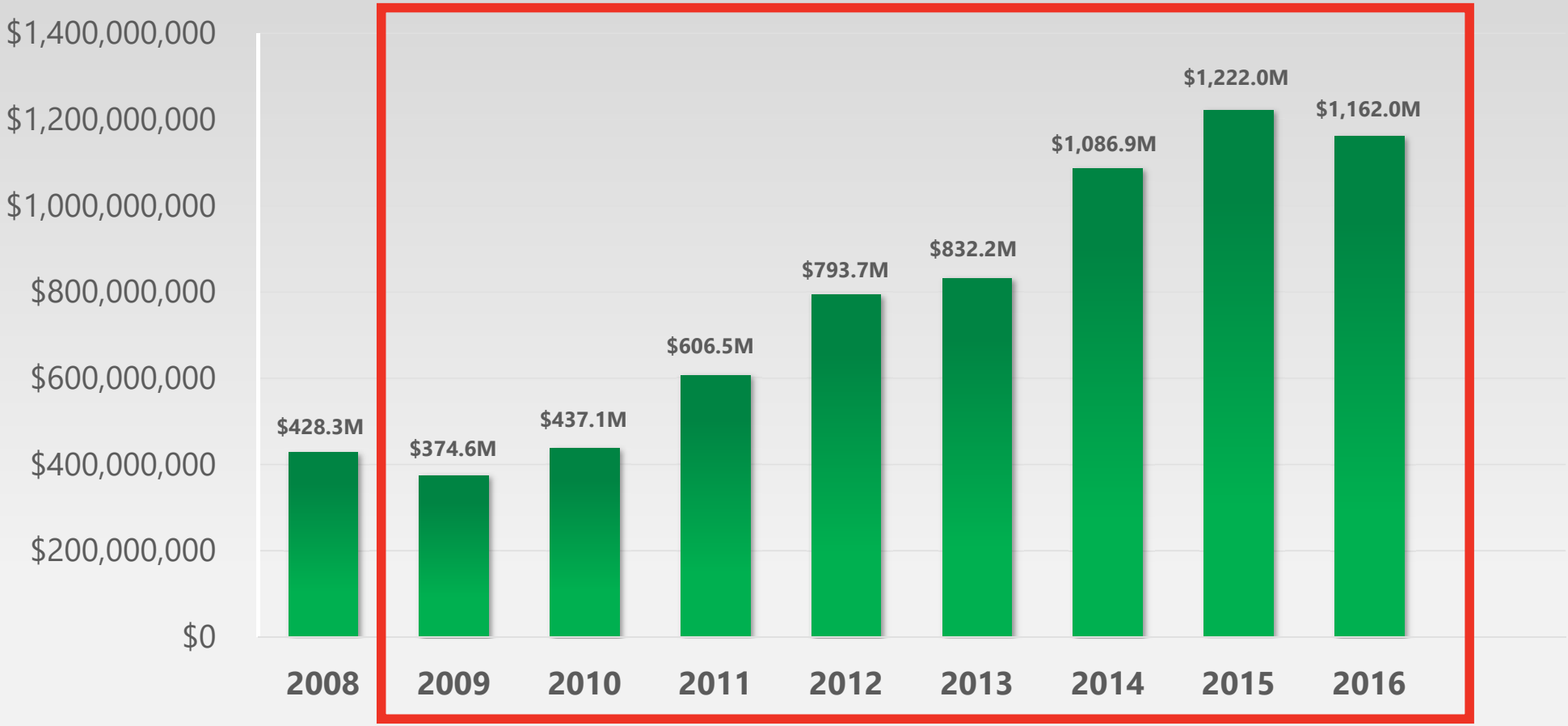
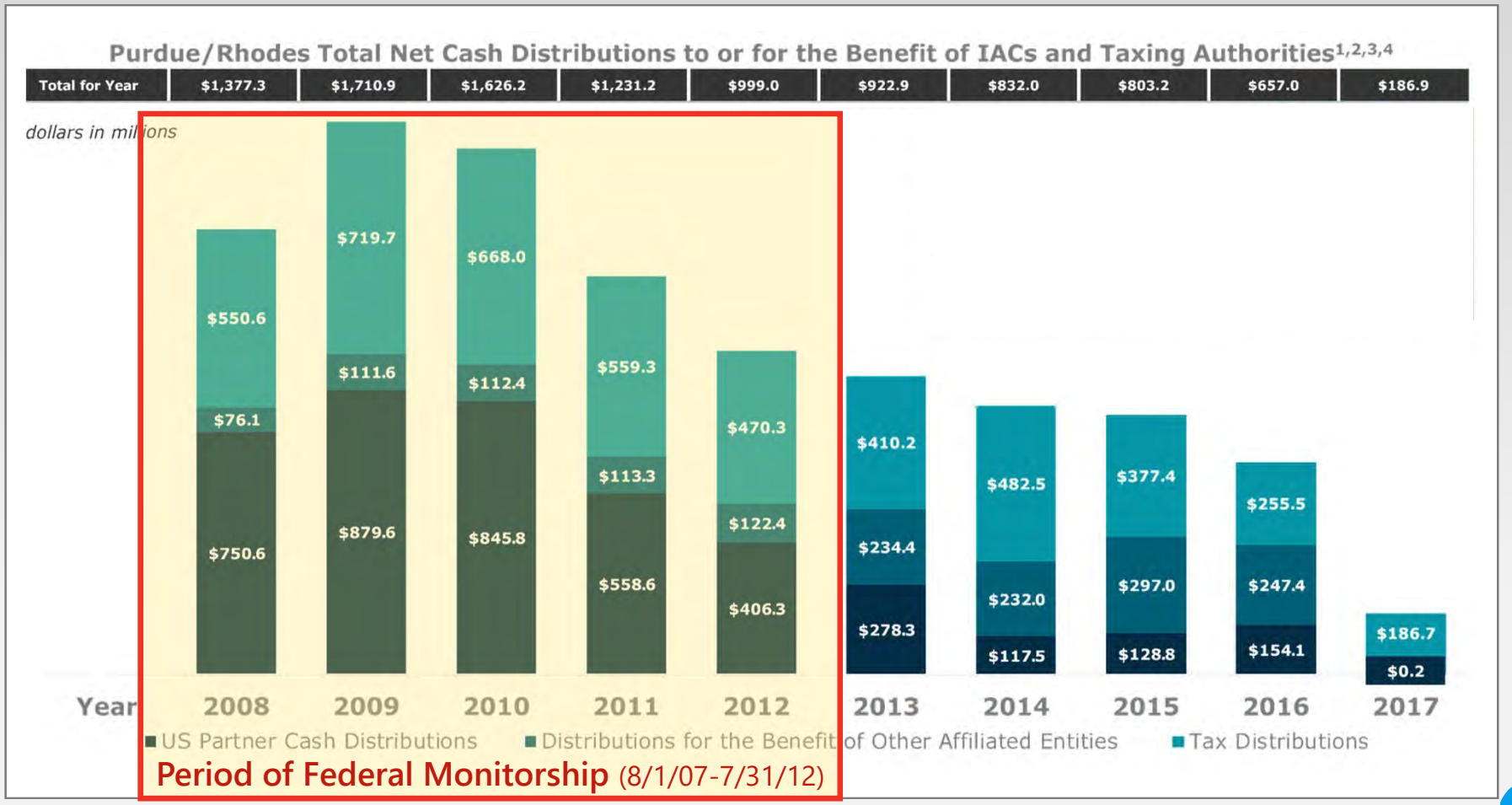


Sources: PPLPC031001244649 (2008-12); PPLPC051000265076 (2013-14); PPLPC045000018249 (2015); PPLPC032000398822 (2016)

Over 2/3 of Distributions Were Made While the Federal Monitor Was Assuring the Board Purdue Was in Compliance with Its CIA

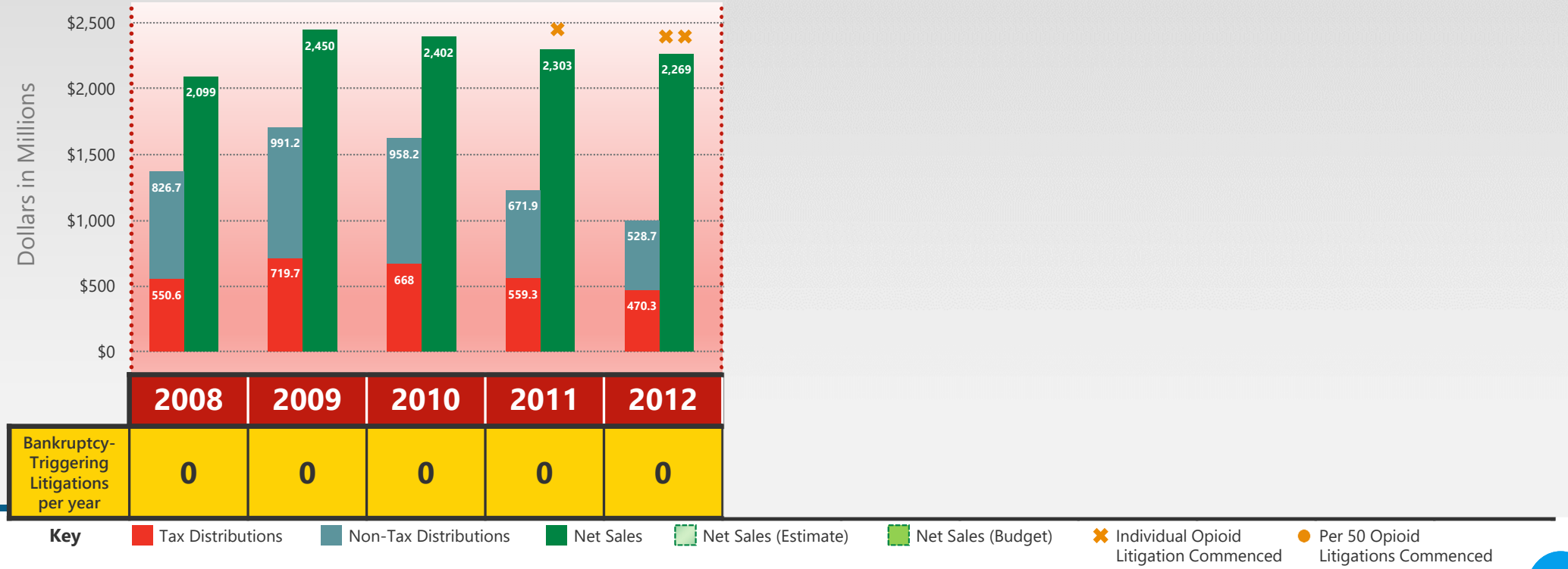


AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11 (SDNY (Bankr.) No. 19-23649-rdd Doc 654-1)

Purdue Did Not Face Meaningful Litigation Until 2017 — And Then Immediately Ceased Distributions

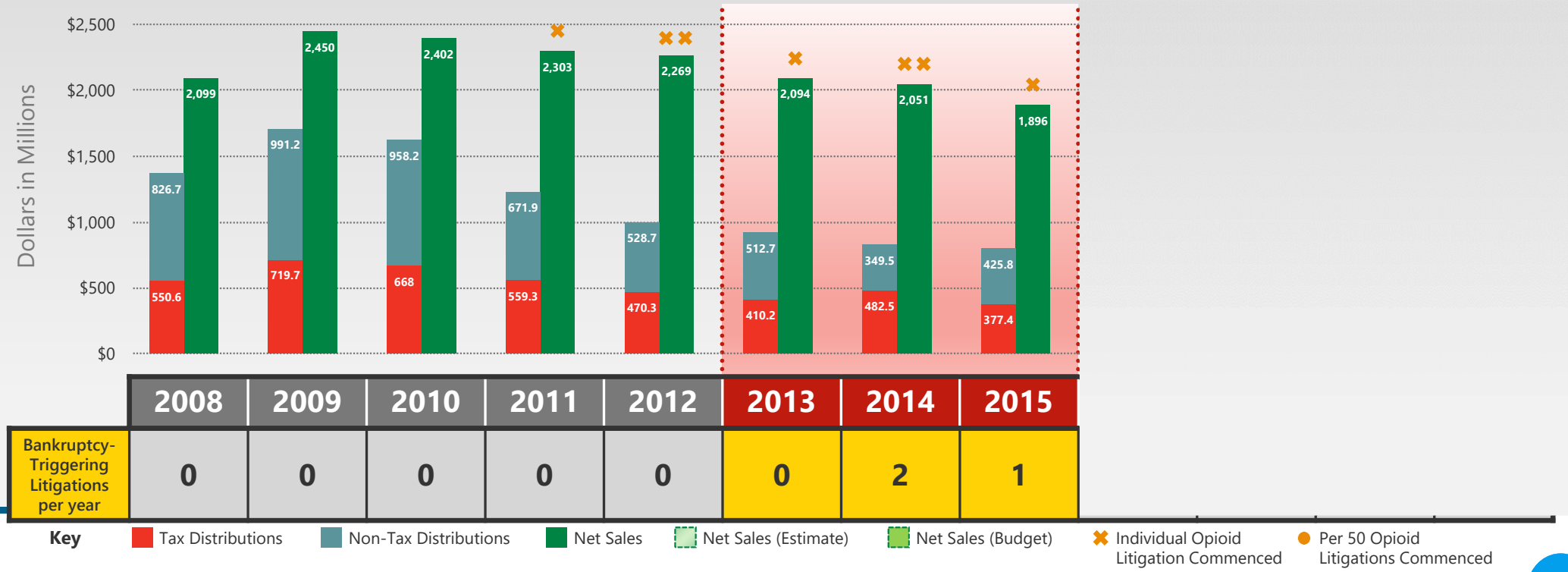
2008–2012: $6,944,600 in Distributions — No New Cases in 5 Years

- By mid-2007, Purdue had settled Federal and State claims, all well within its ability to pay
- Purdue was subject to a federal monitor through July 2012 to ensure compliance with its CIA
- None of the cases that ultimately triggered bankruptcy were filed in these years



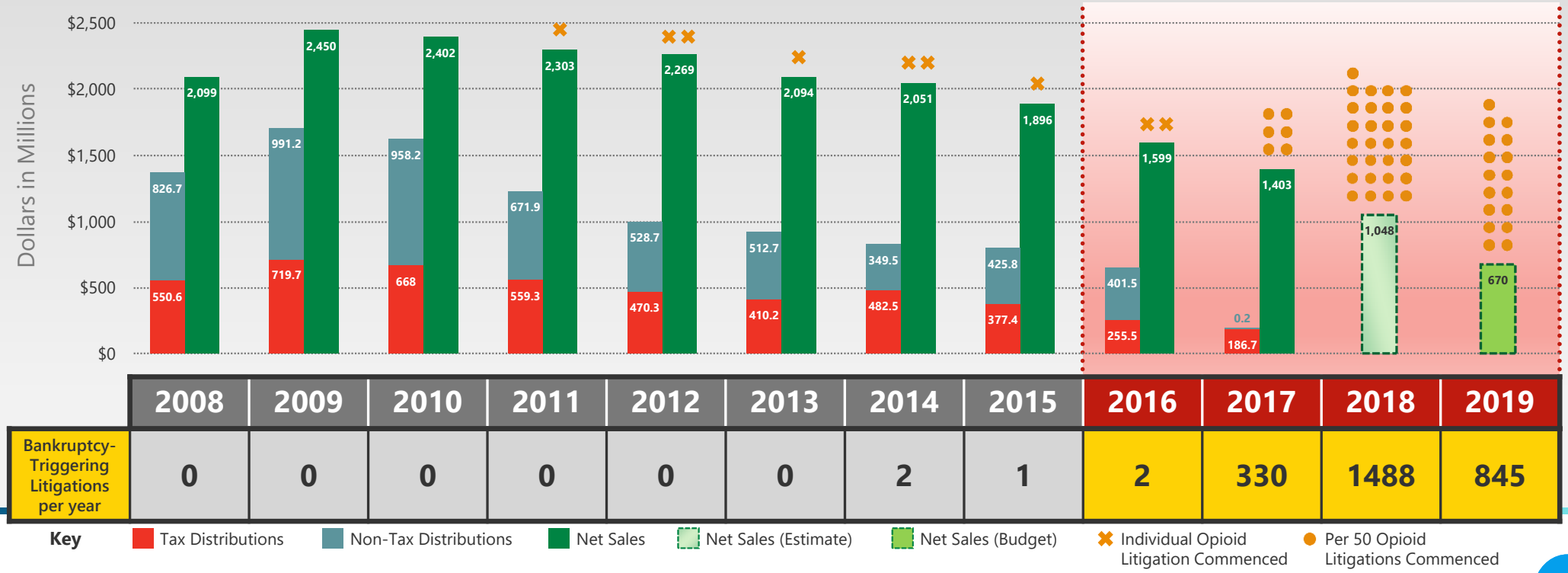
2013–2015: $2,588,100,000 In Distributions — 3 New Cases in 3 Years

- Purdue began receiving requests for information and subpoenas related to marketing of opioids
- In 2015, Purdue settled New York's investigation paying $75,000, and a longstanding Kentucky litigation for $24 million over 8 years



2016: $657,000,000 In Distributions – 2 New Cases

- Only 2 more governmental litigations filed
- No reason to believe governmental investigations/litigations could not be resolved at or below Kentucky payment, which was inflated due to a procedural default



After 2007, Management Consistently Advised The Board That Litigation Risk Was Low And Declining

In January 2008, Management Advised the Board That All OxyContin Litigation Could Be Closed Out for $200 Million

January 11, 2008 Board Agenda Book:

Funds Available for Investment

- Given the recent Stein decision Purdue will have significant funds to deploy.
- Thoughts:
  - Looking forward to 2009 and assuming more favorable developments this could grow to over $2 billion.
  - The $1.2 billion end 2008 balance could be allocated, for example, as follows:
    - Working Capital (at 2 months sales) = $0.3 billion
    - Restricted Cash for insurance, lease etc = $0.1 billion
    - Possible Reserve for Closing Out OxyContin Litigation = $0.2 billion
    - Reserve to fund POA & other internal products into say 201X =
    - Distributions (tax distributions already funded) =
    - New products not already funded =

    } $0.5 billion
  - If exclusivity is maintained even into 2009 the investment funds would increase.

PURDUE

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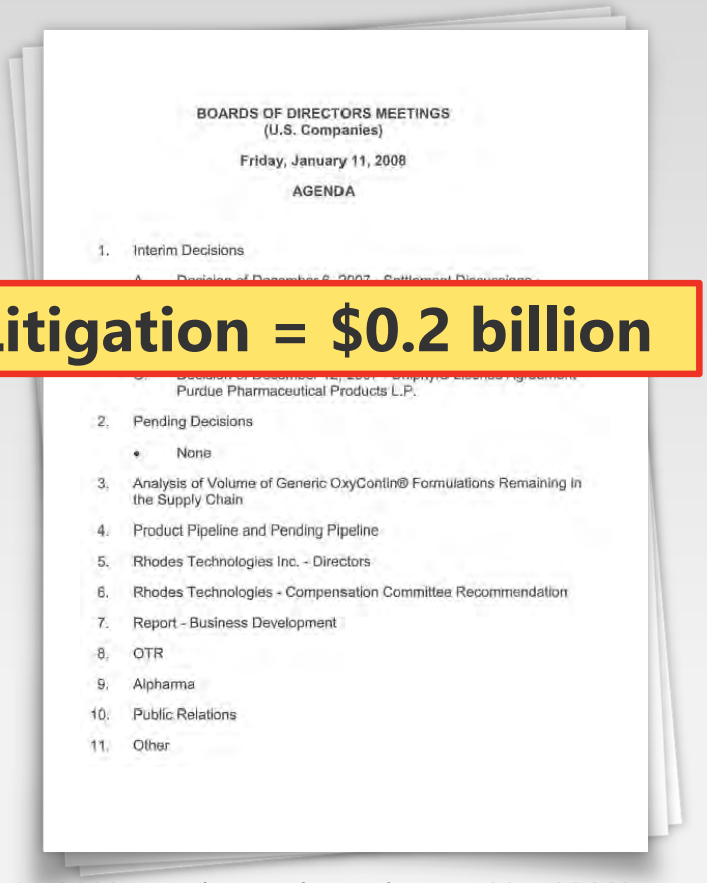
- **Possible Reserve for Closing Out OxyContin Litigation = $0.2 billion**



BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Friday, January 11, 2008

AGENDA

1. Interim Decisions
   - Purdue Pharmaceutical Products L.P.
2. Pending Decisions
   - None
3. Analysis of Volume of Generic OxyContin® Formulations Remaining in the Supply Chain
4. Product Pipeline and Pending Pipeline
5. Rhodes Technologies Inc. - Directors
6. Rhodes Technologies - Compensation Committee Recommendation
7. Report - Business Development
8. OTR
9. Alpharma
10. Public Relations
11. Other

1/11/2008 Board Agenda Book (PPLP004400663)

In 2009, Management Projected Shrinking Legal Fees

November 3, 2009 Board Agenda Book:

Legal Fees

$MMs	2005 Actual	...	2008 Actual	2009 Budget	2009 Latest Estimate	2010 Budget Proposal	Variance - '10 vs. '09 Favorable/ (Unfavorable)
Product Litigation[1]	**$74.7**		**$18.6**	**$20.0**	**$15.0**	**$10.0**	**$5.0**
Antitrust	**0.8**		**0.5**	**6.0**	**1.4**	**2.4**	**(1.0)**
Government Related Litigation	**9.1**		**3.5**	**3.0**	**2.5**	**2.0**	**0.5**
Oxy Patent - U.S.	0.7		1.8	6.5	2.0	3.6	(1.6)
Oxy Patent - ex. U.S.	4.1		13.9	5.3	7.0	7.5	(0.5)
Tramadol	-		11.8	1.0	10.9	1.7	9.2
Tramadol Cost Recoveries	-		(6.1)	(0.7)	(6.4)	(0.7)	(5.7)
Other Patent Litigation	1.9		2.0	1.5	1.5	4.0	(2.5)
Total Patent Litigation	**6.7**		**23.3**	**13.6**	**15.0**	**16.1**	**(1.1)**
Patent Prosecution	10.9		15.4	12.3	15.6	15.3	0.3
Patent Due Diligence	0.3		0.7	1.1	1.4	1.4	0.0
Total Patent Prosecution	**11.2**		**16.1**	**13.4**	**17.1**	**16.7**	**0.4**
All Other Legal Fees[2]	24.4		16.1	13.4	12.5	13.7	(1.3)
TOTAL LEGAL FEES	**$126.8**		**$78.0**	**$69.3**	**$63.5**	**$61.0**	**$2.5**

Footnotes:

1. Insurance recoveries collected to date total $337 mm ($134 mm for settlements, $203 mm for legal fees).
2. All Other includes insurance coverage, corporate litigation & non-litigation, employment litigation and Chadbourne corporate fees. Chadbourne's fee budget on this line is $7.7 mm, consistent with prior years. In addition, the product litigation budget includes $1.2 mm in Chadbourne fees.

PURDUE

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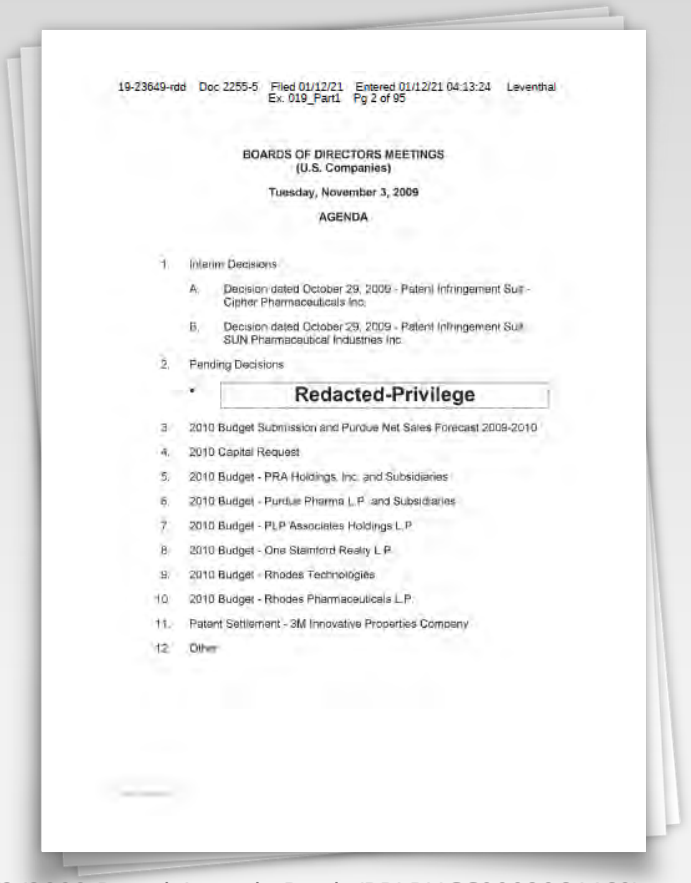


19-23649-rdd Doc 2255-5 Filed 01/12/21 Entered 01/12/21 04:13:24 Leventhal Ex. 019_Part1 Pg 2 of 95

BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

Tuesday, November 3, 2009

AGENDA

1. Interim Decisions
   - A. Decision dated October 29, 2009 - Patent Infringement Suit - Cipher Pharmaceuticals Inc.
   - B. Decision dated October 29, 2009 - Patent Infringement Suit - SUN Pharmaceutical Industries Inc.
2. Pending Decisions
   - Redacted-Privilege
3. 2010 Budget Submission and Purdue Net Sales Forecast 2009-2010
4. 2010 Capital Request
5. 2010 Budget - PRA Holdings, Inc. and Subsidiaries
6. 2010 Budget - Purdue Pharma L.P. and Subsidiaries
7. 2010 Budget - PLP Associates Holdings L.P.
8. 2010 Budget - One Stamford Realty L.P.
9. 2010 Budget - Rhodes Technologies
10. 2010 Budget - Rhodes Pharmaceuticals L.P.
11. Patent Settlement - 3M Innovative Properties Company
12. Other

11/3/2009 Board Agenda Book (PPLPUCC9002964468)

By 2010, Products Liability Litigation Against Purdue Was Almost Nonexistent

Year	Number of Products Liability Suits Pending Against Purdue	Number Being Actively Litigated
2010-11	24	3
2011-12	21	3
2012-13	21	3
2013-14	19	1
2014-15	18	0
2015-16	19	0

Lev. Opp. Exhs. 40 at -574; 47 at -208; 62 at -655; 74 at -570; 77 at-304 (Ernst & Young-Audited Combined Financial Statements of Purdue Pharma LP and Certain Associated Companies)) PPLPMDL0040000537, PPLPC029000544175, POK003285615, PPLPC011000090527, PPLPC021000890262)

By 2013, Management Projected Almost a 20% Reduction in Legal Fees over the Next Four Years

2013 10-Year Plan: Legal Fees Projected for All Litigation ($ millions)

2013	2014	2015	2016	2017
51	49.9	48.2	44.1	42.2

6/21/2011 Purdue 10-Year Plan (PPLPC042000023888); May 9, 2013 10-Year Plan (PPLPC063000003584)

By 2013, Future Governmental Litigation Was Expected to be De Minimis

2013 10-Year Plan: Legal Fees Projected for Government Litigation ($ millions)

2013	2014	2015	2016	2017	2018	2019
1.5	1.0	1.0	1.1	1.2	1.2	1.3

May 9, 2013 10-Year Plan (PPLPC063000003584)

In 2014, The Board Was Advised That Legal Fees Were Expected to Decline by Almost 70% over the Next Decade

May 15, 2014 Board Agenda Book:

Operating Expenses – G&A and Legal Fees

	2013A	2014LE	2015	2016	2017	2018	2019	2020	2021	2022	2023
G&A	152	132	110	107	104	102	100	99	80	50	40
as % of net sales	7%	9%	10%	10%	10%	10%	9%	9%	13%	17%	22%
Legal Fees	69	45	43	43	42	42	42	43	22	22	22
as % of net sales	3%	3%	4%	4%	4%	4%	4%	4%	4%	7%	12%

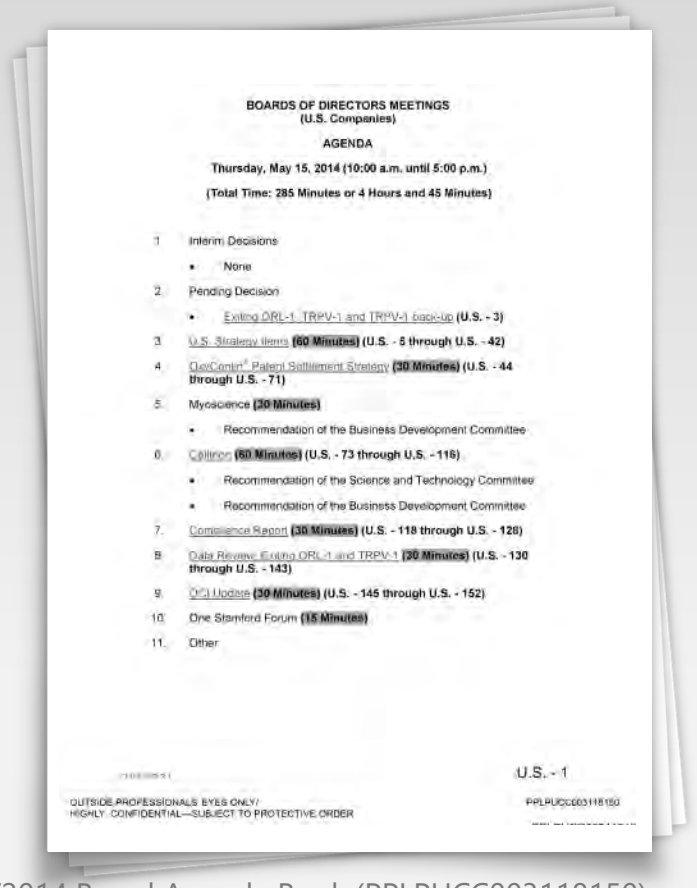
Key Assumptions

G&A
- Assume headcount to decrease by 20 in 2014.
- Assume 0% increase for G&A through 2020 due to implementation of offsetting efficiencies including further headcount reductions.
- Project Slim and Strategic Savings included in forecast, including the subletting of the 4th and 5th floors of One Stamford Forum.
- Post-2020, assume G&A flexed to net sales.

Redacted For Privilege

5/2014 Purdue: Funds Available for Growth PURDUE CONFIDENTIAL

U.S. - 8



BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

AGENDA

Thursday, May 15, 2014 (10:00 a.m. until 5:00 p.m.)

(Total Time: 285 Minutes or 4 Hours and 45 Minutes)

1. Interim Decisions
   - None
2. Pending Decision
   - Exiting ORL-1, TRPV-1 and TRPV-1 back-up (U.S. - 3)
3. U.S. Strategy Items (60 Minutes) (U.S. - 5 through U.S. - 42)
4. OxyContin® Patent Settlement Strategy (30 Minutes) (U.S. - 44 through U.S. - 71)
5. Mycoscience (30 Minutes)
   - Recommendation of the Business Development Committee
6. Celltrion (60 Minutes) (U.S. - 73 through U.S. - 116)
   - Recommendation of the Science and Technology Committee
   - Recommendation of the Business Development Committee
7. Compliance Report (30 Minutes) (U.S. - 118 through U.S. - 128)
8. Data Review: Exiting ORL-1 and TRPV-1 (30 Minutes) (U.S. - 130 through U.S. - 143)
9. OPI Update (30 Minutes) (U.S. - 145 through U.S. - 152)
10. One Stamford Forum (15 Minutes)
11. Other

U.S. - 1

OUTSIDE PROFESSIONALS EYES ONLY/
HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

PPLPUCC003118150

5/15/2014 Board Agenda Book (PPLPUCC003118150)

In 2016, The Board Was Advised That Purdue's Litigation Risk Was Low

January 15, 2016 Board Agenda Book:

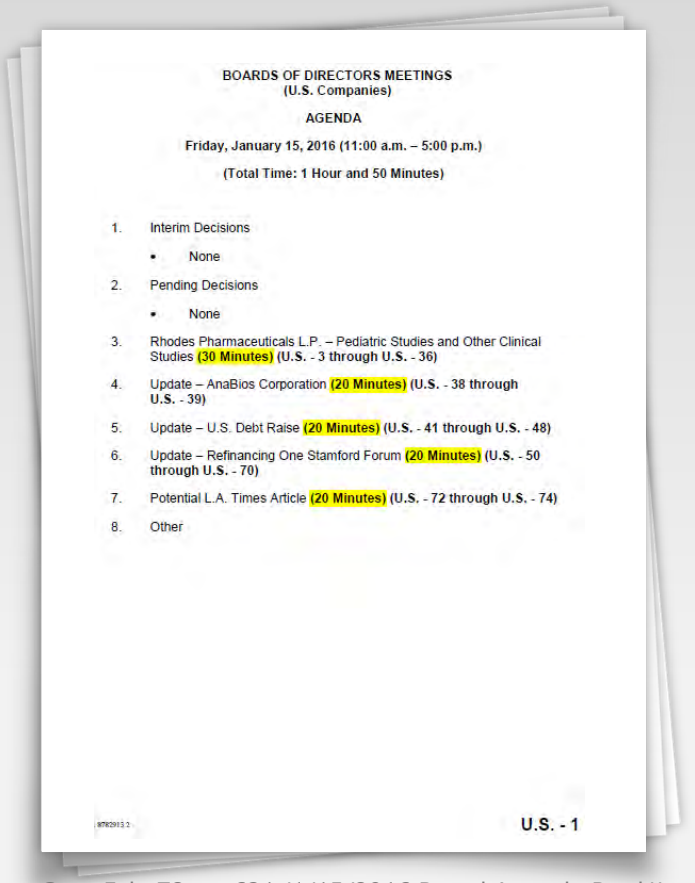
Major Potential Risks to the current cash flow outlook

	Risks
Coventry	• Aptensio's commercial potential (high) • Further delays in FDA Approvals (high)
Purdue	• Redacted • Litigations (low) • Redacted

Coventry lean operating structure limits their ability to offset financially its commercial risks

CONFIDENTIAL 5

U.S. - 46



BOARDS OF DIRECTORS MEETINGS
(U.S. Companies)

AGENDA

Friday, January 15, 2016 (11:00 a.m. – 5:00 p.m.)

(Total Time: 1 Hour and 50 Minutes)

1. Interim Decisions
   - None
2. Pending Decisions
   - None
3. Rhodes Pharmaceuticals L.P. – Pediatric Studies and Other Clinical Studies (30 Minutes) (U.S. - 3 through U.S. - 36)
4. Update – AnaBios Corporation (20 Minutes) (U.S. - 38 through U.S. - 39)
5. Update – U.S. Debt Raise (20 Minutes) (U.S. - 41 through U.S. - 48)
6. Update – Refinancing One Stamford Forum (20 Minutes) (U.S. - 50 through U.S. - 70)
7. Potential L.A. Times Article (20 Minutes) (U.S. - 72 through U.S. - 74)
8. Other

U.S. - 1

Lev. Opp. Exh. 72 at -631 (1/15/2016 Board Agenda Book))

In 2016, Management Projected A 25% Drop in Legal Fees over the Next 4 Years

Historical and Projected Legal Fees as of March 11, 2016 (in millions)

2014	2015	2016E	2017E	2018E	2019E	2020E
47	48	51	47	46	41	38

Purdue's Mar. 11, 2016 Rating Agency Presentation (RSF00075228))

In 2016, Board Was Advised That Outside Counsel Reviewed Purdue's Commercial Compliance Program And Gave It A Positive Review

Bottom Line

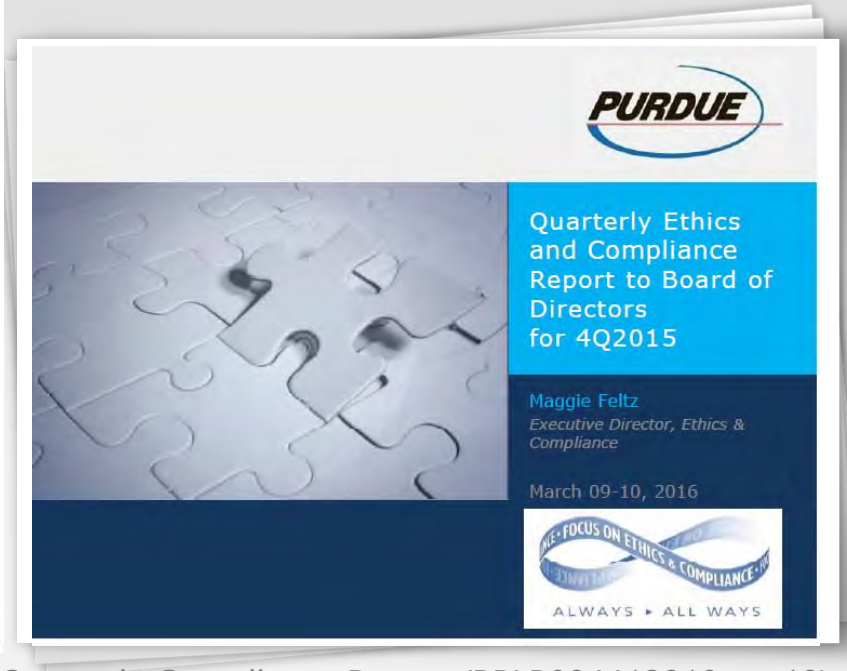
Purdue continues to have strong systems and processes in place to prevent and detect violations of law, regulations, and Company policies, and to remediate issues before they become significant problems.

There have been no significant compliance issues in the 4th quarter, 2015.

This report focuses on:

- Positive review of Commercial Compliance program by outside counsel
- 2016 Ethics & Compliance Program Priorities
- Summary of Investigations
- Sunshine Act Update

PURDUE CONFIDENTIAL | 2



4Q 2015 Quarterly Compliance Report (PPLP004412818 at -19)

The Family Board Members Did Not Know Or Expect That Purdue Would Face Judgments It Could Not Pay

- The families frequently discussed the future of Purdue
- In their extensive email traffic about distributions, neither side expressed any concern about litigation risk
- Jon Sackler compared the differing views of the A and B Sides to the difference between the Buffet approach to investing and a hedge fund/activist approach
- The B Side urged lower distributions
- It offered to put its distributions back into Purdue as subordinated debt, exposing it to all risks the Company faced

The Family Board Members Did Not Know Or Expect That Purdue Would Face Judgments It Could Not Pay

- **November 15, 2014 email from Jon Sackler to Board:**

Recently, a difference of opinion has emerged on what constitutes good financial management of our businesses. . . . .

One point of view seems to be inspired by the current "activist" hedge fund playbook as practiced by people like Carl Icahn and Dan Loeb. It typically involves pulling cash out of operations. . . .

In contrast to the activists, a different point of view, espoused by people like Buffett and Munger, takes a generally more positive view of managements and boards and the protection of investments that underpin long-term wealth creation. . . . Buffett and Munger love cash on the balance sheet. . . .

Given all of the above, and cognizant of the fact that we have already distributed $105 million this year (well in excess of industry peer group norms), at this time the Raymond family prefers to leave the remaining cash in the business for the purpose of maximizing the likelihood that we can execute successfully on our stated strategy.

RS0599001

Side B Board Members Proposed Lending Side B Distributions Back To Purdue in Return for Subordinated Debt

- **June 28, 2015 email from Steve Ives to Richard, Jon and David Sackler RE: Discussions with Jonathan White**

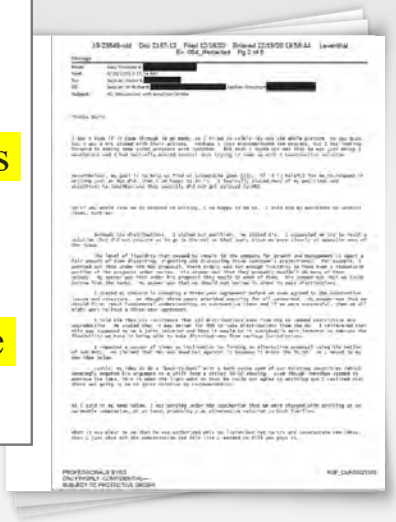
1. I strongly entertained the notion that my hope was to reach a satisfactory proposal that resulted in the lowest acceptable amount of cash coming out of the company. ***

4. Further to #1 above I queried why the sub debt notion would not be acceptable. ***

So, in summary what messages did I leave with JW?

1. My concern over the needs of the business; cash distributions should be tempered at this time for the good of the business. ***

4. I continued to push the notion of sub debt as a means of putting both families on equal footing as to their fundamental desires (cash distributions on one hand and strengthening the business on the other). ***



RS0599103

Side B Board Members Worked Up Terms for the Subordinated Debt That Side B Offered To Take

- **Aug. 13, 2015 David Sackler email to Richard and Jonathan Sackler and Steve Ives RE: Sub debt proposal**

. . . 3 month T bill plus 700 BP . . . .

For all future distributions our family has the option to take our 50% share in additional principal of THIS note. So if it's got 5 years of term left, our distribution share creates more debt at a 5 year term . It's just adding principal. . . . (This provision is subject to revision pending a senior lender's covenants. . . .)

Should we chose NOT to add to the principal future distributions need to be split
25% to the Mortimer family
25% to the Raymond family
50% to loan pay down. . . .

. . . The company can choose to prepay at any time without penalty, subject to any conditions in the senior credit agreement. . . .

Lev. Opp. Exh. 66 (RSF OLK00021534)

Side B Board Members Analyzed Comparable Companies in Assessing Distributions — And Urged Lower Distributions

- **October 27, 2014 email from David Sackler to Richard and Jonathan Sackler, Ralph Snyderman, Peter Boer, Ake Wikstrom, Paulo Costa:**

> Paulo asked me to try my hand at creating an index [of comparable companies] that most closely mirrored our business. . . .
>
> [W]hen we talk about distributions, I think this is the most powerful data I've seen....
>
> I realize I'm preaching to the choir, but any distribution from this point isn't supported by comparable companies. . . . From a comp[a]rables or business point of view, it makes no sense.

RSNY1500355

The UCC's 10 Dated, Distorted, Non-Probative Documents

10 Dated, Distorted, Non-Probative Documents

- Against all of this evidence, the Unsecured Creditors Committee ("UCC") points to 10 documents — out of 90 million — to try to show actual fraud
- The 10 documents have 4 things in common:
  1. They are old, dating from 2006-2008
  2. To the extent any of them reflects a concern about litigation risk, that risk was eliminated not long after the document was written
  3. None of the 10 reflects any concern about litigation at the time the distributions were made, in 2008-16
  4. They are unrelated to any of the criminal conduct Purdue pled to in 2020

1. November 20, 2006 Email from Jonathan to Richard Sackler re: "Pharma Issues" (Hurley Ex. 62/Leventhal Ex. 2)

- The first is a November 2006 email in which Jonathan Sackler wrote that "***contingent liabilities hover over the business***"
- That was true in November 2006
  - The validity of the OxyContin patent was under attack — in litigation largely won by January 2008 (PDD9316304986; PPLPC012000111357-58; PPLPC012000144630-33; PPLPMDL0040000413; PPLPC012000270692)
  - PPLP's CEO wrote, on December 21, 2006, that DOJ investigation "remains the single most significant legal risk we face" — it settled in May 2007 (12/21/06 Year-End Business Update (PPLPUCC003920061 at -63))
  - The state consumer protection and Medicaid matters were hovering until the 76 state settlements were entered in mid-2007 *(Id.)*
  - More than 1,000 products liability lawsuits were hovering — Purdue settled or disposed of substantially all of them between December 2006 and May 2007 (PPLPC012000372436 at slide 3; PPLPUCC003920061 at -63; PPLPC012000111351; PPLPC012000144629)

PPLPC057000003694

1. November 20, 2006 Email from Jonathan to Richard Sackler re: "Pharma Issues" (Hurley Ex. 62/Leventhal Ex. 2)

- The sentence stating that "***contingent liabilities hover over the business***" continues: "***and there's a great need to protect the company by maximizing free cash***"
  - That is, keep cash in Purdue — which is exactly what the Board did in 2006
  - Only $1 million in non-tax distributions were made in 2006 (UCC-prepared Baker Ex. 14)
- The UCC quotes the sentence saying that "***the industry is … a permanent whipping boy for the politicians, regulators, and trial bar***" —
  — but ignores the next sentence: "***Against that headwind, valuable innovations are still generally well rewarded***."
- This 2006 email does not show that the risk of litigation was a concern in 2008-16, when the distributions were made — and all of the contemporaneous documents from 2008-16 shows that it was not

PPLPC057000003694

2. February 27, 2007, Stuart Baker Email to Richard Sackler (Hurley Ex. 65)

- This email is 2 sentences long and says nothing about litigation
- The subject is "David Board Membership"
- Stuart Baker wrote:

> "All you need to do is tell me that Raymond, Beverly, and Jon agree, and I will prepare the necessary papers. Please be sure to tell them (including David) that I recommend against David becoming a Director at this time."

- David was 26 years old, worked at a hedge fund and had no experience at Purdue
- Nothing in this email mentions litigation or intimates it had anything to do with Baker's recommendation
- On the UCC's logic, since Baker did not object when David joined the Board in 2012, there was obviously no concern about litigation risk in 2012

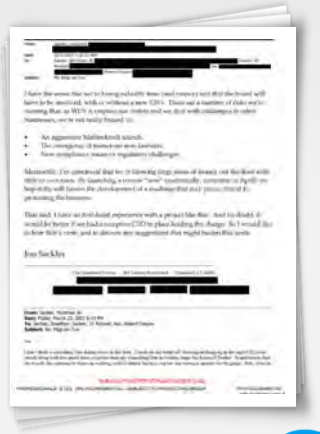
PPLPUCC000555709

3. March 25, 2007, Jonathan Sackler Email to Mortimer and Richard Sackler and Robert Shapiro (Preis Ex. 187)

- Jonathan Sackler writes that he wants Purdue to hire a consulting firm to advise on the questions: "*What opportunities should Purdue pursue, what is the appropriate infrastructure to support it, and what should it cost?*"
- He identifies three risks:

> - An aggressive Mallinckrodt launch.
> - The emergence of numerous new lawsuits.
> - New compliance issues or regulatory challenges.

- Purdue had not yet settled with the federal government or the states
- Products liability lawsuits were expected and filed after the federal plea and settlement
  - The Board was informed in January 2008 they could be closed out with a $200 million reserve (1/11/2008 Board Agenda Book (PPLP004400663)



PPLPUCC004057767

3. March 25, 2007, Jonathan Sackler Email to Mortimer and Richard Sackler and Robert Shapiro (Preis Ex. 187)

- The products liability suits were settled for manageable amounts, dismissed or became almost entirely dormant between 2008-11

  (PPLPUCC003920061 at -63; PPLPMDL0040000406; PPLPC012000221199; PPLPC012000270690;PPLPC012000323983-84; (PPLPMDL0040000574))

- Mallinckrodt was one of the competitors suing to invalidate the OxyContin patent
  - The crowning patent victory — a finding of no "inequitable conduct" — was won in January 2008 against Mallinckrodt and 2 others

    (PDD9316304986; PPLPC012000144630-33, PPLPMDL0040000412; PPLPC012000270692)

- This 2007 email is not evidence of any concern about opioid litigation when the distributions were made in 2008-2016

PPLPUCC004057767

4. March 22, 2007, Email from Jonathan Sackler to Kathe and Richard Sackler and Robert Shapiro (Preis Ex. 209)

- Jonathan Sackler again writes that he wants Purdue to hire a consulting firm "to review strategic options for the business, like a McKinsey," in light of 4 issues:
  1. "The ongoing risks created by the WDVA (in other words, if there's a future perception that Purdue has screwed up on compliance, we could get murdered)"
  2. "An uncertain contingent liabilities picture"
  3. "An uncertain exclusivity asset"
  4. "Unexploited generics opportunities"
- Nos. 1 and 4 are business risks
- Nos. 2 and 3 are the same litigation risks discussed in his 3/25/07 email that were resolved not long after the email was written
- This 2007 email is not evidence of any concern about opioid litigation when the distributions were made in 2008-2016

PPLPUCC900482494

5. May 13, 2007, email from Richard Sackler to Elon Kohlbert re: "News Coverage" (Hurley Ex. 63)

- The UCC falsely states that this email is talking about "liability related to the opioid crisis" (UCC Exceptions Motion ¶20)
- The subject of the email is **Subject:** RE: news coverage — the media — not litigation
- The UCC points to the sentence: *"I'm not confident that this is something that will blow over. My sense is that it may get a lot worse in the coming weeks"*
- The UCC ignores that — in the next email in the same chain — Richard writes two days later:

> "The good news is that things simmered down very quickly, and the story doesn't seem to have excited the masses. We've received a lot of support from the medical community, and so my fears seem to be for naught. I'm very much relieved, and now we are planning on how to handle the future for the business."

- This email does not reflect any concern about litigation at all

PWG004474511

6. May 17, 2007, Email from David Sackler to Jonathan and Richard Sackler and Steve Ives re "Idea" (Hurley Ex. 64)

David: "We're rich? For how long? Until which suits get through to the family?"

Jon: "[R]est assured that there is no basis to sue 'the family'"

David: "[A]sk yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us."

- David Sackler was 26 years old, worked at a hedge fund and had no involvement at Purdue
- He was apprehensive that the family would be sued in the wake of Purdue's 2007 guilty plea, which had been entered one week earlier
- Jonathan Sackler, who was a Purdue director, was right
- None of the hundreds of suits filed in the wake of Purdue's 2007 guilty plea named the family — and all were settled, dismissed or dormant within a few years

PPLPUCC002683256

6. May 17, 2007, Email from David Sackler to Jonathan and Richard Sackler and Steve Ives re "Idea" (Hurley Ex. 64)

- In 2012, 5 years after writing this email, David Sackler joined the PPI Board — the last thing anyone expecting a flood of opioid litigation would have done
- In 2015, 8 years after writing this email, he (together with Richard and Jonathan Sackler) proposed that Side B lend its distributions back to Purdue in return for subordinated debt
  - That would expose Side B to all of Purdue's litigation risk
  - It is inexplicable if any of them anticipated major opioid litigation
- This 2007 email does not show any concern about litigation in 2008-2016, when the distributions were made — and all of the evidence from 2008-2016 shows that there was no concern about litigation then

PPLPUCC002683256

7. June 22, 2007, Email from David Sackler to Jonathan, Mortimer, Richard and Kathe Sackler re: SEPR (Hurley Ex. 68)

- This is another email by 26 year-old David Sackler — to two cousins, his father and uncle, all of whom are Purdue directors
- The UCC falsely states that in this email "*David worried that Purdue's 'future liabilities' could 'decimate' a merger.*" (UCC Exceptions Motion ¶23)
- He was actually concerned that negative publicity (Purdue had just pled guilty) could decimate a merger because "analysts could very well start saying crazy things about future liabilities"

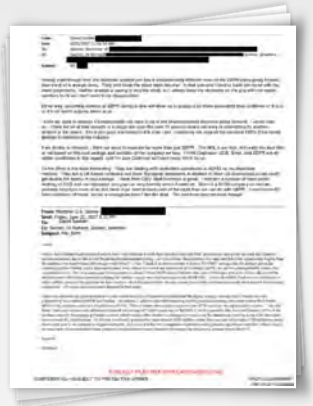
> "**[W]e have absolutely no idea how our negative publicity will play with investors. It may be that we're tainted and the negative press around Oxy will decimate a smaller company's stock price**.... If we merge with a company like SEPR the **analysts could very well start saying crazy things about future liabilities** and we could see the value of our investment seriously diminished....

PWG004473999

- This 2007 email is not probative of any concern about litigation risk — and certainly not in 2008-16, when the distributions were made

8. June 25, 2007, Email from David Sackler to Jonathan, Mortimer and Richard Sackler re: SEPR (Hurley Ex. 66)

- Another email by 26 year-old Purdue-outsider David Sackler, to his cousin, father and uncle, all of whom were Purdue directors
- The subject is a potential merger with Sepracor, Inc (SEPR)
- David asks whether the family really wants to be in the pharmaceutical business
- He also says he will "support the decision 100%" if his cousin, father and uncle want to stay in the industry
- This 2007 email is not probative of any concern about litigation risk at any time



PWG0044 73999

9. July 24, 2007, Memo from Peter Boer to Jon Sackler About a Potential Sale of All of the Families' Pharmaceutical Assets (Hurley Ex. 69)

- Peter Boer was a former W.R. Grace executive who later served as an outside director of PPI
- He talks about his experience at Grace, which had asbestos liability
- Writing in the wake of Purdue's 2007 guilty plea, he says that legal liabilities will impact the sale value of Purdue "until interest in litigation has died down"
  - All of the litigation filed after the federal plea was settled or dormant by 2010-2011
- The UCC falsely states that the memo "recommend[ed] the Sacklers take 'defensive measures'"
- He did not recommend that the family take defensive measures, and no one took any defensive measures.

PPLPUCC90000491386

9. July 24, 2007, Memo from Peter Boer to Jon Sackler About a Potential Sale of All of the Families' Pharmaceutical Assets (Hurley Ex. 69)

- Mr. Boer wrote:

> "[I]t may be that overseas assets with limited transparency and jurisdictional shielding from U.S judgments will be less attractive to litigants than domestic assets. Obviously, this factor depends on how the ownership is structured, and I presume the family has taken most of the appropriate defensive measures."

- He had no idea what the organizational structure of the family's holdings was
- The B side's ownership of the IACs has always been based in the US
- The B side trusts that own Purdue were settled in 1974 and 1989 — years before OxyContin was launched
- This 2007 email — written by a non-family member, which generated no action by the family — does not show any concern about litigation in 2008-2016, when the distributions were made

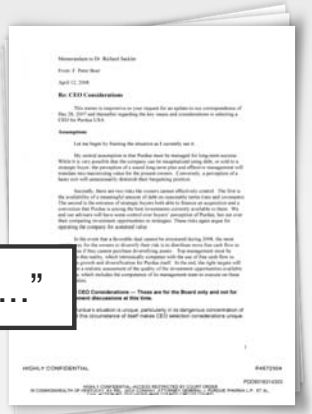
PPLPUCC90000491386

10. April 12, 2008 Memo Re: CEO Considerations (Hurley Ex. 70)

- The subject of this email is CEO loyalty in context of possible sale or recapitalization of Purdue
- The UCC deceptively states that this memo "***lamented Purdue's dangerous concentration of risk***." (UCC Exceptions Motion ¶25)
- The memo identified the risk it is discussing 3 times — and it is not opioid litigation
- It was Purdue's "***period of [patent] exclusivity [for OxyContin], currently estimated to be through 2013***" (Memo at pp. 2 (first para. under Priority 1), 3, 4)
- The memo says nothing about opioid litigation and emphasizes the importance of compliance with law:

> "[Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement…."

- This memo does not evince any concern about opioid litigation risk



4/08 CEO Considerations Memo, p. 2 (PDD9316314304)

"Badges of Fraud" Do Not Evidence Actual Intent

"Badges of Fraud" Do Not Evidence Actual Intent

The badges of fraud operate as **circumstantial evidence** of fraudulent intent.

Direct evidence establishes that Purdue made the distributions in good faith and without reason to believe it would face insurmountable opioid-related litigation.

Prepetition complaints asserting fraudulent transfer did not plead, and the facts do not reflect, the presence of most of the traditional badges of fraud.

In re Chin, 492 B.R. 117, 132 (Bankr. E.D.N.Y. 2013)

"The availability of badges of fraud as circumstantial evidence fulfills an important function, but the utility of a checklist can only go so far."

In re Stanton, 457 B.R. 80, 94 (Bankr. D. Nev. 2011)

"Because they are only evidence of the likelihood of fraud, badges of fraud are not given equal weight; and sometimes the circumstances indicate they should be given no weight at all."

All Distributions Were Made In The Ordinary Course Of Business

- **The distributions occurred regularly, after formal approval by PPI's Board of Directors.**
- **This is the opposite of a suspect strategy to evade an anticipated debt.**

Lippe v. Bairnco Corp., 249 F. Supp. 2d 357, 384 (S.D.N.Y. 2003) *aff'd*, 99 F. App'x 274 (2d Cir. 2004)

No reasonable jury could conclude that quarterly dividends paid over ten-year period were intended *"to keep the assets away from asbestos creditors."*

Distributions Were Not A Secret

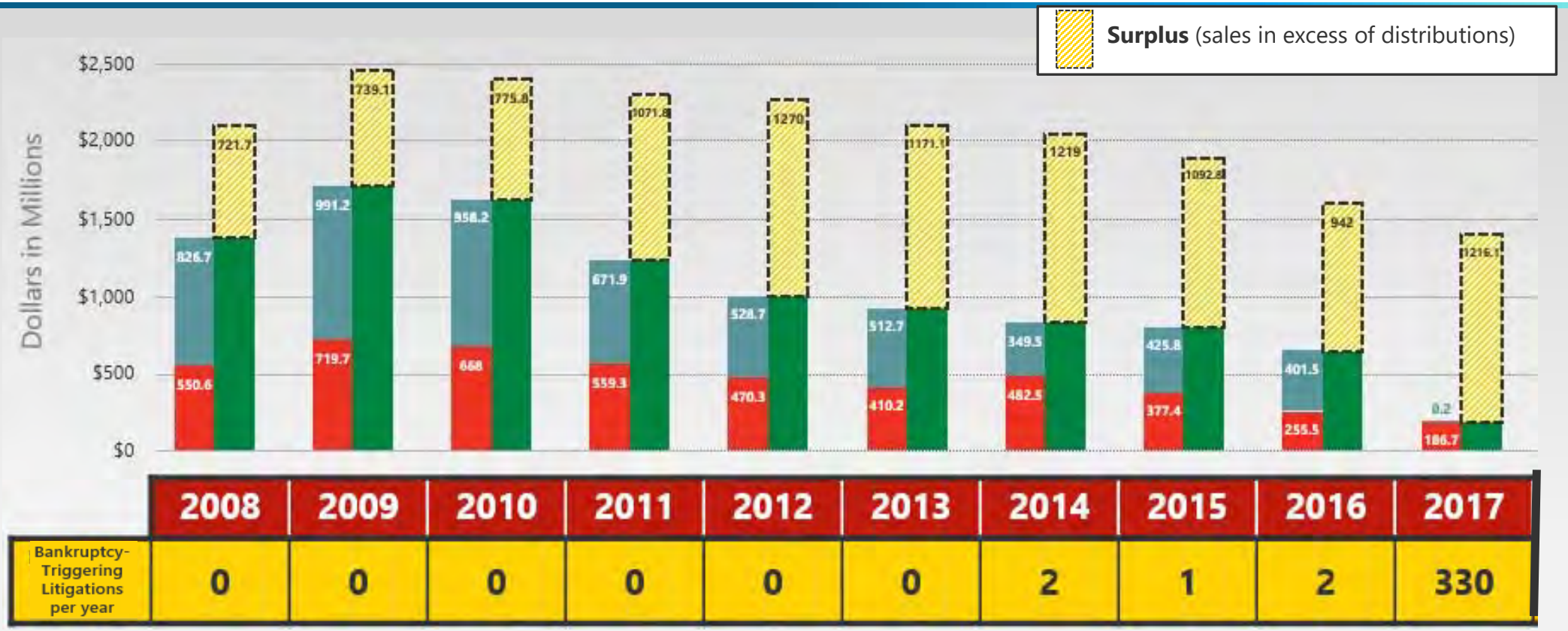
- Publicly reported
- Many paid in taxes to governmental Claimants

Forbes

> Forbes estimates that the combined value of the drug operations, as well as accumulated dividends over the years, puts the Sackler family's net worth at a conservative $14 billion.

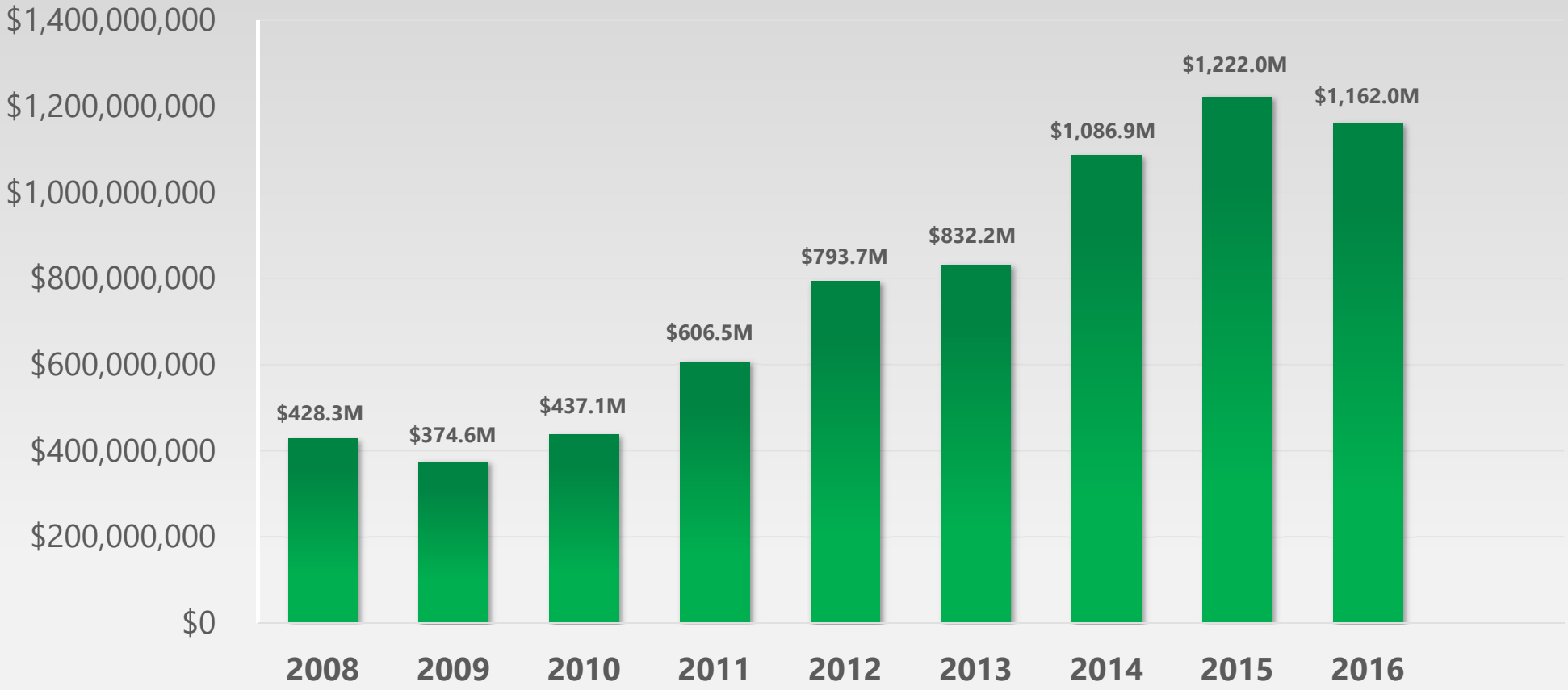
Alex Morrell, The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families, FORBES (Jul. 1, 2015), https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#2b664fa475e0 (cited in NY AG FAC ¶420)

Distributions Were Always A Fraction Of Net Sales



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Bankruptcy-Triggering Litigations per year	0	0	0	0	0	0	2	1	2	330

The Board Left Enormous Amounts of Unrestricted Cash In Purdue After Distributions



Sources: PPLPC031001244649 (2008-12); PPLPC051000265076 (2013-14); PPLPC045000018249 (2015); PPLPC032000398822 (2016)

Constructive Fraudulent Transfer

Claimants Must Prove Transfers Were Made Without Fair Consideration While The Transferor:

1. **Was insolvent** (DCL §§271, 273)
2. **Was undercapitalized** (DCL §274) **or**
3. **Believed or intended to incur debts beyond the transferor's ability to pay as the debts mature** (DCL §275)

Claimants Cannot Make Any of These Showings

- **Purdue was profitable when distributions were made and did not have meaningful funded or trade debt**
- **It had billions in annual sales and enormous amounts of unrestricted cash**
- **It had no significant litigation**
- **Its only material potential liabilities today are the disputed and unliquidated litigation claims that emerged after the last of the distributions**

Purdue Was Not Insolvent When The Transfers Were Made

New York Debtor & Creditor Law: §271

*"A person is insolvent when the present fair salable value of his assets is less than the amount that will be required to pay his **probable** liability on his existing debts as they become absolute and matured."*

- **Purdue was not insolvent unless, at the time of each distribution, it was "probable" it would face insurmountable opioid-related litigation and judgments**
- **Claimants bear the burden of proving insolvency**

McCarthy v. Estate of McCarthy, 145 F. Supp. 3d 278, 286 (S.D.N.Y. 2015)

Hindsight Cannot Guide The Analysis

FSP, Inc. v. Societe Generale, 2005 WL 475986, at *15 (S.D.N.Y. Feb. 28, 2005)

Whether transferor was solvent *"must be gauged at the time of the transfer and not with the benefit of hindsight."*

In re Trinsum Group, Inc., 460 B.R. 379, 392 (Bankr. S.D.N.Y. 2011)

"[I]nsolvency of the transferor… cannot be presumed from subsequent insolvency at a later point in time."

Speculative Liabilities Are Not "Probable"

FSP, Inc. v. Societe Generale, 2005 WL 475986, at *15 (S.D.N.Y. Feb. 28, 2005)

> *"The hypothetical existence of liabilities, from future tort claims … is not considered for purposes of a fraudulent conveyance analysis. … [Plaintiff]'s fraudulent conveyance counterclaim is, therefore, legally insufficient because it is premised on the [defendant]'s lack of sufficient assets to pay its debtor creditors as a result of future potential tort claims of an unknown monetary amount."*

Speculative Liabilities Are Not "Probable"

Shelly v. Doe, 249 A.D.2d 756, 757 (3d Dep't 1998)

"***In our view the amount of his probable debt to respondent should not be considered as it was entirely speculative in 1993***. *Therefore, we find that respondent did not establish that Shelly was rendered insolvent by the transfer of the firearms, thereby precluding respondent's utilization of Debtor and Creditor Law §273.*"

Tae H. Kim v. Ji Sung Yoo, 311 F. Supp. 3d 598, 616 (S.D.N.Y. 2018)

"***[I]t cannot be said that Ji Sung had probable liability in the context of the DOL on those debts at the time of the Condo's conveyance***. *It took the DOL investigating and assessing penalties and the FLSA Action entering a judgment to get Ji Sung to pay lawful wages; the evidence has not established that there was probability he would have been 'required to pay' that liability absent those actions occurring.*"

Speculative Liabilities Are Not "Probable"

In re Edgewater Med. Ctr., 373 B.R. 845, 855 (N.D. Ill. Bankr. 2007)

"***To reach a finding of insolvency … the court would have to disregard the large amounts of cash the debtor had on hand and speculate on what the Department of Human Services would have done if it had discovered the Medicare fraud***. *The court declines to engage in that type of speculation and finds and concludes that the plaintiff has not met its burden of proving insolvency.*"

Mere Existence of Uncertain and Disputed Claims Is Insufficient

McCarthy v. Estate of McCarthy, 145 F. Supp. 3d 278, 286 (S.D.N.Y. 2015)

> *"'Claims that are inchoate, uncertain, and contested have no present value and cannot be considered an asset of the [transferor].'"*

Lippe v. Bairnco Corp.

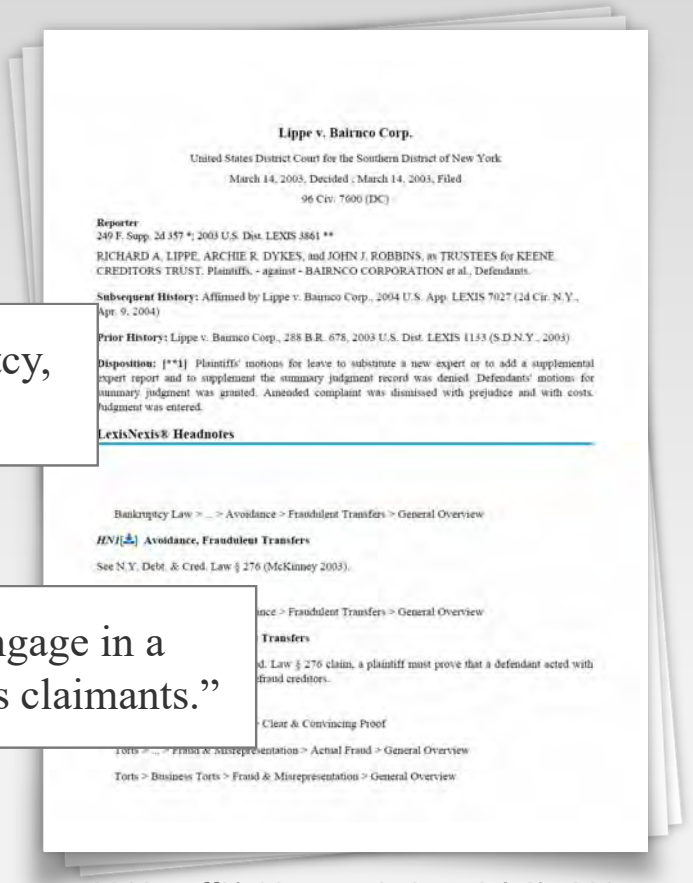
Lippe v. Bairnco is the leading case on how disputed and unliquidated mass-tort liability factors into the fraudulent transfer analysis.

The plaintiffs contended that Keene, which had manufactured asbestos products:

> "knew in the early 1980s, more than a decade before it went into bankruptcy, that someday it would be overrun by asbestos personal injury cases"

And that:

> "Keene and its management consequently concocted a grand scheme to engage in a series of corporate transactions to hide Keene's assets from future asbestos claimants."



Lippe v. Bairnco Corp.

United States District Court for the Southern District of New York

March 14, 2003, Decided ; March 14, 2003, Filed

96 Civ. 7600 (DC)

Reporter
249 F. Supp. 2d 357 *; 2003 U.S. Dist. LEXIS 3861 **

RICHARD A. LIPPE, ARCHIE R. DYKES, and JOHN J. ROBBINS, as TRUSTEES for KEENE CREDITORS TRUST, Plaintiffs, - against - BAIRNCO CORPORATION et al., Defendants.

Subsequent History: Affirmed by Lippe v. Bairnco Corp., 2004 U.S. App. LEXIS 7027 (2d Cir. N.Y., Apr. 9, 2004)

Prior History: Lippe v. Bairnco Corp., 288 B.R. 678, 2003 U.S. Dist. LEXIS 1133 (S.D.N.Y., 2003)

Disposition: [**1] Plaintiffs' motions for leave to substitute a new expert or to add a supplemental expert report and to supplement the summary judgment record was denied. Defendants' motions for summary judgment was granted. Amended complaint was dismissed with prejudice and with costs. Judgment was entered.

LexisNexis® Headnotes

Bankruptcy Law > ... > Avoidance > Fraudulent Transfers > General Overview

HN1[] **Avoidance, Fraudulent Transfers**

See N.Y. Debt. & Cred. Law § 276 (McKinney 2003).

...ince > Fraudulent Transfers > General Overview

Transfers

...d. Law § 276 claim, a plaintiff must prove that a defendant acted with ...fraud creditors.

...Clear & Convincing Proof

Torts > ... > Fraud & Misrepresentation > Actual Fraud > General Overview

Torts > Business Torts > Fraud & Misrepresentation > General Overview

Lippe v. Bairnco Corp., 249 F. Supp. 2d 357, 360 (S.D.N.Y. 2003), *aff'd*, 99 F. App'x 274 (2d Cir. 2004)

Lippe v. Bairnco Corp.

In evaluating Keene's solvency, the court stated that

> … no one could predict the future…

Id. at 379-80

and focused on the debtor's **actual experience** with asbestos lawsuits.

To determine whether, at the time of each transfer, it was reasonable to infer that Keene was insolvent, the court considered:

- The actual number of cases filed and predicted to be filed against Keene;
- Cases filed against Manville, another major asbestos manufacturer; and
- Keene's success in defending against liability or settling cases for manageable sums or within existing insurance limits.

Lippe v. Bairnco Corp.

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Bankruptcy Law > ... > Avoidance > Fraudulent Transfers > General Overview

HN2[] **Avoidance, Fraudulent Transfers**

To prevail on a N.Y. Debt. & Cred. Law § 276 claim, a plaintiff must prove that a defendant acted with actual intent to hinder, delay, or defraud creditors.

Evidence > Burdens of Proof > Clear & Convincing Proof

Torts > ... > Fraud & Misrepresentation > Actual Fraud > General Overview

Torts > Business Torts > Fraud & Misrepresentation > General Overview

Lippe Ruled Keene Was Not Insolvent

Keene was hotly contesting many of these cases and it believed that many of the cases were meritless and that the amounts sought were exaggerated.

249 F. Supp. 2d at 380

From 1984 through 1990, it won 97% of the cases that went to verdict, and lost only a total of $192,143 in the cases in which there were adverse verdicts.

Id.

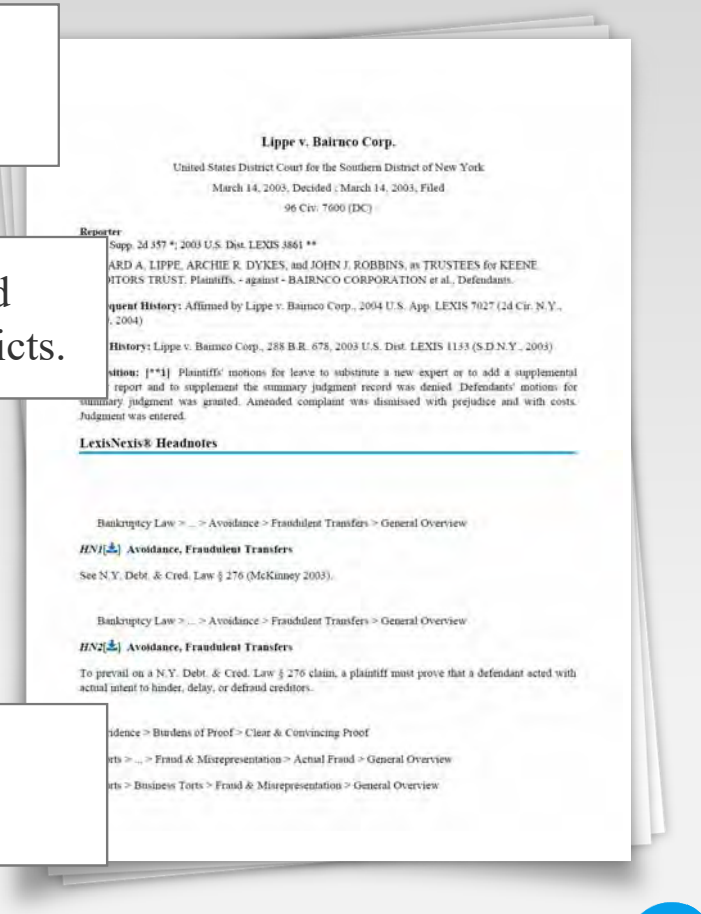
While

Keene believed the asbestos problem to be a serious one…

Id. at 381

this

…does not constitute evidence that Keene knew that someday it would be overwhelmed by the asbestos cases.



Lippe v. Bairnco Corp.

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rts > ... > Fraud & Misrepresentation > Actual Fraud > General Overview

rts > Business Torts > Fraud & Misrepresentation > General Overview

Application of *Lippe* Factors to Purdue

- The **actual number of cases** filed and predicted to be filed against Purdue.
  - Minimal until 2017.
- **Purdue's success in defending against liability** or **settling cases for manageable sums** or within existing insurance limits.
  - All within Purdue's ability to pay.

Purdue's 2020 Guilty Plea and Civil Settlement Do Not Establish Its Insolvency As Against Its Owners

Purdue's 2020 Guilty Plea and Civil Settlement Do Not Establish Its Insolvency As Against Its Owners

- In its guilty plea, Purdue agreed to accept a criminal fine of $3.544 billion and entry of a forfeiture judgment of $2 billion
  - Purdue was required to pay only $225 million, in partial satisfaction of the forfeiture
  - The entirety of the $3.544 billion criminal fine will be treated as an allowed, unsubordinated, general unsecured claim in the bankruptcy
  - The remaining $1.775 billion of the forfeiture will be satisfied by the first $1.775 billion in value that Purdue confers on state, tribal and local governments under the Plan of Reorganization
- In its civil settlement Purdue paid nothing — it agreed that the US will have an allowed, unsubordinated, general unsecured claim of $2.8 billion

Purdue's 2020 Guilty Plea and Civil Settlement Do Not Establish Its Insolvency As Against Its Owners

- Purdue's plea and settlement have no collateral estoppel effect against former directors who had no control over Purdue when it agreed to enter into them

  Stichting Ter Behartiging Van de Belangen Van Oudaandeelhouders In Het Kapitaal Van Saybolt Int'l B.V. v. Schreiber, 327 F.3d 173, 184, 186 (2d Cir. 2003)

- Nothing was litigated
- Purdue had no motivation to litigate
  - It had a motivation to settle with DOJ to get out of bankruptcy and become a public benefit company
- Purdue had no motivation to minimize dollars it was not paying
  - It had a motivation to minimize out-of-pocket dollars to maximize payments to victims

Purdue's 2020 Guilty Plea and Civil Settlement Do Not Establish Its Insolvency As Against Its Owners

- The merits of DOJ's claims were not litigated when the Bankruptcy Court approved Purdue's entry into the plea agreement and settlement
- The Court did not find that any of the facts admitted or denied by Purdue in the plea or settlement was true
- A debtor cannot settle itself into insolvency for purposes of establishing its own fraudulent transfer claim against its owners
- Insolvency must be judged at the time of each challenged transfer, not in hindsight
- The plea and settlement do not allege the dates when the financial liabilities Purdue agreed to were incurred
  - They allege only that Purdue's misconduct occurred over a span of eleven years, from 2007-2018

Purdue's 2020 Guilty Plea and Civil Settlement Do Not Establish Its Insolvency As Against Its Owners

- Purdue's insolvency at the time of each alleged transfer is a question of fact, and the evidence proves that Purdue was not insolvent when distributions were made

Purdue Was Adequately Capitalized And Did Not Intend To Incur Debts Beyond Its Ability To Pay

Purdue Was Adequately Capitalized

- Purdue was **profitable** at all relevant times and had **billions** in annual sales.
- Purdue had **huge amounts of unrestricted cash** on hand, more than a billion dollars a year — every year — from 2014 on.
- Purdue had **no meaningful financial or trade debt**.
- Purdue **survived for over a decade after the first challenged transfers** and at least two years after the last challenged transfer in 2017.

MFS/Sun Life Trust-High Yield Series v. Van Dusen Airport Servs. Co., 910 F. Supp. 913, 944 (S.D.N.Y. 1995)

(collecting cases that find adequate capitalization where the company paid their creditors for at least 10 to 12 months after the transfer)

> *"That the company remained viable so long after the LBO strongly suggests that its ultimate failure cannot be attributed to inadequacy of capital as of the date of the buyout."*

Purdue Did Not Intend To Incur Debts Beyond Its Ability To Pay

In re Nirvana Rest., 337 B.R. 495, 509 (Bankr. S.D.N.Y. 2006)

"Section 275 requires proof of ***the debtor's subjective intent*** or belief that it will incur debts beyond its ability to pay as they mature."

(citing *MFS/Sun Life Trust-High Yield Series v. Van Dusen Airport Servs. Co.*, 910 F. Supp. 913, 943 (S.D.N.Y. 1995))

To the extent Delaware or Connecticut law applies and imposes a "reasonably should have believed" standard, Purdue's distributions were not fraudulent because future judgments were not probable when the distributions were made.

Contemporaneous Market Data Shows That Sophisticated Market Participants Did Not Foresee The Flood Of Litigation Against Purdue Or Other Manufacturers

The Importance Of Contemporaneous Market Data

In re Iridium Operating LLC, 373 B.R. 283, 346-351 (Bankr. S.D.N.Y. 2007)

Courts view "*traditional valuation techniques and contemporaneous market evidence*," including a company's stock prices and "*assessments [by] market analysts*" as "*critical piece[s] of information in valuing a company*."

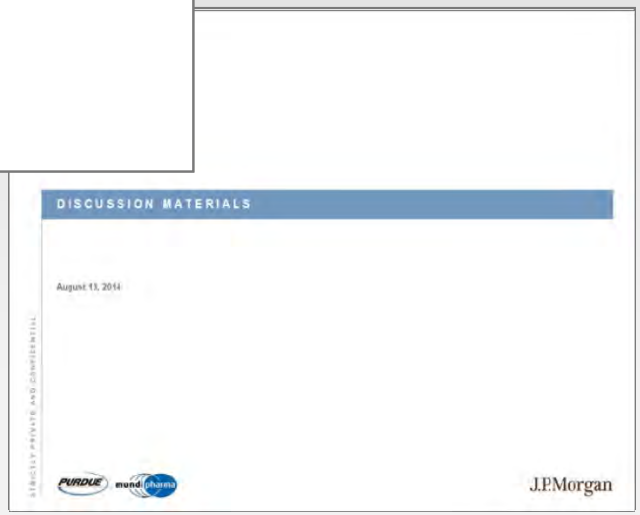
In 2014, JPMorgan Opined That Purdue Could Borrow $1 to $1.5 Billion

2014 JPMorgan Debt Capacity Analysis

Purdue retained JPMorgan to prepare a "comprehensive valuation and debt capacity analysis" in connection with a potential capital raise

- **J.P. Morgan opined that "the Company can raise approximately $1-$1.5bn" in debt financing**

JPMorgan Debt Capacity Presentation (8/13/14) at Slide 41



In 2016, S&P Found Purdue Creditworthy With Minimal Financial Risk

2016 Indicative Credit Ratings — Standard & Poor's

	Current Ratings	Scenario 1
Corporate Credit Rating	N/A	BB
Outlook	N/A	Stable
Senior Secured/Recovery	N/A	BBB-/1

- A historically conservative financial policy (this is the first debt placement) and very low leverage metrics support our "minimal" financial risk assessment.

April 7, 2016 S&P Indicative Ratings Letter

In 2016, Moody's Found Purdue Creditworthy With A Stable Outlook

2016 Indicative Credit Ratings — Moody's

Indicative Ratings

Moody's has assigned the below Indicative Ratings:

Corporate Family Rating at Ba3
Probability of Default Rating at Ba3-PD
$100million Senior Secured Revolving Credit Facility at Ba3 (LGD 3)
$400 million Senior Secured Term Loan at Ba3 (LGD 3)

Outlook: Stable

The Ba3 indicative Corporate Family Rating is supported by Purdue's low financial leverage… This will allow the company to absorb considerable operating or legal setbacks with minimal risk of debt impairment.

March 30, 2016 Moody's Indicative Ratings Letter

Comparable Opioid Manufacturers' Access To Capital Markets Shows Why Purdue Did Not Foresee Liabilities Beyond Its Ability to Pay Before 2017

Market Data Confirms The Absence Of Any Perceived Risk from Opioid Litigation Before 2017

Comparable companies' access to capital markets and credit ratings confirm that — at the time the distributions were made —

- **Sophisticated participants in the debt markets did not perceive substantial credit risk to opioid manufacturers, and**
- **Rating agencies did not view opioid litigation as a basis for a downgrade**

Comparable companies : **Mallinckrodt, Endo, Teva, and Amneal — all defendants in the MDL** (*In re: National Prescription Opiate Litigation*, Case No. 17-mdl-2804)

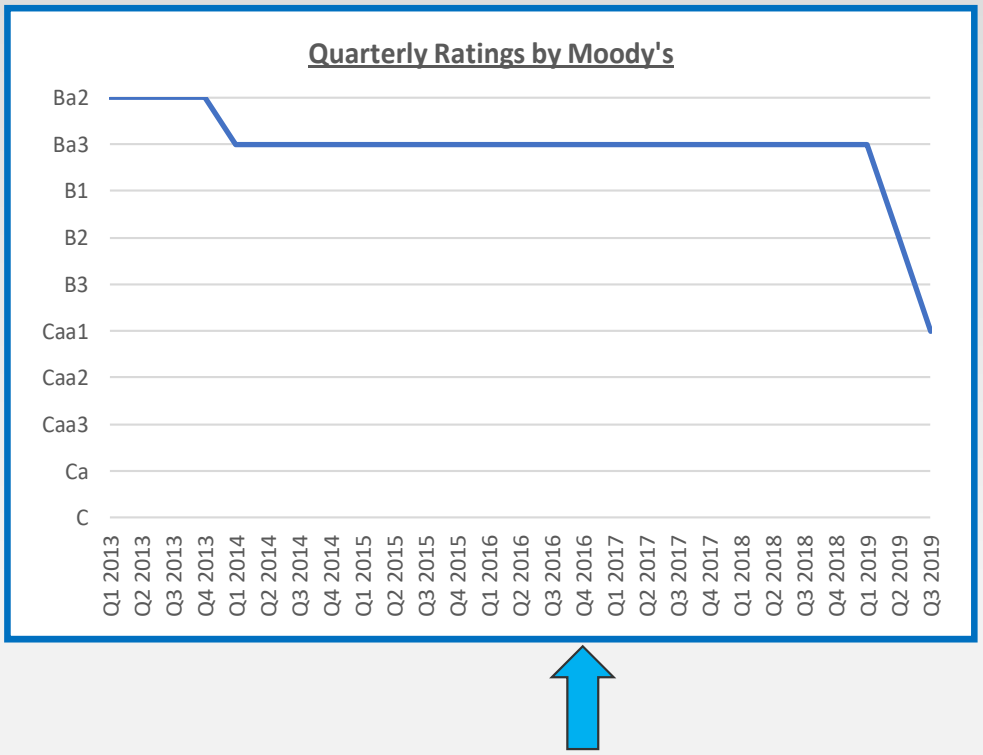
Comparable Opioid Manufacturers' Accessed Capital Markets And Raised New Bond Financing During And After The Time Distributions Were Made

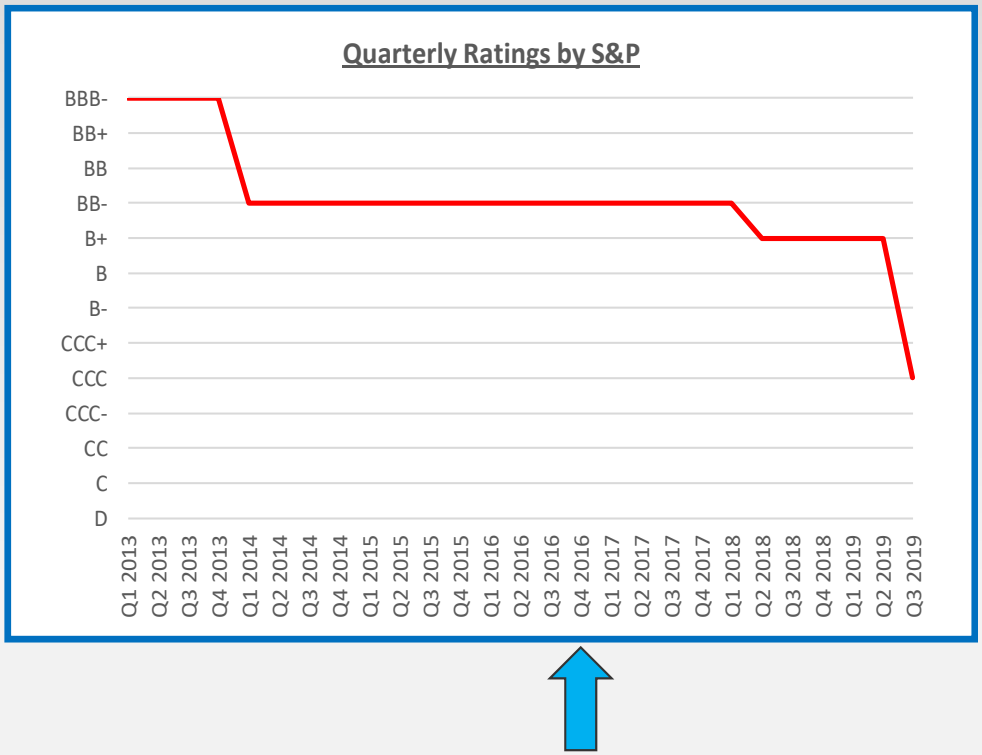
1. Mallinckrodt: 2014 and 2015
2. Endo: 2013, 2014, 2015, 2017 and 2019
3. Teva: 2011, 2012, 2015, 2016 and 2018
4. Amneal: 2018

See In re Iridium Operating LLC, 373 B.R. 283, 349 (Bankr. S.D.N.Y. 2007) (*ability to raise debt financing in the capital markets "is an indication of both solvency and capital adequacy"*)

Credit Ratings Of Comparable Opioid Manufacturers — Mallinckrodt

Mallinckrodt

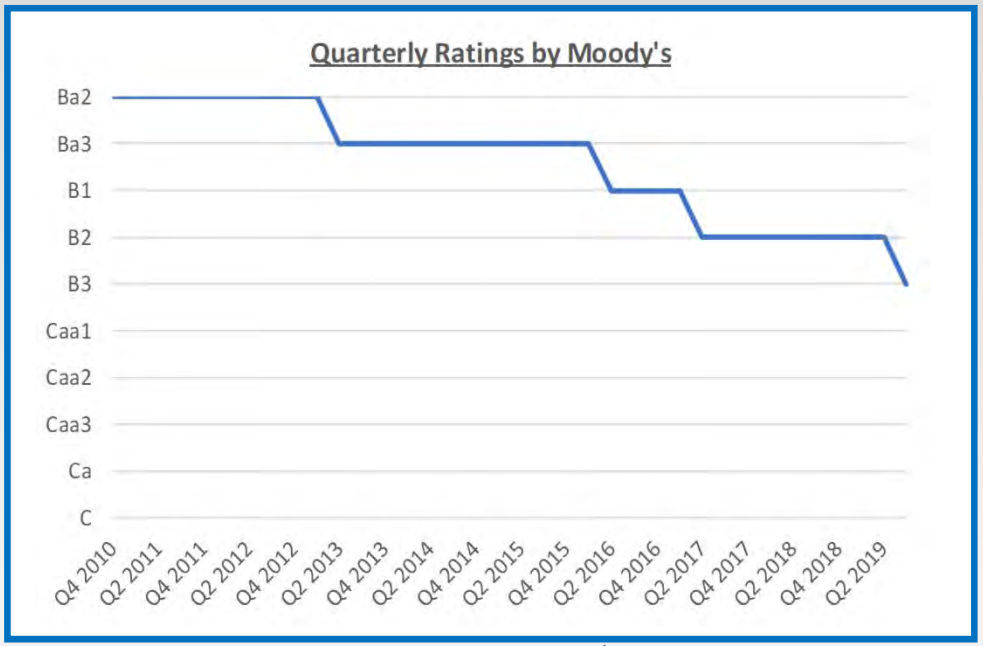


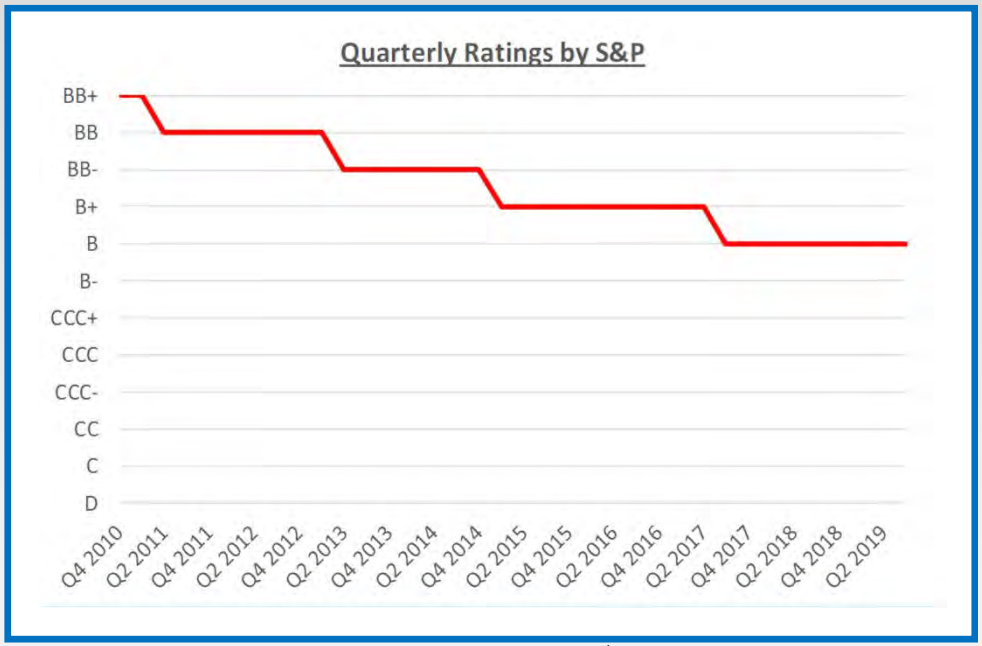


Source: Moodys.com (Rating Reports: March 2013 – September 2019), Bloomberg

Credit Ratings Of Comparable Opioid Manufacturers — Endo

Endo International

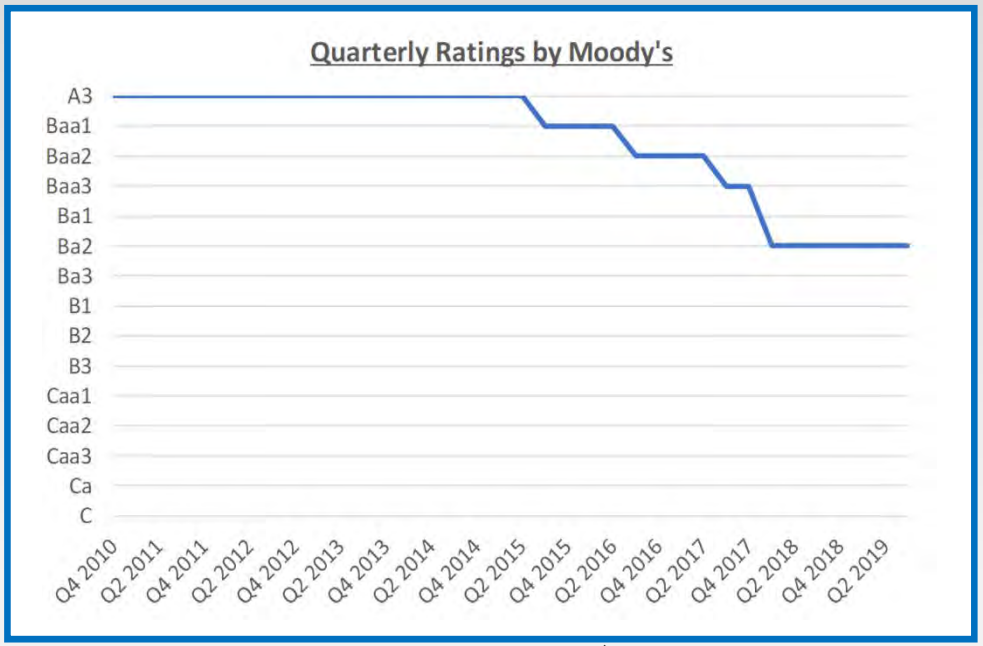


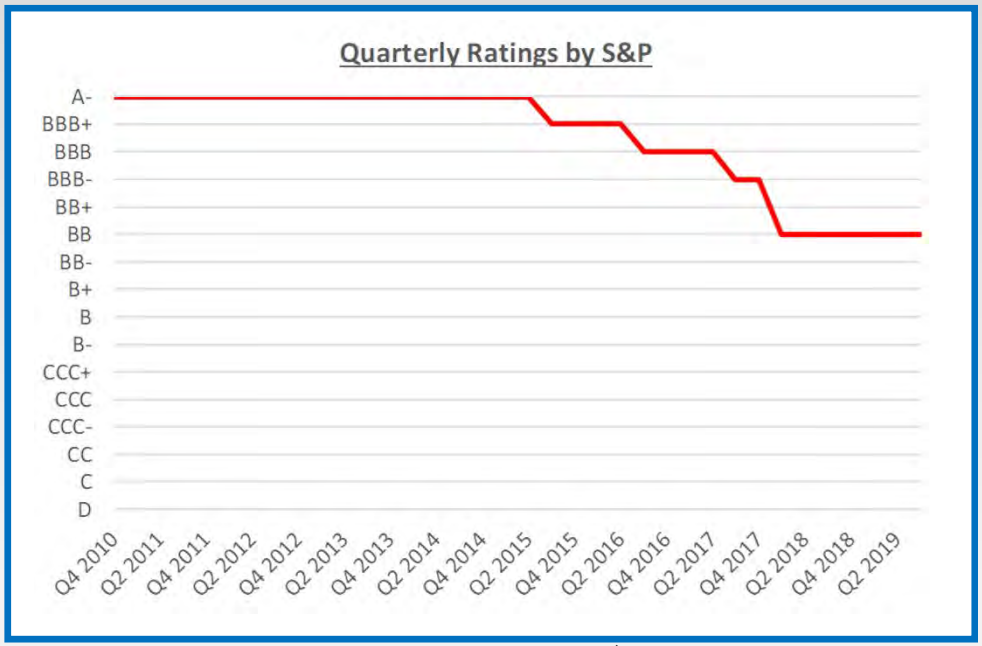


Source: Moodys.com (Rating Reports June 2013 – July 2019), Bloomberg

Credit Ratings Of Comparable Opioid Manufacturers — Teva

Teva Pharmaceuticals

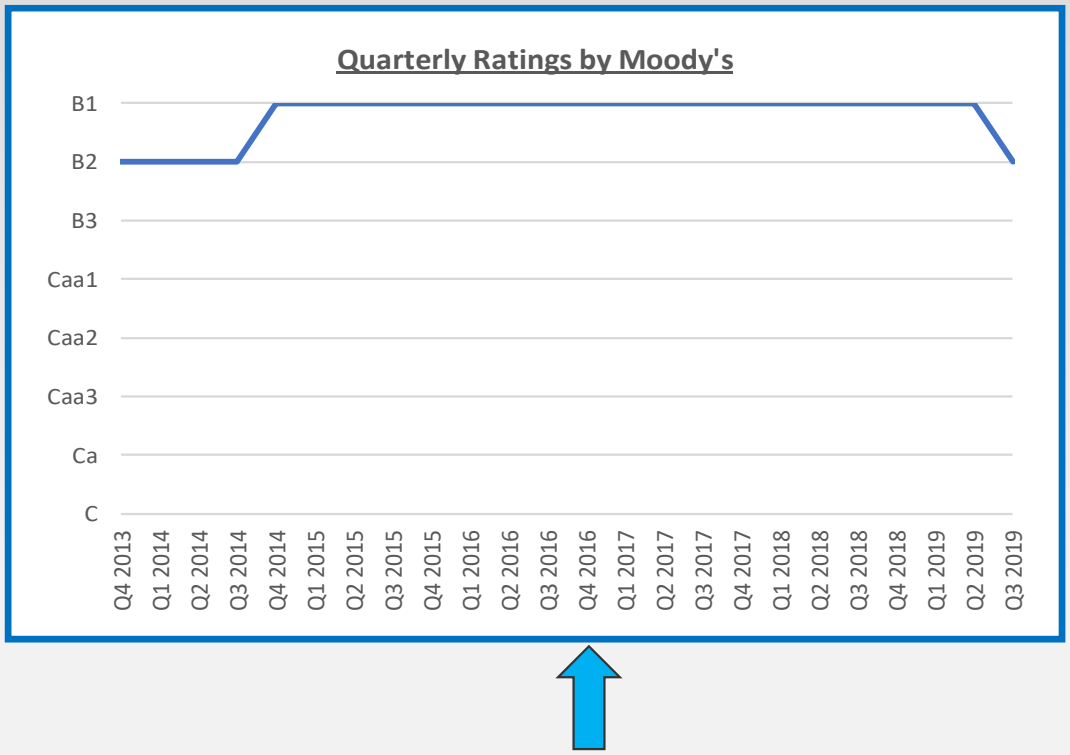




Source: Moodys.com (Rating Reports January 2010 – August 2019), Bloomberg

Credit Ratings Of Comparable Opioid Manufacturers — Amneal

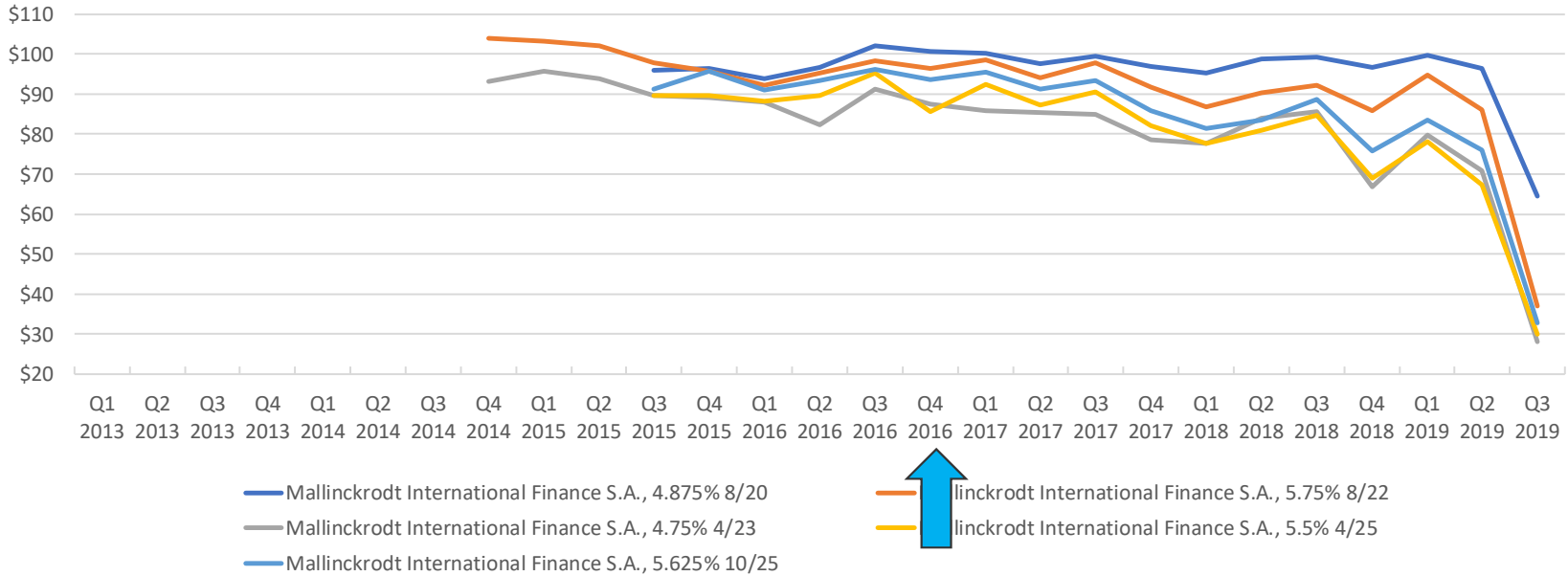
Amneal Pharmaceuticals



Source: Moodys.com (Rating Reports October 2013 – November 2019), Bloomberg

Bond Prices of Comparable Opioid Manufacturers Confirm No Perceived Credit Risk from Opioid Litigation Until 2018/2019 — Mallinckrodt

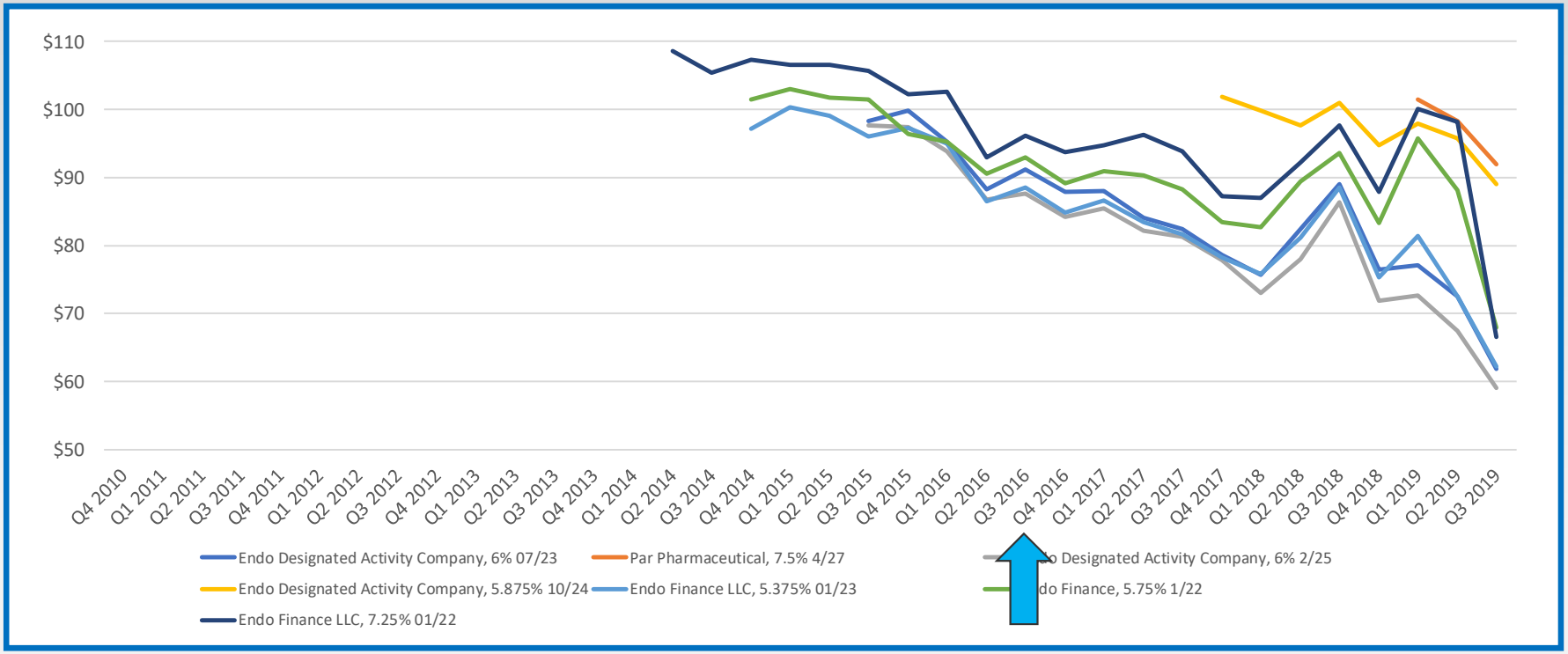
Mallinckrodt



Source: Bloomberg, Excludes Ludlow Corp, 8.0% 3/25 issued in 1993 as the bond is issued by a separate entity

Bond Prices of Comparable Opioid Manufacturers Confirm No Perceived Credit Risk from Opioid Litigation Until 2018/2019 — Endo

Endo International



Source: Bloomberg

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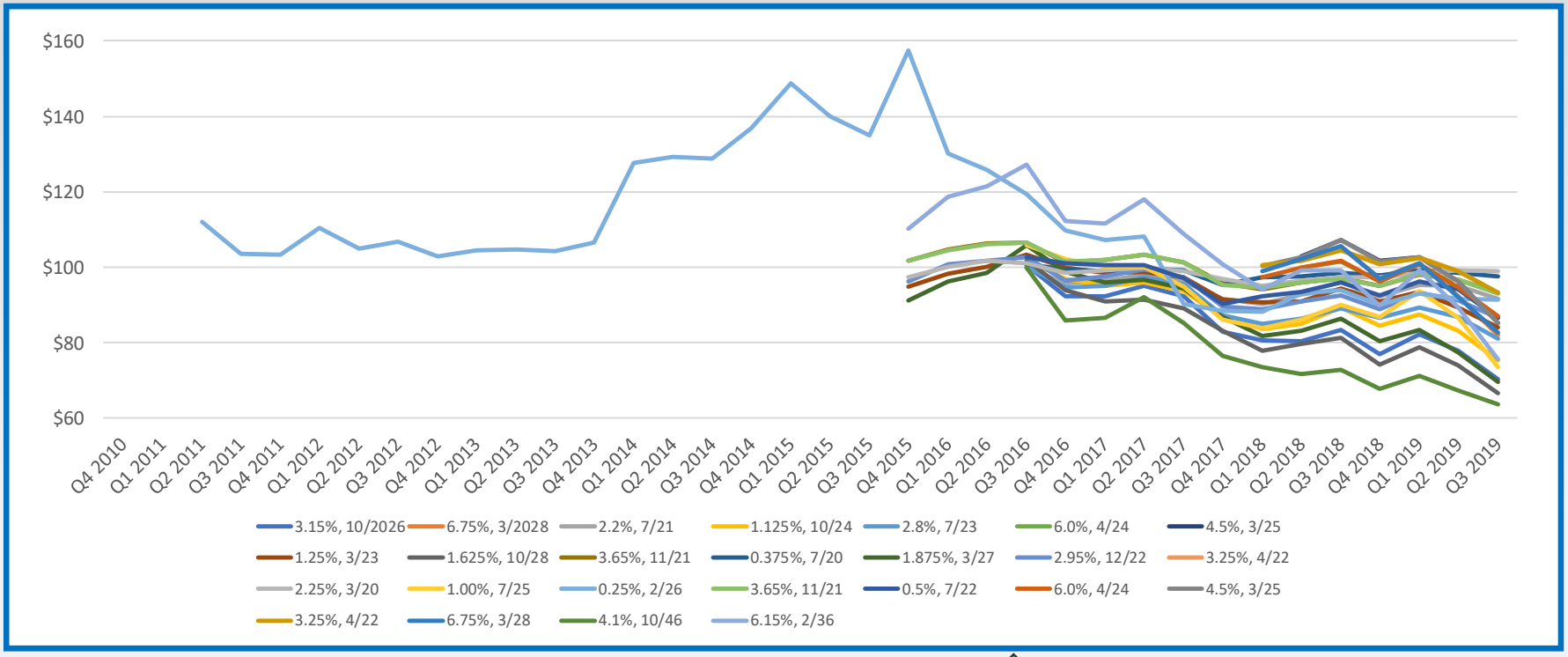
Teva Pharmaceuticals



Source: Bloomberg

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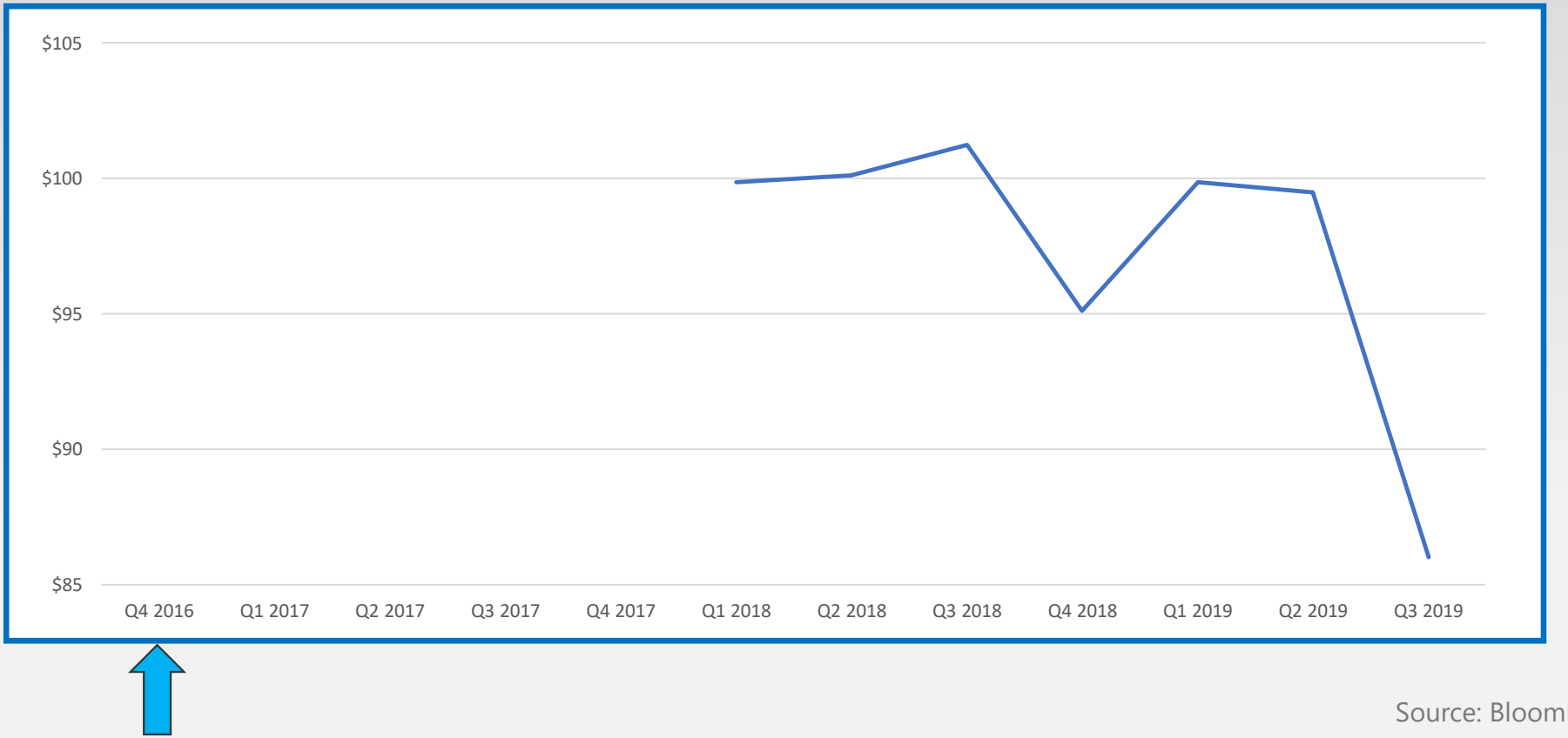
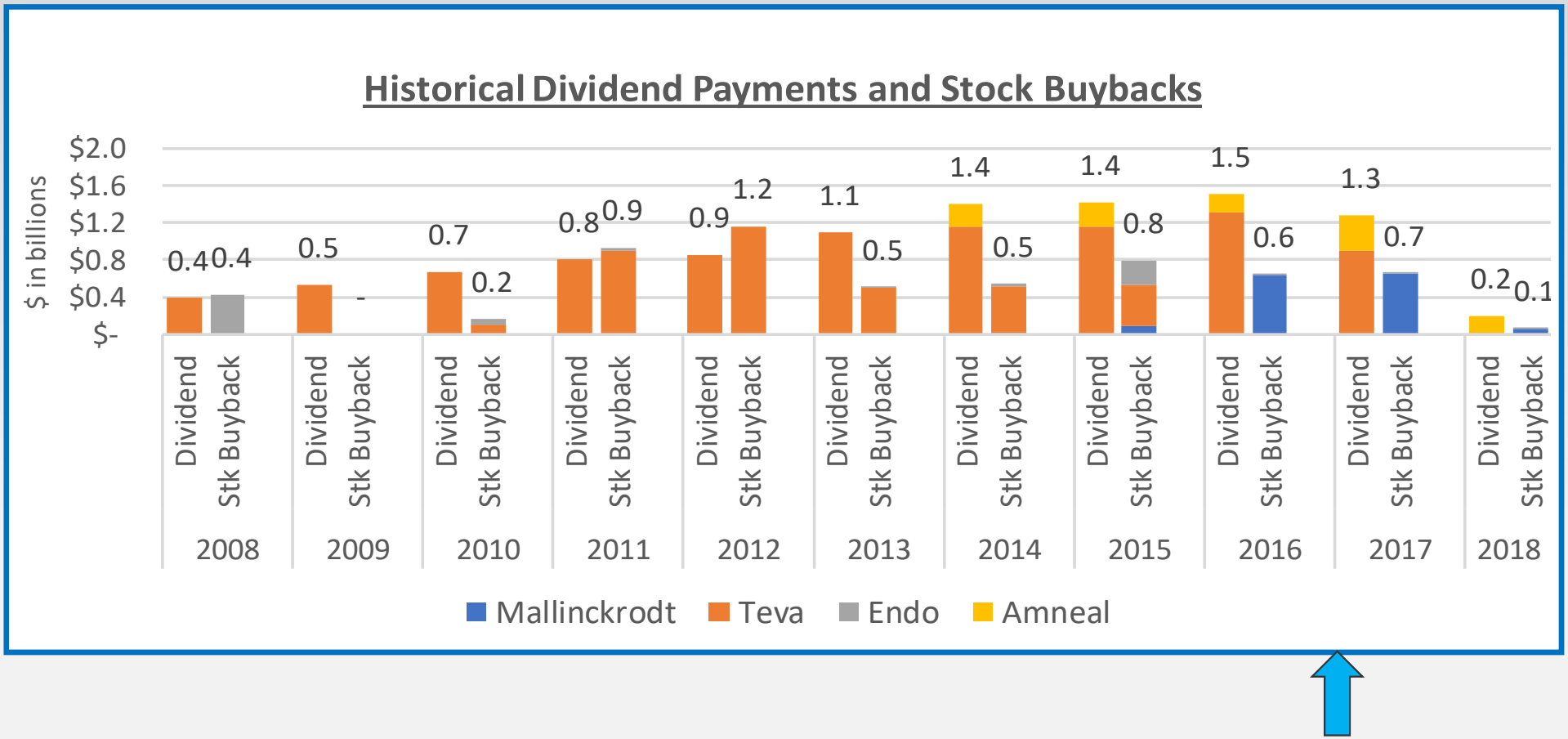


Source: Bloomberg

Dividend And Stock Buy-Back Activity of Comparable Opioid Manufacturers Confirm They Perceived Themselves As Healthy Until 2018



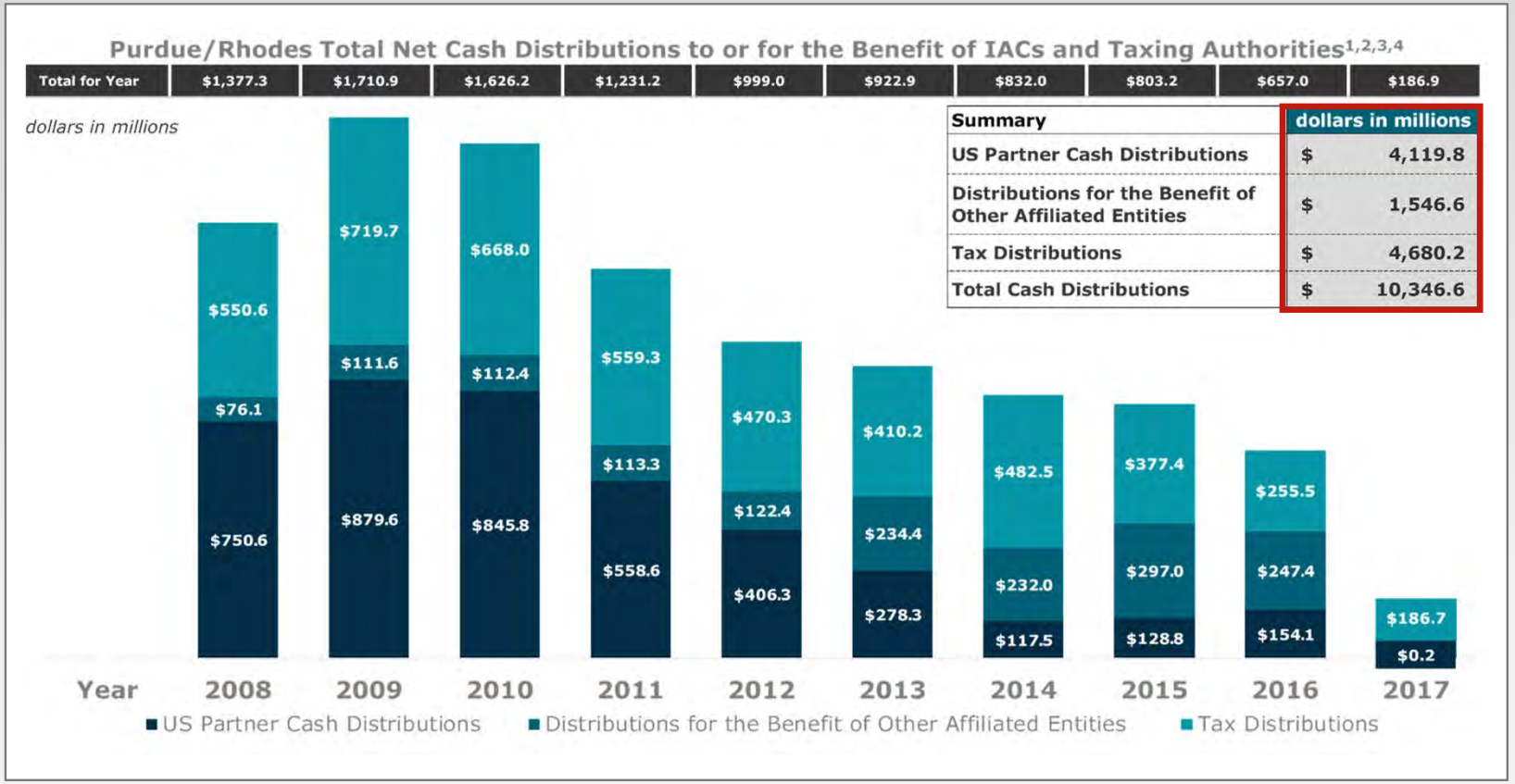
Comparable Manufacturers' Experience with Opioid Litigation Shows Why Purdue Did Not Foresee Liabilities Beyond Its Ability to Pay Before 2017

No Public Disclosures Of Opioid Litigation By Comparable Opioid Manufacturers Until 2018 — After Distributions Ended

Number Of Opioid-Litigation Disclosures in 10-K				
Year Disclosed	**MNK**	**ENDP**	**TEVA**	**AMRX**
2013	*0*	*No 10K*	*No 10K*	*No 10K*
2014	*0*	*No 10K*	*No 10K*	*No 10K*
2015	*0*	*0*	*No 10K*	*No 10K*
2016	*0*	*0*	*No 10K*	*No 10K*
2017	*0*	*0*	*No 10K*	*No 10K*
2018	*1*	*1*	*0*	*No 10K*
2019	*2*	*4*	*1*	*1*

Tax Distributions

Almost Half of All Distributions Were Tax Distributions: The Governmental Claimants Already Received These



dollars in millions	
$	4,119.8
$	1,546.6
$	4,680.2
$	10,346.6

AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11 (SDNY (Bankr.) No. 19-23649-rdd Doc 654-1)

Distributions Fall Into Three Categories: US Partner Distributions

1. "US Partner Distributions"

- Transfers to the limited partners of Purdue Pharma L.P.
- Eventually transferred to trusts of which certain Sackler family members are beneficiaries

	Summary	dollars in millions	
1.	US Partner Cash Distributions	$	4,119.8
	Distributions for the Benefit of Other Affiliated Entities	$	1,546.6
	Tax Distributions	$	4,680.2
	Total Cash Distributions	$	10,346.6

AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Distributions Fall Into Three Categories: Ex-US Distributions

2. "Ex-US Distributions"

- Distributions made to Pharmaceutical Research Associates L.P. ("PRA")
- Reinvested in affiliates of PRA

Summary	dollars in millions	
US Partner Cash Distributions	$	4,119.8
2. **Distributions for the Benefit of Other Affiliated Entities**	$	1,546.6
Tax Distributions	$	4,680.2
Total Cash Distributions	$	10,346.6

AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Distributions Fall Into Three Categories: Tax Distributions

3. "Tax Distributions"

- Distributions made by PPLP to BR Holdings, or Beacon and Rosebay, for taxes associated with Purdue's income
- Approximately 90% actually paid for taxes

Summary	dollars in millions	
US Partner Cash Distributions	$	4,119.8
Distributions for the Benefit of Other Affiliated Entities	$	1,546.6
3. Tax Distributions	$	4,680.2
Total Cash Distributions	$	10,346.6

AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Tax Distributions Were Used For Legitimate Business Purposes

Tax Distributions were made and predominantly (≅ 90%) used for the legitimate purpose of satisfying tax liabilities associated with Purdue's business

In re Sunbeam Corp., 284 B.R. 355, 371 (Bankr. S.D.N.Y. 2002)

"Where the funds are ultimately used for legitimate corporate purposes, then the transfer is not fraudulent[.]"

Purdue Received Reasonably Equivalent Value For Tax Distributions

- **Purdue's payments of Tax Distributions were offset by Purdue's right not to incur tax liabilities itself**

  In re Northlake Foods, Inc., 715 F.3d 1251, 1256 (11th Cir. 2013)

  Tax distributions by pass-through entity to owners not avoidable because debtor received benefit *"of freeing up cash that otherwise would have been dedicated to paying [its] tax liability."*

- **Expert evidence will show that the amount of Tax Distributions is roughly equivalent to the amount of tax Purdue would have paid if PPLP had been a corporation**

Avoiding Distributions Used To Pay Taxes Would Be Punitive

In re Tronox Inc., 464 B.R. 606, 618 (Bankr. S.D.N.Y. 2012)

"[C]ourts have recognized that the purpose of fraudulent conveyance law is remedial rather than punitive."

- **Tax Distributions were used to pay taxes satisfied legitimate liabilities that otherwise would have been Purdue's**
- **The family members and their trusts do not have those funds**
- **Tax Distributions already have been paid to the ***same governmental entities*** that have asserted claims against the families**

Fraudulent Transfer Claims Seeking Ex-US Distributions Cannot Succeed Against The Individuals Or Trusts

Distributions Can Be Recovered Only From:

1. **Initial transferees**
2. **The entity for whose benefit the initial transfer was made or**
3. **Subsequent transferees**

11 U.S.C. 550(a);
In re Finley, Kumble, Wagner, Heine, Underberg, Manley, Myerson & Casey,
130 F.3d 52, 56 (2d Cir. 1997)

Family Members and Trusts Are Not Transferees of Ex-US Distributions

- **The Sackler family members and trusts never received the funds**
- **The funds must be recovered from the Ex-US entities that actually received them**

In re Finley, 130 F.3d 52, 57 (2d Cir. 1997)

"[T]he minimum requirement of status as a 'transferee' is dominion over the money or other asset."

Mack v. Newton, 737 F.2d 1343, 1360 (5th Cir. 1984)

Transfers invested by transferee and not received by owner of transferee cannot be recovered from owner.

Ownership of Transferee Entities Is Insufficient

In re Delta Phones, Inc., 2005 WL 3542667 (Bankr. N.D. Ill. Dec. 23, 2005)

"[T]hat a shareholder holds some ownership interest in a corporation does not somehow mean that all transfers made to the corporation or by it are automatically made for the benefit of the shareholder under section 550(a)(1)."

Id. at *6

Any benefit they received did not *"derive directly from the [initial] transfer"* but instead derived from the *"use to which it [was] put by the transferee"* – this is insufficient to impose "beneficiary" liability

Id. at *5

Timeliness Defenses

Section 548(a): 2-Year Limitations Period

Section 548(a) of the Bankruptcy Code permits the estate to avoid transfers that occurred within 2 years before the petition date (September 15, 2019).

The only distribution from Purdue that occurred within that period was a Tax Distribution of $35 million on December 21, 2017.

Section 544(b)(1): The Limitations Period of "Other Applicable Law"

Delaware Law: 6 DEL. CODE §17-607(c)

- ***Three years from date of transfer, without exception***.

New York Law: Rev. L.P. Act § 121.607(c)

- *Three years from date of transfer, without exception.*

Connecticut Law: Conn. Gen. Stat. §52-552j

- *Four-years from date of transfer; or*
- *One-year discovery period for actual-intent fraud.*

New York Law: CPLR §213 (1), (8)

- *Six-year limitations period; or*
- *Two years from the date of discovery for actual-intent fraud.*

Delaware's 3-Year Statute of Repose Limits Any Potential Fraudulent Transfer Recovery

- The Bankruptcy Court, sitting in New York, applies New York choice-of-law rules to determine which state's law determines the statute of limitations
- Under New York law, the law of the state in which a partnership (PPLP) is organized determines the liability of its limited partners (N.Y. Rev. L.P.A. §121-901)
- Therefore, Delaware's 3-year statute of repose (6 Del. Code § 17-607(c)) limits any potential fraudulent transfer recovery to amounts transferred three years before the first fraudulent transfer claim was asserted

The 6-Year Limitations Period of the Federal Debt Collection Procedures Act Does Not Apply Under § 544(b) For 2 Independent Reasons

1. 28 U.S.C. §3003(c) provides that the FDCPA "shall not be construed to supersede or modify the operation of" the Bankruptcy Code
   - "[T]reating the FDCPA as applicable law under 544(b) would impermissibly modify" the Bankruptcy Code (*In re Mirant*, 675 F.3d 530, 535 (5th Cir. 2012))
2. The United States did not have a ripe FDCPA claim as of the petition date — it had only a "claim for a debt" under 28 U.S.C. §3001(a)(2), not a "debt" within §3002(3)
   - Therefore, the U.S. cannot serve as a triggering creditor under 11 U.S.C. §544(b)

The Doctrine of *Nullum Tempus* Does Not Extend the Look-Back Period

- A bankruptcy estate cannot invoke a sovereign's limitations period, like *nullum tempus*, for the benefit of private creditors

Ultima Homes, Inc. (In re Vaughan Co., Realtors), 498 B.R. 297 (Bankr. D. N.M. 2013)

> *"Because the IRS is only permitted to use a ten-year look back period in order* ***to perform a government function****, the Trustee is likewise limited under Section 544(b)."*

- Because the Uniform Voidable Transactions Act ("UVTA") provision extinguishing claims more than 4-years post-transfer expressly applies to governmental entities (UVTA §1(4) & (11), § 9), it operates as a waiver of *nullum tempus* by all states that have adopted it

- The official commentary to the UVTA and its predecessor, the Uniform Fraudulent Transfer Act, states that the purpose of the 4-year statute of repose was to overrule a case applying *nullum tempus* to actions brought by a sovereign creditor.

(UVTA § 9, Comment 1)

Discovery Rule Is Inapplicable

Distributions were not concealed.

- **Billions took the form of tax distributions paid to the Claimants**
- **States have been conducting investigations into Purdue, in which they have sought and obtained information concerning distributions, since at least 2014**
- **States have had the right to documents and information on demand since 2007**
- **Intense media coverage has reported for years that the Sackler families' wealth is derived from Purdue**

Forbes

> Forbes estimates that the combined value of the drug operations, as well as accumulated dividends over the years, puts the Sackler family's net worth at a conservative $14 billion.

Alex Morrell, The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families, FORBES (Jul. 1, 2015), https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#2b664fa475e0 (cited in NY AG FAC ¶420)

Distributions Within 6 Years Of NY Complaint (At Most)

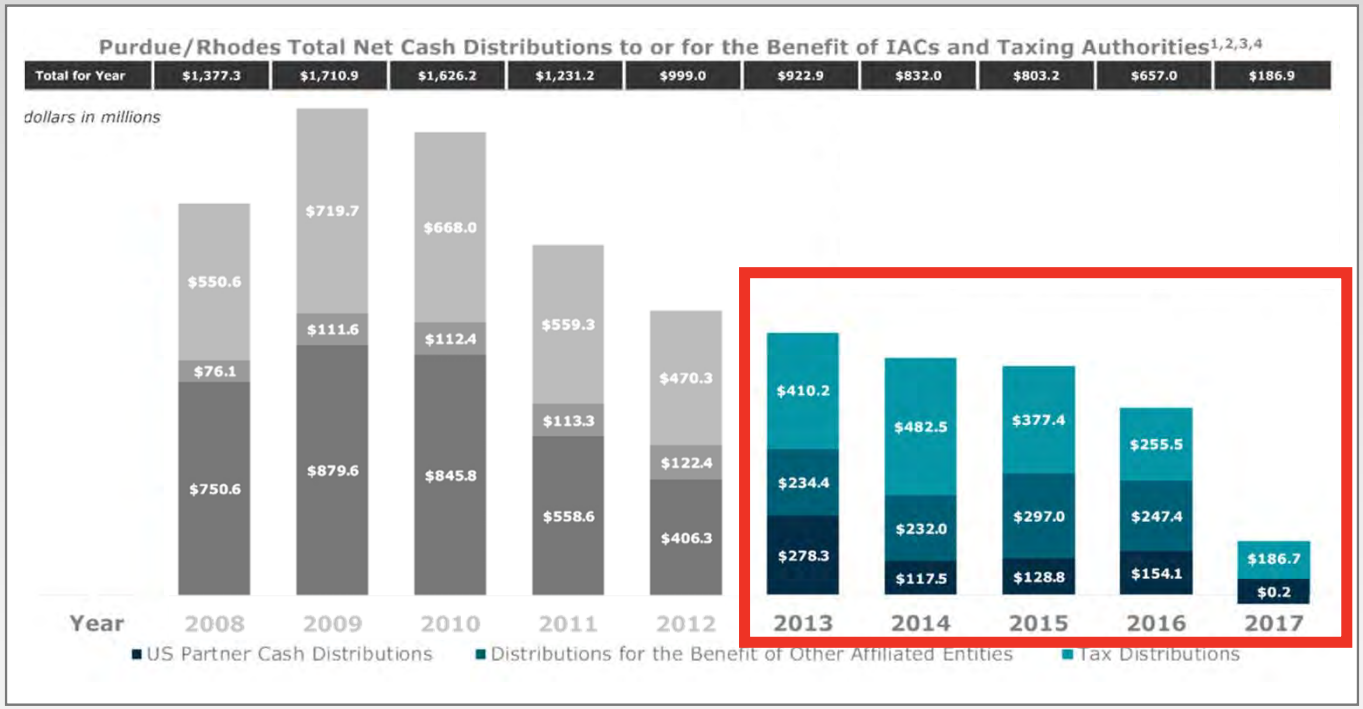
Partner Distributions:
$678,900,000

Tax Distributions:
$1,712,300,000

Ex-US Distributions:
$1,010,800,000

Total:
$3,402,000,000

Amounts include transfers made in the period of January 1 to March 28, 2013.



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Distributions Within 4 Years Of NY Complaint (At Most)

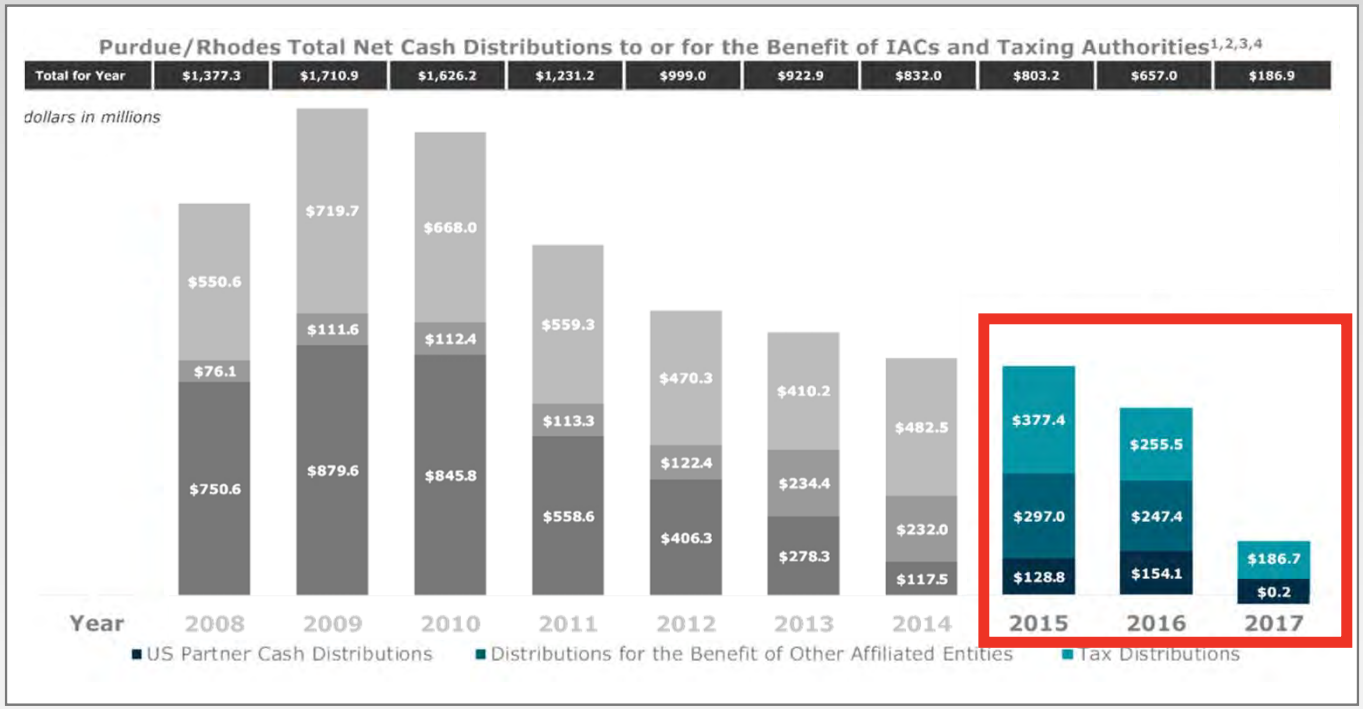
Partner Distributions:
$283,100,000

Tax Distributions:
$819,600,000

Ex-US Distributions:
$544,400,000

Total:
$1,647,100,000

Amounts include transfers made in the period of January 1 to March 28, 2015.



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Distributions Within 3 Years Of NY Complaint (At Most)

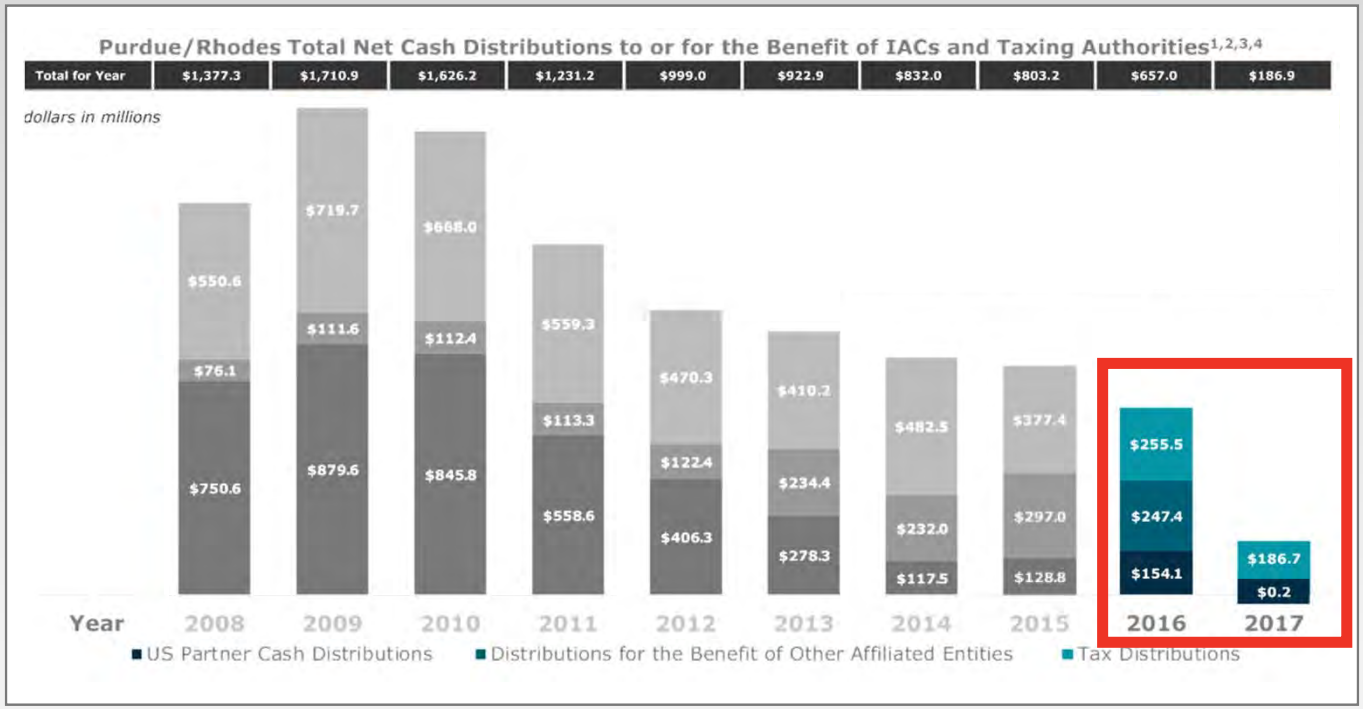
Partner Distributions:
$154,300,000

Tax Distributions:
$442,200,000

Ex-US Distributions:
$247,400,000

Total:
$843,900,000

Amounts include transfers made in the period of January 1 to March 28, 2016.



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11

Four Insurmountable Fraudulent Transfer Problems

1. There was no intent to defraud — Purdue did not in fact perceive a threat from opioid litigation before 2017 and did not face meaningful litigation until 2017

2. When the avalanche of litigation hit in 2017, the Board immediately ceased distributions

3. Purdue was not insolvent when the distributions were made — its sales were in the billions, and the Board left enormous amounts of cash in Purdue every year *after* distributions

4. Purdue's — and other opioid manufacturers' — experience with opioid litigation and access to capital markets shows why Purdue did not anticipate liabilities beyond its ability to pay

Alter Ego Claims

Claimants Must Pierce Each Intermediate Entity Between PPLP And The Assets They Seek

- No evidence of requisite "domination and control"
  - Indirect ownership does not establish control
  - Evidence of involvement in Purdue's business shows only proper board oversight
- No evidence Purdue's business form was a sham and used to commit a wrong
  - Tort allegations are not enough
  - Purdue was a legitimate business selling FDA-approved medications
  - No evidence Purdue was established for fraudulent purposes
  - Distributions to owners were made in accordance with corporate formalities
  - No evidence of "siphoning" — "the improper taking of funds that the owner was not legally entitled to receive" (*Martin Hilti Family Tr. v. Knoedler Gallery, LLC*, 386 F. Supp. 3d 319, 361 (S.D.N.Y. 2019))

Alter Ego Claims Regarding PPLP Fail Under Delaware Law

- **Because PPLP is a Delaware limited partnership, Delaware law governs alter ego claims to disregard its separateness**
- **Limited partnerships do not have "corporate veils" to be pierced**

In re Heritage Organization LLC, 413 B.R. 438, 514 n. 64 (Bankr. N.D. Tex. 2009)

"[T]he alter ego theory cannot be used to attempt to pierce the entity veil of [Delaware limited partnerships] to reach their respective limited partners" (Delaware law)

Pinebrook Props. Ltd. v. Brookhaven Lake Prop. Owners Ass'n., 77 S.W.3d. 487, 499 (Tex. App. 2002)

"[T]he theory of alter ego, or piercing the corporate veil, is inapplicable to partnerships" (rejecting alter ego theory for limited partnerships) (Texas law)

Delaware's Limited Partnership Statute Dictates When Another Person Can Be Held Liable For Debts Of The Limited Partnership

6 Del. C. §17-403(b)

*"**[A] general partner of a limited partnership has the liabilities of a partner in a partnership** . . . to persons other than the partnership and the other partners"*

See also In re LJM2 Co-Inv., L.P., 866 A.2d. 762, 772 (Del. Ch. 2004)

6 Del. C. §17-303(a)

*"**A limited partner is not liable for the obligations of a limited partnership unless he or she is also a general partner or**, in addition to the exercise of the rights and powers of a limited partner, he or she **participates in the control of the business**"*

Delaware's Limited Partnership Statute Dictates When Another Person Can Be Held Liable For Debts Of The Limited Partnership

6 Del. C. §17-303(a)

A limited partner is liable for participation only when "***persons who transact business with the limited partnership [do so] reasonably believing, based upon the limited partner's conduct, that the limited partner is a general partner***."

In re LJM2 Co-Inv., L.P., 866 A.2d 762, 772 (Del. Ch. 2004)

"The basic premise of limited partnership law is that general partners are personally liable for partnership obligations . . . ***if the limited partner does participate in the control of the business, he or she is only liable to persons who transact business with the limited partnership reasonably believing … that the limited partner is a general partner."***

Alter Ego Claims Regarding PPLP Fail Under Delaware Law

- The limited partner of PPLP is PRA, a Delaware limited partnership
- No evidence that PRA—or its ultimate owners, Sackler family members—were sufficiently involved in the business of PPLP to be liable for the partnership's debts
- Delaware's partnership statute provides that participating in the control of the business, for purposes of imposing partnership liability, does ***not*** include:
  - Consulting with or advising employees
  - Causing someone to take or approve any action with respect to the business
  - Voting shares with respect to a matter involving a conflict of interest, or
  - Serving as an officer or director of any person having a business relationship with the partnership (6 DEL. C. §17-303(b))

Alter Ego Claims Regarding PPLP Fail Under Delaware Law

- No claimant has alleged facts that rise to the level required to impose liability under the statute, and there are none
- In its motion to dismiss briefing, Oregon abandoned its effort to disregard PPLP's separateness, tacitly conceding the point

Plaintiff's Opposition to Individual Former Directors' Motion to Dismiss at 20, *State v. Purdue Pharma L.P., et al.*, No. 19-CV-22185 (Or. Cir. Ct. Sept. 11, 2019)

- PPI is liable as general partner of PPLP
- The relevant question is therefore whether PPI can be pierced

Alter Ego Claims Regarding PPI Fail Under New York Law

- **Because PPI is a New York corporation, New York law governs claims alter ego claims to disregard its separateness**

  Matter of Morris v. New York State Dep't of Taxation & Fin., 82 N.Y.2d 135, 141–42 (1993)

  New York law requires proof that *"(1) the owners exercised complete domination of the corporation in respect to the transaction attacked; and (2) that such domination was used to commit a fraud or wrong against the plaintiff, which resulted in plaintiff's injury."*

  "The party seeking to pierce the corporate veil must establish that the owners, through their domination, abused the privilege of doing business in the corporate form to perpetrate a wrong or injustice against that party such that a court in equity will intervene."

- **Because there is no conflict between New York and Delaware veil-piercing law, cases from both states are instructive**

  Hamlen v. Gateway Energy Servs. Corp, 2017 WL 6398729, *11 (S.D.N.Y. Dec. 8, 2017)

  "New York and Delaware veil-piercing law do not materially differ."

Purdue's Corporate Form Was Not Used To Perpetrate A Fraud Or Injustice

- ***<u>It is not enough to show that the corporation engaged in tortious activity</u>***
- **The Claimant must show *<u>additional</u>* wrongdoing, amounting to abuse of the corporate form that injured the Claimant**

Medi-Tec of Egypt Corp. v. Bausch & Lomb Surgical,
2004 WL 415251, at *4 (Del. Ch. Mar. 4, 2004)

To satisfy the ***"fraud or injustice"*** element, a plaintiff must show that "***the corporate form in and of itself*** *operates to serve some* ***fraud or injustice***."

McAnaney v. Astoria Fin. Corp.,
665 F. Supp. 132, 143 (E.D.N.Y. 2009)

"Two elements must be shown in order to pierce the corporate veil: (i) that the owner exercised ***complete dominion over the corporation with respect to the transaction*** *at issue; and (ii) that* ***such domination was used to commit a fraud or wrong that injured the party seeking to pierce*** *the veil"*

Purdue's Corporate Form Was Not Used To Perpetrate A Fraud Or Injustice

TNS Holdings, Inc. v. MKI Sec. Corp., 92 N.Y.2d. 335, 339–40 (1998)

"An inference of abuse does not arise . . . where a corporation was formed for legal purposes or is engaged in legitimate business."

Walnut Hous. Assoc. 2003 L.P., v. MCAP Walnut Hous. LLC, 136 A.D.3d. 403, 404 (1st Dep't 2016)

A plaintiff must establish facts ***"supporting an inference that a corporation, through its alter ego, has created a sham entity designed to defraud investors and creditors."***

(*Citing Crosse v. BCBSD, Inc.*, 836 A.2d. 492 (Del. 2003))

Claimants Bear A Heavy Burden To Pierce PPI

Pauley Petroleum Inc. v. Cont'l Oil Co., 239 A.2d. 629, 633 (Del. 1968)

A court will pierce a corporation's veil only in an exceptional case.

Trevino v. Merscorp, Inc., 583 F.Supp.2d 521, 525 (D. Del. 2008)

Courts recognize that *"limiting one's personal liability is a traditional reason for a corporation,"* and absent the *"specific intent to escape liability for a specific tort . . . the cause of justice does not require disregarding the corporate entity."*

ICT Pharms., Inc. v. Boehringer Ingelheim Pharms., Inc., 147 F.Supp.2d 268, 274 (D. Del. 2001)

Piercing the corporate veil is an "*extraordinary remedy*"

No Evidence Sackler Family Members "Dominated And Controlled" PPI

Skouras v. Admiralty Enterprises, Inc., 386 A.2d. 674, 681 (Del. Ch. 1978)

*"Mere control and **even total ownership** of one corporation by another **is not sufficient to warrant the disregard of a separate corporate entity**."*

National Gear & Piston, Inc. v. Cummins Power, 975 F. Supp. 2d 392, 404 (S.D.N.Y. 2013)

*"[A]llegations of… a parent's ownership and operation of a subsidiary **– even exclusively for the parent's gain –** do not merit piercing the corporate veil."*

No "Domination And Control" of PPI

Factors evidencing domination and control are absent:

- Undercapitalization
- Failure to observe corporate formalities
- Nonpayment of dividends
- The insolvency of the corporation at the relevant time
- "Siphoning" by the dominant stockholder
- Absence of corporate records
- That the corporation is merely a facade for the operations of the dominant stockholder

See MAG Portfolio Consult, GMBH v. Merlin Biomed Group LLC, 268 F.3d 58, 63 (2d Cir. 2001)

Purdue Observed Corporate Formalities

Board meeting minutes, quarterly reports, and financial update presentations for the Board were rigorously maintained.

PURDUE PHARMA INC.

Minutes of a Meeting of the Board of Directors

February 14, 2008

PURDUE PHARMA INC.

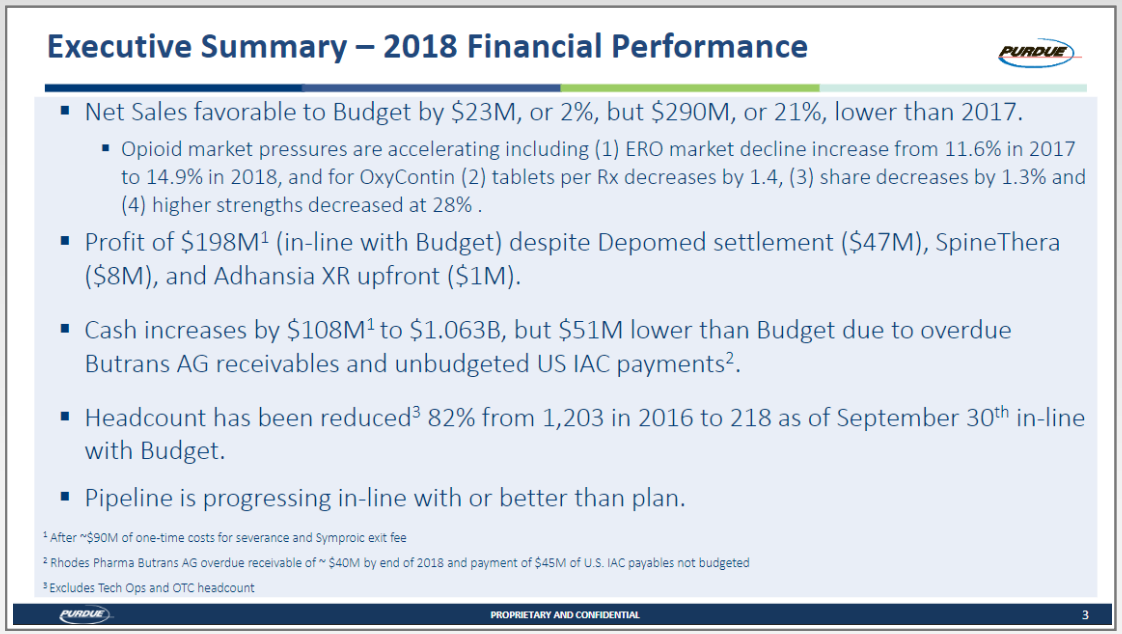
Minutes of a Meeting of the Board of Directors

November 6, 2008

PURDUE PHARMA INC.

Minutes of a Meeting of the Board of Directors

September 23, 2009



Executive Summary – 2018 Financial Performance

- Net Sales favorable to Budget by $23M, or 2%, but $290M, or 21%, lower than 2017.
  - Opioid market pressures are accelerating including (1) ERO market decline increase from 11.6% in 2017 to 14.9% in 2018, and for OxyContin (2) tablets per Rx decreases by 1.4, (3) share decreases by 1.3% and (4) higher strengths decreased at 28% .
- Profit of $198M[1] (in-line with Budget) despite Depomed settlement ($47M), SpineThera ($8M), and Adhansia XR upfront ($1M).
- Cash increases by $108M[1] to $1.063B, but $51M lower than Budget due to overdue Butrans AG receivables and unbudgeted US IAC payments[2].
- Headcount has been reduced[3] 82% from 1,203 in 2016 to 218 as of September 30th in-line with Budget.
- Pipeline is progressing in-line with or better than plan.

[1] After ~$90M of one-time costs for severance and Symproic exit fee

[2] Rhodes Pharma Butrans AG overdue receivable of ~ $40M by end of 2018 and payment of $45M of U.S. IAC payables not budgeted

[3] Excludes Tech Ops and OTC headcount

PROPRIETARY AND CONFIDENTIAL 3

See e.g., Minutes of a Meeting of its Board of Directors, Purdue Pharma Inc., Nov. 6, 2008 (PPLP004415441); Minutes of a Meeting of the Board of Directors, Purdue Pharma Inc., Feb. 14, 2008 (PPLP004415351); Minutes of a Meeting of the Board of Directors, Purdue Pharma Inc., Sept. 23, 2009 (PPLP004415581)

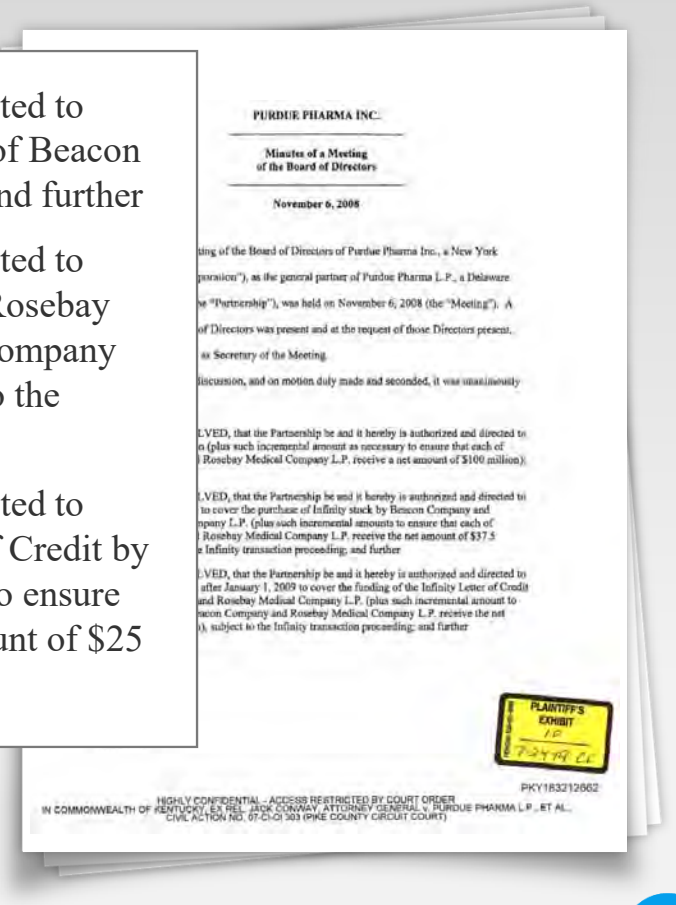
See e.g., Finance Update and 2019 Budget Proposal

Purdue Paid Dividends Only After Formal Board Approval

RESOLVED, that the Partnership be and it hereby is authorized and directed to distribute $200 million (plus such incremental amount as necessary to ensure that each of Beacon Company and Rosebay Medical Company L,P. receive a net amount of $100 million); and further

RESOLVED, that the Partnership be and it hereby is authorized and directed to distribute $75 million to cover the purchase of Infinity stock by Beacon Company and Rosebay Medical Company L.P. (plus such incremental amounts to ensure that each of Beacon Company and Rosebay Medical Company L.P. receive the net amount of $37.5 million), subject to the Infinity transaction proceeding; and further

RESOLVED, that the Partnership be and it hereby is authorized and directed to distribute $50 million after January 1, 2009 to cover the funding of the Infinity Letter of Credit by Beacon Company and Rosebay Medical Company L.P. (plus such incremental amount to ensure that each of Beacon Company and Rosebay Medical Company L.P. receive the net amount of $25 million), subject to the Infinity transaction proceeding;


PURDUE PHARMA INC.

Minutes of a Meeting
of the Board of Directors

November 6, 2008

PLAINTIFF'S EXHIBIT

PKY183212662

HIGHLY CONFIDENTIAL - ACCESS RESTRICTED BY COURT ORDER
IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL.,
CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

See e.g. Minutes of a Meeting of the Board of Directors, Purdue Pharma Inc., Nov. 6, 2008 (PPLP004415441); Minutes of a Meeting of the Board of Directors, Purdue Pharma Inc., Sept. 23, 2009 (PPLP004415581)

Claimants' Purported "Siphoning" Allegations Do Not Establish Domination And Control Of PPI

- The entity that made the challenged distributions was PPLP, not PPI
- Therefore, the fact of the distributions does not establish "domination and control" over PPI, the entity whose separateness must be disregarded
- To disregard PPLP's separateness, it is not enough that family members sat on the Board of PPI and approved distributions from PPLP that benefitted them
- Distributions were a regular occurrence and always board-approved

Deering Milliken, Inc. v. Clark Estates, Inc., 43 N.Y.2d. 545, 551 (1978)

Dividends are not siphoning when they are predictable and regular.

In re The Heritage Org., L.L.C., 413 B.R. 438, 517 n.69 (Bankr. N.D. Tex. 2009)

"[S]iphoning funds is different than making distributions . . . that are permitted by law"
(Applying Delaware law)

All Dividends Were Board-Approved

The payment of regular dividends following formal board approval shows that the shareholders followed corporate formalities and treated the business as a *distinct entity*.

United States v. Pisani, 646 F.2d 83, 88 (3d Cir. 1981)

Corporate formalities were **not observed** where, among other things, **dividends were not paid**.

Schoenberg v. Romike Props., 251 Cal. App. 2d 154, 167 (1967)

Failure to pay dividends was evidence of controlling shareholder's use of corporate funds as if they were his own.

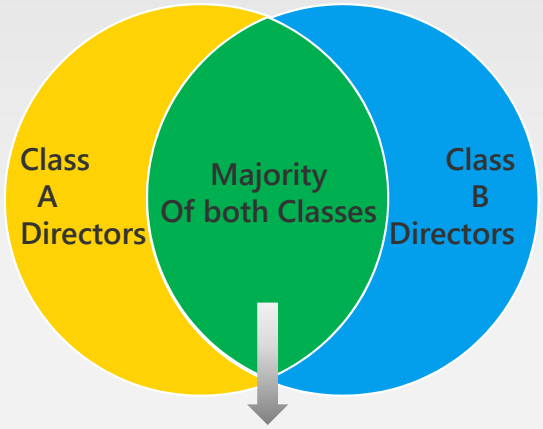
All Dividends Were Board-Approved

- The Board included distinguished outside directors from prominent institutions
- At the relevant times — when distributions were made — it was not "probable" that Purdue would face liabilities beyond its ability to pay
- Purdue had consistently been able to resolve litigations and investigations for manageable amounts
- Its sales were in the billions and it had enormous amounts of unrestricted cash on hand — more than a billion dollars a year from 2014 on
- Its internal forecasts consistently saw the risk of litigation as low and declining
- It had a comprehensive internal compliance program and relied on prominent law firms for outside compliance advice

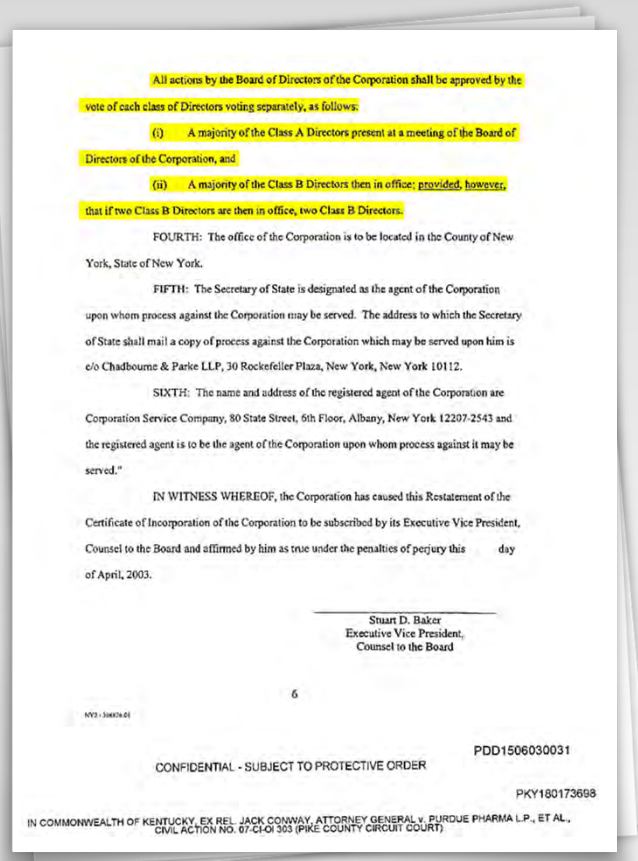
Allegations Insufficient To Show "Domination And Control"

- **Under PPI's governing documents, the A Side and the B Side directors had to jointly agree on all decisions:**

> All actions by the Board … shall be approved by … A majority of the Class A Directors … [and] A majority of the Class B Directors.



Approval Required for Board Actions



All actions by the Board of Directors of the Corporation shall be approved by the vote of each class of Directors voting separately, as follows:

(i) A majority of the Class A Directors present at a meeting of the Board of Directors of the Corporation, and

(ii) A majority of the Class B Directors then in office; provided, however, that if two Class B Directors are then in office, two Class B Directors.

FOURTH: The office of the Corporation is to be located in the County of New York, State of New York.

FIFTH: The Secretary of State is designated as the agent of the Corporation upon whom process against the Corporation may be served. The address to which the Secretary of State shall mail a copy of process against the Corporation which may be served upon him is c/o Chadbourne & Parke LLP, 30 Rockefeller Plaza, New York, New York 10112.

SIXTH: The name and address of the registered agent of the Corporation are Corporation Service Company, 80 State Street, 6th Floor, Albany, New York 12207-2543 and the registered agent is to be the agent of the Corporation upon whom process against it may be served."

IN WITNESS WHEREOF, the Corporation has caused this Restatement of the Certificate of Incorporation of the Corporation to be subscribed by its Executive Vice President, Counsel to the Board and affirmed by him as true under the penalties of perjury this day of April, 2003.

Stuart D. Baker
Executive Vice President,
Counsel to the Board

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PDD1506030031

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PKY180173698

IN COMMONWEALTH OF KENTUCKY, EX REL. JACK CONWAY, ATTORNEY GENERAL v. PURDUE PHARMA L.P., ET AL., CIVIL ACTION NO. 07-CI-01303 (PIKE COUNTY CIRCUIT COURT)

Restated Certificate of Incorporation of PPI as of March 4, 2003 art. III (PKY180173691, —698); Amendment of Certificate of Incorporation §3, amending art. III (PPLP004415886, —889)

Allegations Insufficient To Show "Domination And Control"

Because ***no one member*** of the family had a controlling equity stake or sufficient voting power to control the Board:

- This is ***unlike*** the typical veil-piercing case, where the corporation has a single or majority shareholder.
- Neither ***side*** of the family has a controlling equity stake.
- To say that all owners, together, have control is to say that 100% of the shares controls the corporation.
- That is always the case and provides no basis to disregard the corporate form.

Allegations Insufficient To Show "Domination And Control"

- A seat on the board does not confer the ability or power to exercise control over the corporation.
- Only a shareholder with sufficient shares to elect a majority of the directors of a corporation is considered to have effective control of a corporation.

The Evidence Undercuts Any Inference Of Control By Richard Sackler

- Claimants admit that Purdue's management ***resented and resisted*** Richard Sackler's interactions with executives — as did other directors, both A and B Side

OR Complaint ¶136:

> In a January 2010 email to Richard, Purdue's then-CEO, John Stewart, pushed back on Richard's insistence on unreasonable rates of growth in Purdue's budget:

January 7, 2010 Email from CEO John Stewart to Richard Sackler:

From: Stewart, John H. (US)
Sent: Thursday, January 07, 2010 7:41 PM
To: Sackler, Dr Richard
Subject: FW: 2010 Budget w/att.

However, increasing the assumed prescription growth rate isn't the way to do it, since it will be obvious to many that the 8% is simply an arbitrary figure – and it will be interpreted as an imposition as opposed to an action that will stimulate the type of business building behaviors we want to encourage.

(PURDUE-COR-00026762)

The Evidence Undercuts Any Inference Of Control By Richard Sackler

March 7, 2012 email from Russell Gasdia to John Stewart

Anything you can do to reduce the direct contact of Richard into the organization is appreciated. I realize he has a right to know and is highly analytical, but diving into the organization isn't always productive (PPLPC012000368569)

See 1 WM. E. KNEPPER & DAN A. BAILEY, LIABILITY OF CORPORATE OFFICERS AND DIRECTORS §1.03 (8th ed. 2019) :

"The oversight function of a board of directors at times creates friction between the board and management with respect to the appropriate degree to which the board becomes involved in management's activities."

Sackler Family Members Did Not Function As A Single Unit

- Evidence demonstrates that family members frequently disagreed
- Oregon alleged in its prepetition complaint only that they "are united by common ownership and control" of Purdue and together held a majority of Board seats
- This is not a plausible theory of domination
- **All shareholders of every company are "united by common ownership," and jointly have the power to appoint Board members and control the company**

The Members of The Sackler Family Often Disagreed — Examples

- In May 2009, Richard Sackler wanted to make an investment that Mortimer Sackler rejected:

On 5/19/09 5:26 PM, "Sackler, Dr Richard" wrote:

PCI is basically worth its cash.

What about buying out this company for its cash and small possibility that Remoxy profit stream will be of some value in the future?

Richard,

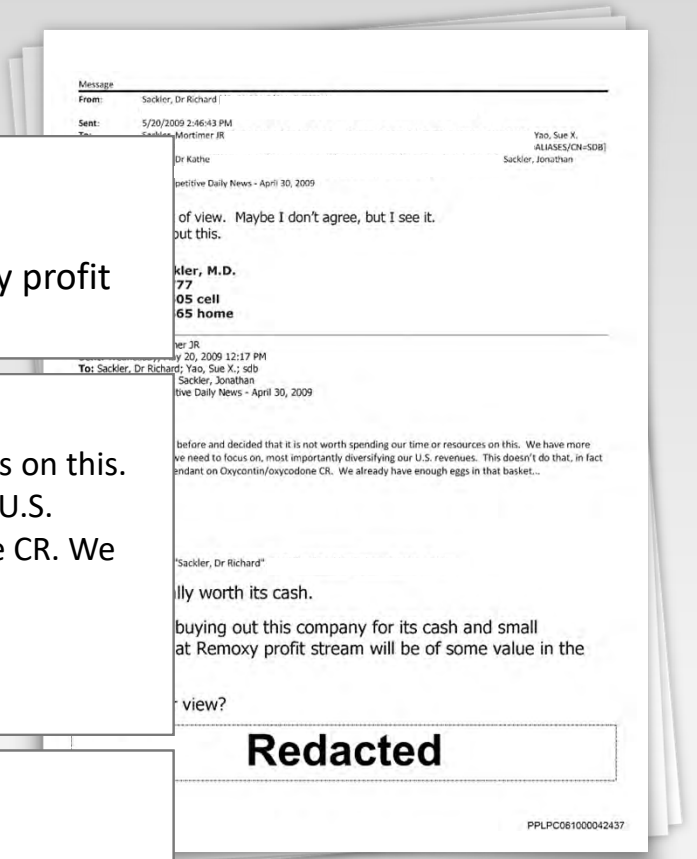
We went through this before and decided that it is not worth spending our time or resources on this. We have more important areas that we need to focus on, most importantly diversifying our U.S. revenues. This doesn't do that, in fact it makes us more dependent on Oxycontin/ocycodone CR. We already have enough eggs in that basket…

Regards,

Mortimer

I see your point of view. Maybe I don't agree, but I see it. Enough said about this.

Richard S. Sackler, M.D.

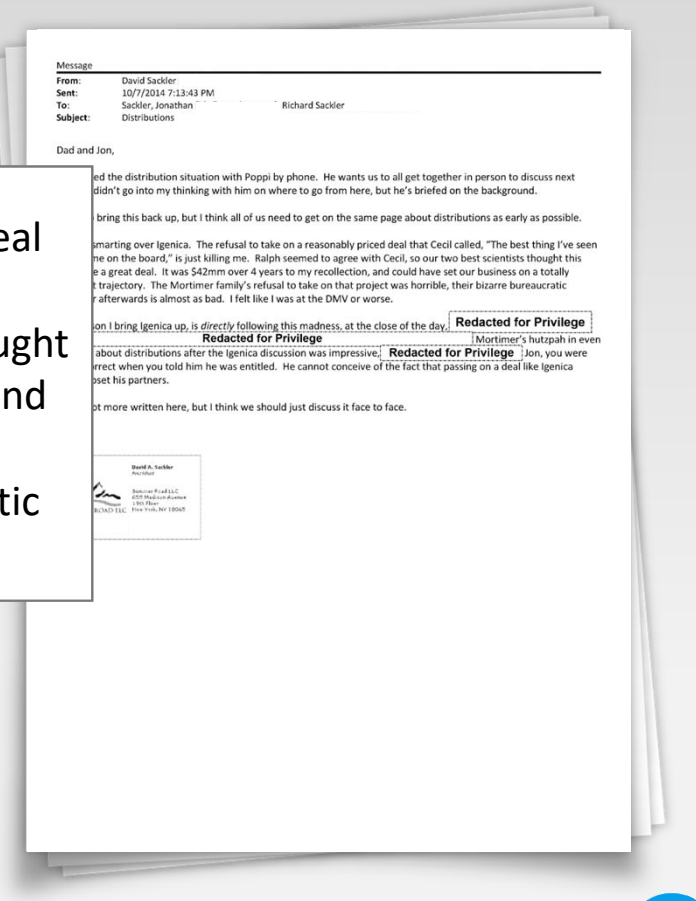


5/19/09 Email From R. Sackler (PLPC061000042437)

The Members of The Sackler Family Often Disagreed — Examples

- In 2014, Side A rejected an investment the B Side supported

I'm still smarting over Igenica. The refusal to take on a reasonably priced deal that Cecil called, "The best thing I've seen in my time on the board," is just killing me. Ralph seemed to agree with Cecil, so our two best scientists thought this would be a great deal. It was $42mm over 4 years to my recollection, and could have set our business on a totally different trajectory. The Mortimer family's refusal to take on that project was horrible, their bizarre bureaucratic behavior afterwards is almost as bad. I felt like I was at the DMV or worse.



Message

From: David Sackler
Sent: 10/7/2014 7:13:43 PM
To: Sackler, Jonathan Richard Sackler
Subject: Distributions

Dad and Jon,

ed the distribution situation with Poppi by phone. He wants us to all get together in person to discuss next
didn't go into my thinking with him on where to go from here, but he's briefed on the background.

bring this back up, but I think all of us need to get on the same page about distributions as early as possible.

marting over Igenica. The refusal to take on a reasonably priced deal that Cecil called, "The best thing I've seen
ne on the board," is just killing me. Ralph seemed to agree with Cecil, so our two best scientists thought this
e a great deal. It was $42mm over 4 years to my recollection, and could have set our business on a totally
trajectory. The Mortimer family's refusal to take on that project was horrible, their bizarre bureaucratic
afterwards is almost as bad. I felt like I was at the DMV or worse.

on I bring Igenica up, is *directly* following this madness, at the close of the day. Redacted for Privilege
Redacted for Privilege Mortimer's hutzpah in even
about distributions after the Igenica discussion was impressive. Redacted for Privilege Jon, you were
rrect when you told him he was entitled. He cannot conceive of the fact that passing on a deal like Igenica
set his partners.

t more written here, but I think we should just discuss it face to face.

- Other examples:
  - B Side's subordinated debt proposals
  - Amounts of distributions

Even Majority Shareholder Status Would Not Suffice To Show Domination And Control

General Star Nat. Ins. Co. v. Adminsitra Asigurarilor de Stat,
713 F. Supp. 2d 267, 279 (S.D.N.Y 2010)

"[T]he exercise of power incidental to majority stock ownership cannot form the basis for disregarding the corporate form . . . . Control over the board of directors by means of shareholder voting rights is a prerogative of any majority shareholder."

Capmark Fin. Group Inc. v. Goldman Sachs Credit Partners L.P.,
491 B.R. 335, 349–350 (S.D.N.Y. 2013)

"[A]llegations do not allege facts beyond relationships 'typical of a majority shareholder or parent corporation'" where the funds were not commingled, the entities were not inadequately capitalized, and all other corporate formalities were observed.

Tycoons Worldwide Group Public Co. Ltd. v. JBL Supply Inc.,
721 F. Supp. 2d 194, 205 (S.D.N.Y. 2010)

"The fact that [the individual] is the majority shareholder and an officer of [the corporation] is not in itself, a basis for piercing the corporate veil."

Distributions Do Not Warrant Disregarding The Corporate Form

- The distributions preceded the avalanche of litigation — and immediately stopped when the litigations hit
- Purdue satisfied its debts, its net sales vastly exceeded total distributions each year, and it had huge amounts of unrestricted cash on hand at all times

Justus v. Miller, 47 Misc.3d. 1210(A), at 3-4 (N.Y. Sup. Ct. Nassau Cnty. 2015)

"Given the temporal degree to which the challenged asset transfers antedate the commencement of Action 1 and . . . the Judgment . . . the Court finds there has been an inadequate showing that any corporate domination . . . was employed so as to defraud the Plaintiffs and deprive them of an opportunity to satisfy their outstanding monetary claims."

See also Deering Milliken, Inc. v. Clark Estates, Inc., 43 N.Y.2d 545, 551 (1978)

Hambleton Bros. Lumber Co. v. Balkin Enters., Inc., 397 F.3d 1217, 1231 (9th Cir. 2005)

Rejecting veil-piercing claim where plaintiff did not make sufficient showing of a *"causal connection between the alleged 'milking' of distributions and [the creditor's] injury."*

Distributions Do Not Warrant Disregarding The Corporate Form

- Purdue was not facing probable liabilities at the time it made the distributions
- A hypothetical future damages claim does not warrant piercing the corporate veil

Sahu v. Union Carbide Corp., 2012 WL 2422757, at *19 (S.D.N.Y. June 26, 2012)

A corporation's *"economic viability is not important for the purpose of looking into the future to see if [the corporation] can pay a specific dollar amount of damages"* — instead, a corporation's *"financial status is material to the extent it sheds light on [its] legitimacy as a corporation."*

Distributions Do Not Warrant Disregarding The Corporate Form

Even if Purdue were unable to meet its debts, that alone would be insufficient to warrant piercing

Art Capital Bermuda Ltd. v. Bank of N.T. Butterfield & Son Ltd., 169 A.D.3d 426, 427 (1st Dep't 2019)

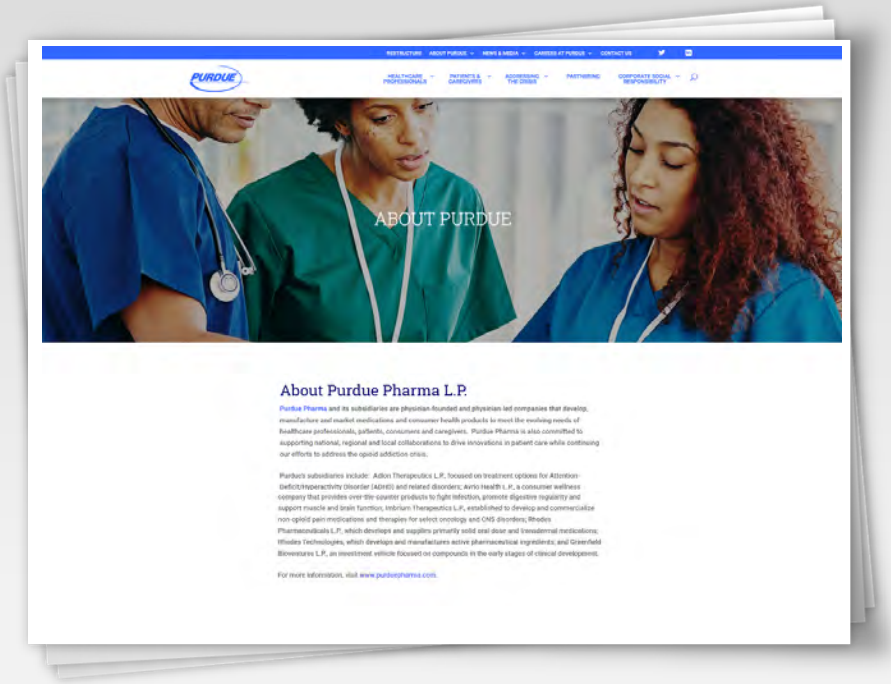
"The fact that Art Capital and Bluefin might not have sufficient assets to satisfy the judgment that the Bank might obtain against them does not warrant piercing the corporate veil."

Kleinman v. Blue Ridge Foods, LLC, 2011 WL 2899428, at *10 (N.Y. Sup. Ct. July 7, 2011)

"[T]he corporate form may not be disregarded merely because the assets of the corporation are insufficient to assure plaintiff the recovery he seeks."

Purdue Was Created For Legitimate Purposes

- Purdue's predecessor antedates the Sackler families' ownership
- Arthur, Mortimer, and Raymond Sackler purchased the company in 1952
- No evidence Purdue was designed for fraudulent purposes or erected as a sham
- Purdue develops, manufactures, and markets FDA-approved medications



See Purdue Pharma Website, purduepharma.com/patients-caregivers/medicines-from-purdue/

Numerous Intermediate Entities Stand Between Purdue And The Sacklers

- To reach the Sackler family members or trusts, Claimants must pierce numerous intermediate entities

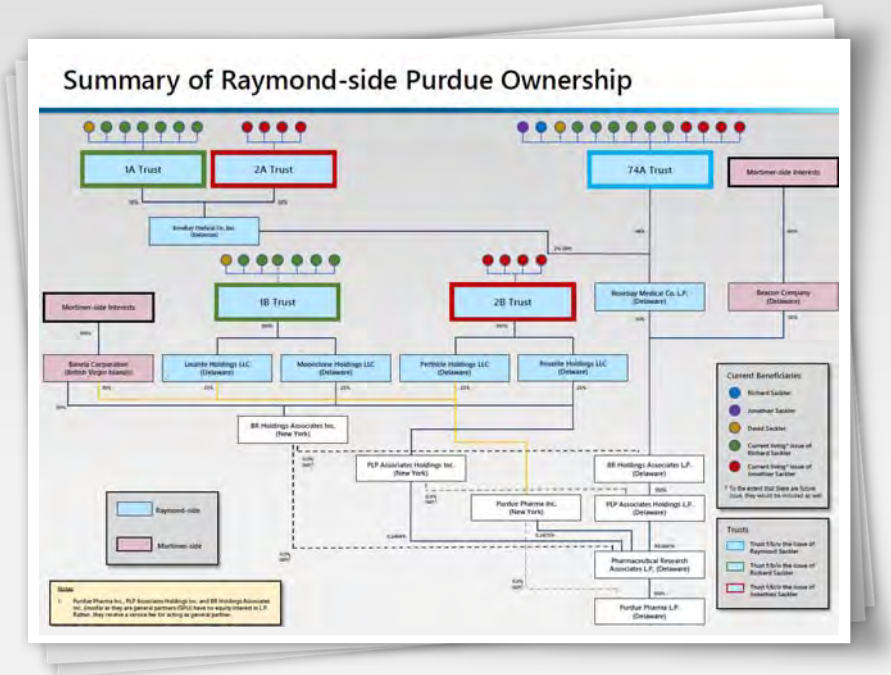
In re Gulf Fleet Holdings, Inc., 491 B.R. 747, 790 (Bankr. W.D. La. 2013)

Where a plaintiff seeks to establish liability for all members of a corporate structure, it must "***establish alter ego liability with respect to each one of the entities***" in that structure.

In re Heritage Org. LLC, 413 B.R. 438, 514 (Bankr. N.D. Tex. 2009)

No "***global application***" of alter-ego theory permitted, unless plaintiff can establish veil piercing at "***each level or layer of ownership … within the multifaceted entity structure***."

See also Gillen v. 397 Properties, L.L.C., 2002 WL 259953, at *1 (Del. Ch. Feb. 15, 2002)



Raymond-side Informational Presentation (November 22, 2019), Supplemental Materials at page 2

Veil-Piercing Has Been Rejected In Similar Cases

Port Chester Elec. Const. Co. v. Atlas, 40 N.Y.2d 652, 657 (1976)

- In *Port Chester Elec. Const.* Co., the New York Court of Appeals rejected a veil piercing claim where the "***external indicia of separate corporate entities [were] at all times maintained***."
- **Although the shareholder served as the *"controlling principal of [the corporations],"* this alone was *"insufficient to justify disregarding the corporate form"* since the shareholder *"respected the separate identities of the corporations"* and *"each of the corporation[s] was pursuing its separate corporate business*."**
- ***"The determinative factor is whether the corporation is a 'dummy' for its individual stockholders who are in reality carrying on the business in their personal capacities for purely personal rather than corporate ends*."**

Claimants' 4 Insurmountable Alter Ego Problems

1. No evidence of the requisite domination and control
   - Indirect ownership does not establish control
   - Evidence of involvement in Purdue's business is not enough
2. No evidence Purdue's business form was a sham or used to commit a wrong
   - Tort allegations are not enough
   - Purdue was a legitimate business selling FDA-approved medications
   - No evidence Purdue was established for fraudulent purposes
   - Distributions to owners were made in accordance with corporate formalities
   - No evidence of siphoning
3. Claimants must pierce each intermediate entity between PPLP and assets they seek
4. Limited partnerships do not have "corporate veils" to be pierced

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 4: Fraudulent Transfer

April 27, 2021

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 5: Underlying Claims Against Purdue, Effect of Criminal Plea, Deceptive Marketing, Preemption

April 27, 2021

Purdue Liability Is Necessary But Not Sufficient to Establish Director Liability

- All of the claims against the directors are dependent on Claimants' proving the underlying liability of Purdue
- The pre-petition claims against Purdue were weak but unmanageable — Purdue filed bankruptcy only because "the sheer number and scale of the Pending Actions is simply unmanageable" (Debtors' Informational Br. at 40 (Dkt. 17))
- Each Claimant must prove misrepresentation, causation, damage — all elements
- Each must establish the validity of the novel nuisance theory under its state's law
- Each must address overarching problems — *e.g.*, preemption, proximate cause
- Purdue's 2020 guilty plea does not help any Claimant establish a claim against Purdue

Purdue's 2020 Guilty Plea Does Not Help Any Claimant Establish A Claim Against Purdue

Purdue's 2020 Guilty Plea Does Not Help Any Claimant Establish A Claim Against Purdue

- Purdue pled guilty to a 3-count Information charging it with conspiracy to defraud the United States and violate the Food, Drug & Cosmetics Act
- Purdue admitted to:
  1. Fraud on the DEA and aiding and abetting prescribers in dispensing prescription drugs without a legitimate medical purpose (Count 1)
  2. Payments to two prescribers to induce them to write prescriptions in violation of the Anti-Kickback Statute (Count 2)
  3. Payments to Practice Fusion in violation of the Anti-Kickback Statute (Count 3)
- Nothing in Purdue's plea suggests that the former directors knew anything about Purdue's misconduct

(Purdue Plea Agmt., Schedule A, pp. 15-18)

Count 1: Fraud on The DEA – 1st Admission by PPLP

- **PPLP admitted that — in the sales data it provided to the DEA in support of its quota allocation requests — it included OxyContin prescriptions written by HCPs listed on Region Zero** (Purdue Plea Agmt., Schedule A, p. 16 ¶e)

Count 1: Fraud on The DEA – 1st Admission by PPLP

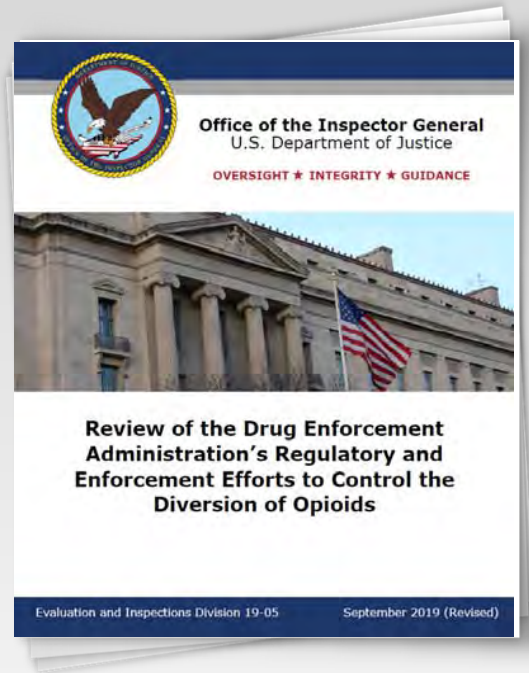
- **Claimants have no similar claims because quota allocation is determined exclusively by the DEA — no one else has quota-setting powers** (21 C.F.R. § 1303.21, *ff.)*
- PPLP did not have the power to stop Region Zero HCPs from prescribing OxyContin—but the State Claimants did have that power and had access to Region Zero information on request
- PPLP did not admit that inclusion of OxyContin prescriptions written by Region Zero HCPs actually affected the DEA's quota allocation in any year, **or did so in a way that affected any particular Claimant, or did so during a year within any applicable statute of limitations**
- The evidence shows that this misconduct had no effect on DEA quotas

DEA Was At All Times Well Aware That OxyContin Was Abused & Diverted

DEA's 2001 OxyContin National Action Plan:

DEA's Response to the OxyContin Crisis

To combat the growing OxyContin crisis, in the spring of 2001 DEA initiated an OxyContin National Action Plan. According to DEA, this was the first time in DEA's history that it developed a plan to target a brand-specific controlled substance with a focus on enforcement and regulatory investigations that targeted key points of diversion. The plan directed DEA field divisions and DEA's Office of Diversion Control (OD) to conduct in-depth investigations of OxyContin's manufacturer and distributors to determine their compliance with regulatory requirements designed to prevent diversion. The plan also sought to coordinate enforcement and intelligence sharing with federal, state, and local agencies; take regulatory and administrative action to limit abusers' access to OxyContin; and conduct outreach, awareness, and education initiatives to educate the public on the dangers of abusing OxyContin.



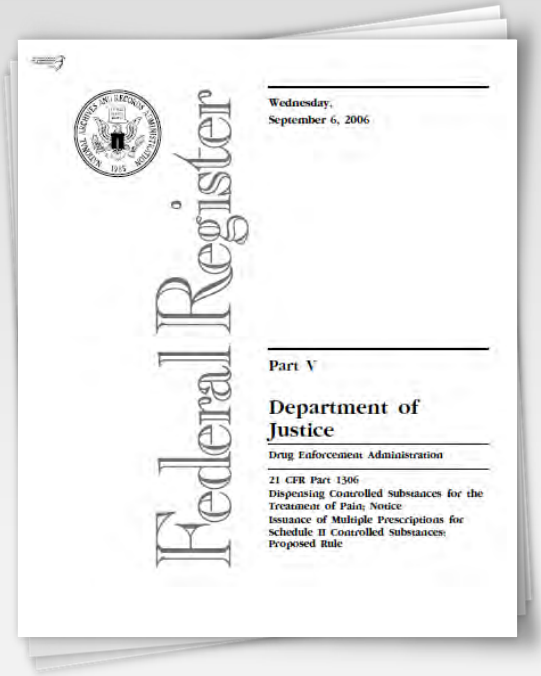
DOJ Office of Inspector General, OEI-19-05, *Review of DEA's Regulatory & Enforcement Efforts to Control the Diversion of Opioids*, at 4-5 (Sept. 2019) (https://oig.justice.gov/reports/2019/e1905.pdf)

DEA Was At All Times Well Aware That OxyContin Was Abused & Diverted

DEA 2006 Policy Statement: *Dispensing Controlled Substances for the Treatment of Pain*

Extent of Abuse in the United States of Controlled Prescription Drugs

The abuse (nonmedical use) of prescription drugs is a serious and growing health problem in this country. . . . A measure of the problem among young people is the 2005 Monitoring the Future (MTF) survey conducted by the University of Michigan. . . . For example, in 2005 ... 5.5 percent of [12th grade] students reported using OxyContin in the past year.



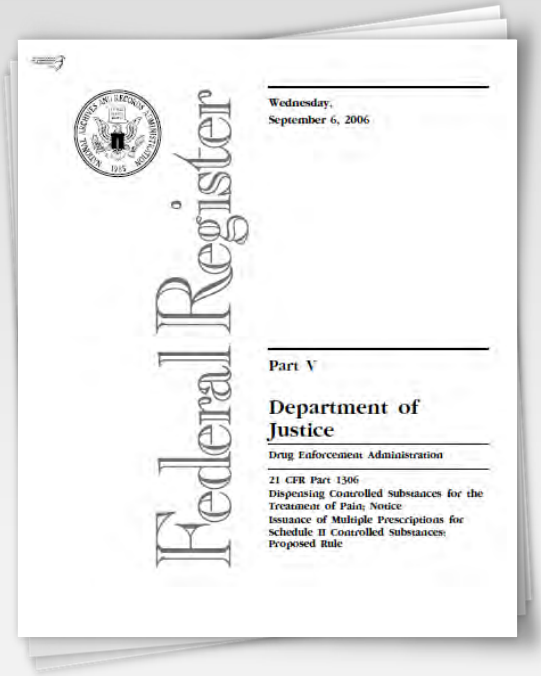
DEA Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52716 (Sept. 6, 2006)

DEA Was At All Times Well Aware That OxyContin Was Abused & Diverted

DEA 2006 Policy Statement: *Dispensing Controlled Substances for the Treatment of Pain*

- *Robert A. Smith, M.D.* (70 FR 33207)—Dr. Smith gave one patient seven to ten prescriptions of OxyContin per visit on a weekly basis. The prescriptions were written in the patient's name as well as the names of the patient's father and her fiancé. Each visit, the patient paid Dr. Smith a $65 fee for the office visit plus an additional $100 for the fraudulent prescriptions.

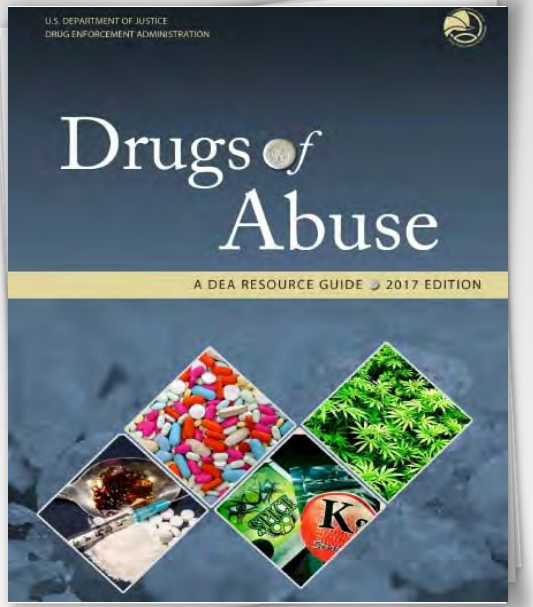
- *James S. Bischoff,, M.D.* (70 FR 12734)—
. . . Dr. Bischoff wrote the boy a prescription for 100 OxyContin, which Dr. Bischoff personally took to a pharmacy to be filled. Dr. Bischoff delivered only 20 tablets to the boy, unlawfully diverting the remaining 80 tablets.



DEA Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006)

DEA Was At All Times Well Aware That OxyContin Was Abused & Diverted

DEA, *Drugs of Abuse* (2017 ed.)

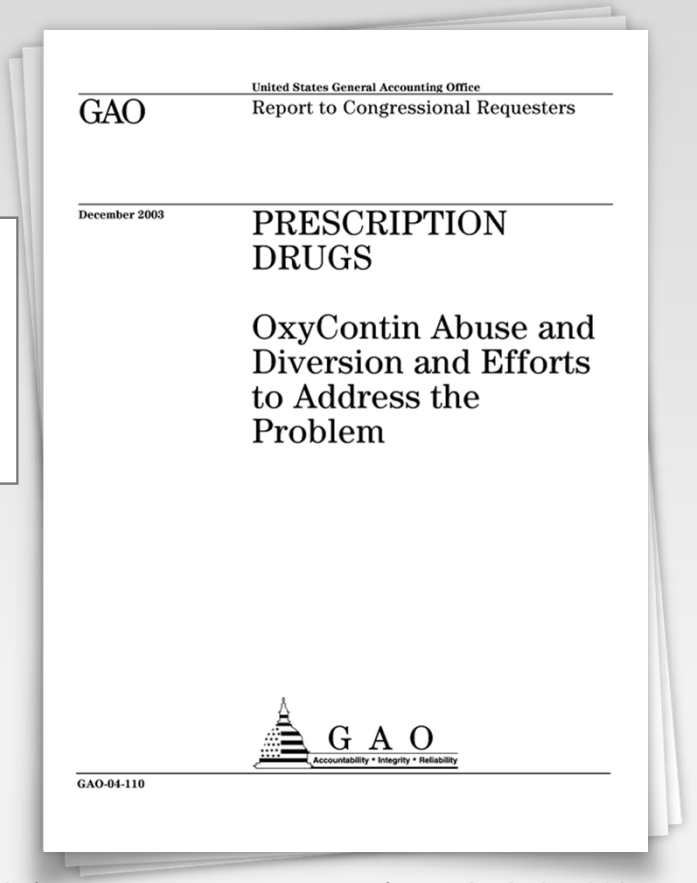


DEA, *Drugs of Abuse: A DEA Resource Guide* 38 (2017 ed.) - https://www.dea.gov/documents/2017/06/15/drugs-abuse

DEA Considered Abuse & Diversion in Setting Purdue's Quota

2003 GAO Report to Congress

In the last several years, DEA has taken the additional step of lowering the procurement quota requested by Purdue for the manufacture of OxyContin as a means for addressing abuse and diversion.



Dec. 2003 GAO Rept. to Congress at 38 (https://www.gao.gov/products/GAO-04-110)

DEA Considered Abuse & Diversion in Setting Purdue's Quota

From: Stedge, Barbara
Sent: Thursday, July 30, 2009 11:24 AM

Subject: FW: 2009 quota letter

Michael,

Can you provide DEA's rationale for granting less than the requested amount?
How is the inventory allowance being determined?

From: Morley, Michael J.
Date: Thursday, July 30, 2009 2:55 PM

Subject: RE: 2009 quota letter

Due to abuse and diversion of oxycodone products, DEA continues to authorize registered dosage form manufacturers a 30% inventory allowance. . . .

Your quota adjustment was assessed on many factors, including but not limited to . . .

* diversion/ abuse concerns

Message
From: Stedge, Barbara

Sent: 8/4/2009 6:03:06 PM
To: Morley, Michael J.
Subject: RE: 2009 quota letter
Attachments: image001.jpg; image002.gif

Michael:

I realize that there are various estimated values and as they change the Year-End projections will change. By updating the planned purchases with the actual quota granted and keeping all other factors the same, the total inventory allowance was 30.8%. Since DEA has applied an inventory allowance of 35.6% it would indicate that some other major factor[such as estimated commercial sales] in DEA's calculation was different.

My apologies if this wasn't clear, but I was trying to identify where the calculation differed. By revising the inventory projection and comparing the allowance to DEA's it was evident that the difference was the result of some other estimated value such as commercial demand as you indicated below.

Thank you for your time in this matter.

Regards,

Barbara Stedge

Director Controlled Substances/DEA Affairs

Purdue

973-837-5065

From: Morley, Michael J.
Sent: Tuesday, August 04, 2009 4:19 PM
To: Stedge, Barbara
Cc: Strait, Matthew J.; Carr, Susan M; Harper-Avilla, Stacy; Sannerud, Christine A
Subject: RE: 2009 quota letter

Good afternoon Barbara,

I'm not exactly sure what you are asking, but I will try to respond to your inquiry.

The tables provided have various estimated values and your calculations are based on these estimated values, i.e. forecasted sales, loss on assay, export requirements, etc.

Looking strictly at the data in your tables:

Your first table estimated 17,605 kg in sales with an estimated year-end inventory of 7,728 kg (44%)
Your second table estimated 17,605 kg in sales with an estimated year-end inventory of 5,409 kg (31%)

I suspect the difference lies in our offices estimated commercial demand vs. your estimated demand, but any difference in the various calculations or estimates will result in different calculated year-end inventory. As mentioned before, our office allows oxycodone dosage form manufacturers a 30% inventory allowance. In addition, due to the switch over to your new product line, our office considered your firm's request for an additional 5.6% inventory allowance.

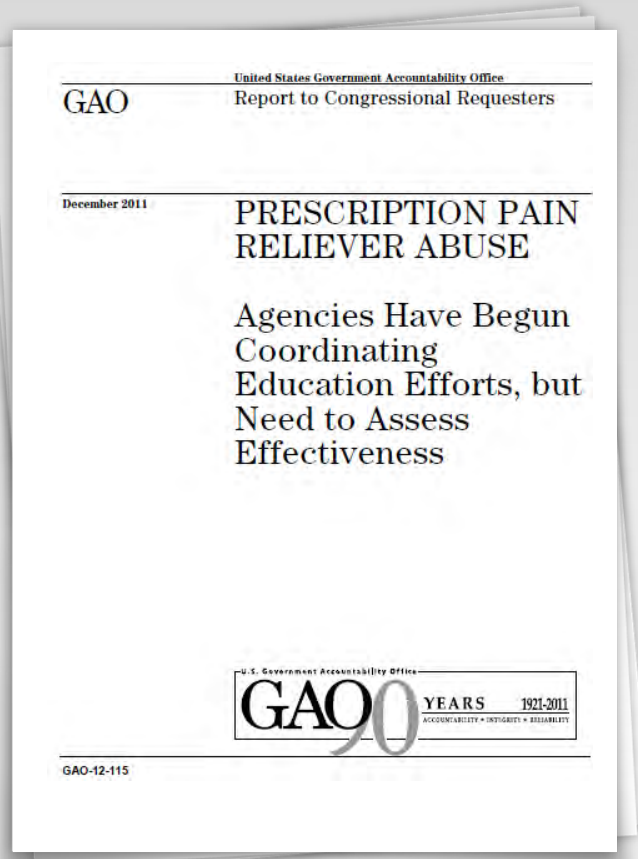
CONFIDENTIAL PWA001036221

July30-Aug. 4, 2009 Email Chain (PWA001036221)

DEA Has Determined That Establishing Quotas Based on Known Diversion "Will Not Appreciably Affect Diversion"

2011 GAO Report to Congress

While [DEA] officials said that they do seek to account for known diversion when setting [Aggregate Production Quotas], they said that establishing quotas based on known diversion for the purpose of reducing the availability of prescribed drugs will not appreciably affect diversion at the retail level and may prevent legitimate patients from having access to medication for legitimate medical needs.


United States Government Accountability Office
GAO
Report to Congressional Requesters

December 2011

PRESCRIPTION PAIN RELIEVER ABUSE

Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness

U.S. Government Accountability Office
GAO 90 YEARS 1921-2011
ACCOUNTABILITY • INTEGRITY • RELIABILITY

GAO-12-115

Dec. 2011 GAO Rept. to Congress at 47 (https://www.gao.gov/assets/590/587301.pdf)

Count 1: Fraud on The DEA – 2nd Admission by PPLP

- Second, PPLP admitted that, with respect to "more than 100 HCPs," PPLP "failed to:

  (1) "report and provide complete and accurate information to DEA about HCPs after the HCPs were flagged by internal anti-diversion programs, in situations in which the Company possessed sufficient information that should have led to a report; and

  (2) "cease detailing HCPs after receiving information suggesting that those HCPs were prescribing opioid products without a legitimate medical purpose and outside the usual course of professional practice"

(Purdue Plea Agmt., Schedule A, p. 16 ¶f)

Count 1: Fraud on The DEA – 2nd Admission by PPLP

- Claimants do not and cannot advance similar claims
  - The States knew the ADD Program — most had insisted Purdue keep it in place
  - They knew that (1) "flagg[ing]" of an HCP did not give rise to a reporting requirement to the States, and (2) receipt of information suggesting that an HCP was misprescribing opioids did not trigger cessation of detailing
- There is no admission by PPLP as to the number or location of the "more than one hundred HCPs"
- There is no admission that any of these HCPs wrote any prescription for a medically unnecessary reason
- There is no admission that any of these HCPs did so during a year within any applicable statute of limitations

Count 1: Fraud on The DEA – 2nd Admission by PPLP

- There is no admission that Purdue's failure to report on or cease detailing these HCPs had any impact on DEA's quota allocation in any year
- There is no admission that any Claimant would have been affected if the unidentified HCPs been reported to DEA
- There is no admission that any prescription written by any of the "more than one hundred HCPs" caused any State to incur any cost
- There is no admission that — if Purdue had ceased detailing any of the HCPs — that would have had any effect on the HCPs' prescribing of Purdue opioids or had any impact on any Claimant

Count 1: Fraud on The DEA – 3rd Admission by PPLP

- PPLP admitted that it "fail[ed] to account for potential downstream diversion of its products in reporting sales numbers to DEA as part of its quota requests"

(Purdue Plea Agmt., Schedule A, pp. 16-17 ¶f)

  - **There is no admission that the failure to account for "potential downstream diversion" had any effect on DEA's quota allocation in any year or on any Claimant**
  - **There is no admission as to the location of any "potential downstream diversion"**
  - **There is no admission that the "potential downstream diversion" ever materialized or, if so, where, in what amount, and whether it occurred within the applicable statute of limitations**

Count 1: Fraud on The DEA – 4th Admission by PPLP

- PPLP admitted that it "knowingly and intentionally conspired and agreed with others to aid and abet HCPs' dispensing, without a legitimate medical purpose and outside the usual course of professional practice … prescription drugs"

  (Purdue Plea Agmt., Schedule A, p. 17 ¶g)

  - There is no admission as to
    - The number of unidentified HCPs
    - Their location
    - The amount or year of their illegal dispensing
    - Whether it affected any Claimant, let alone did so within the applicable statute of limitations

Count 2: Payments to Two HCPs

- In Count 2, PPLP admitted that, from June 2009 to March 2017, it unlawfully offered "payments in the form of speakers fees and other payments (*e.g.*, travel, lodging, consulting fees) to two HCPs with at least one purpose to induce those HCPs to write more prescriptions of Purdue opioid products, for which payment was made in whole or in part under a Federal healthcare program…."

  (Purdue Plea Agmt., Schedule A, p. 17 ¶h)

  - There is no suggestion that either HCP was deceived about the properties of Purdue's products
  - There is no admission that the payments actually affected the number of Purdue prescriptions the two HCPs wrote
  - There is no suggestion that either HCP prescribed Purdue products to a patient for medically unnecessary reasons

Count 2: Payments to Two HCPs

- There is no admission that either HCP prescribed Purdue products to a patient who, as a consequence, suffered from abuse, addiction or death
- There is no admission as to the location of the two HCPs
- There is no admission that any Claimant was financially affected by any prescription written, given that the prescriptions were paid for "in whole or in part under a Federal healthcare program"— and there is no indication that any Claimant paid for any other portion
- There is no admission as to the year in which the improper payments were made or whether they—or any consequent prescriptions—occurred within the applicable statute of limitations

Count 3: Practice Fusion

- In Count 3, PPLP admitted that, effective March 1, 2016, it entered into a one-year contract with Practice Fusion — a cloud-based electronic health records platform — to run a Clinical Decision Support program on its platform to alert HCPs to conduct pain assessments and document pain treatment plans
- PPLP admitted that "one purpose" of this was to increase Purdue's opioid sales, "portions of which were paid for by federal health care programs, in violation of the Anti-Kickback Statute" (Purdue Plea Agmt., Schedule A, pp. 17-18 ¶¶m, o)
  - There is no admission that any HCP was deceived by a Practice Fusion alert
  - There is no admission that any prescription written as a result of a Practice Fusion alert wrote lacked a legitimate medical purpose
  - There is no admission that any patient who received a prescription as a result of a Practice Fusion alert suffered from abuse, addiction or death

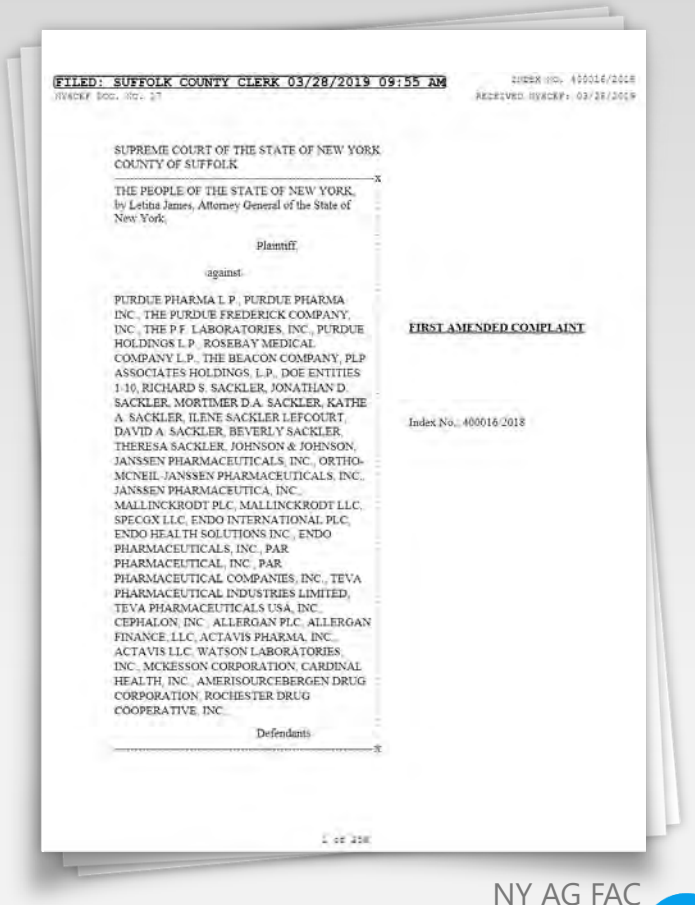
Count 3: Practice Fusion

- There is no admission that any prescription written as a result of a Practice Fusion alert had any impact on any Claimant, given that some portion of the prescriptions "were paid for by Federal healthcare programs"
  — and there is no indication that any Claimant paid for any other portion

Claimants' Deceptive Marketing Claims

Claimants' Deceptive Marketing Claims against Purdue

- New York alleges 10 representative misrepresentations
- DOJ adopted none of them in its criminal and civil settlements with Purdue and the family
- None supports a claim against the Individuals
- There is no allegation the Individuals approved, directed or encouraged any of the alleged Purdue misrepresentations
- Substantial evidence establishes that the supposed misrepresentations are in fact true
- The Claimants and the federal government made many of the same representations


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

Plaintiff,

against

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., THE P.F. LABORATORIES, INC., PURDUE HOLDINGS L.P., ROSEBAY MEDICAL COMPANY L.P., THE BEACON COMPANY, PLP ASSOCIATES HOLDINGS, L.P., DOE ENTITIES 1-10, RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, DAVID A. SACKLER, BEVERLY SACKLER, THERESA SACKLER, JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN PLC, ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, ROCHESTER DRUG COOPERATIVE, INC.,

Defendants

FIRST AMENDED COMPLAINT

Index No.: 400016/2018

NY AG FAC

Alleged Misrepresentation No. 1:
Risk of Addiction from Chronic Opioid Therapy Is Low

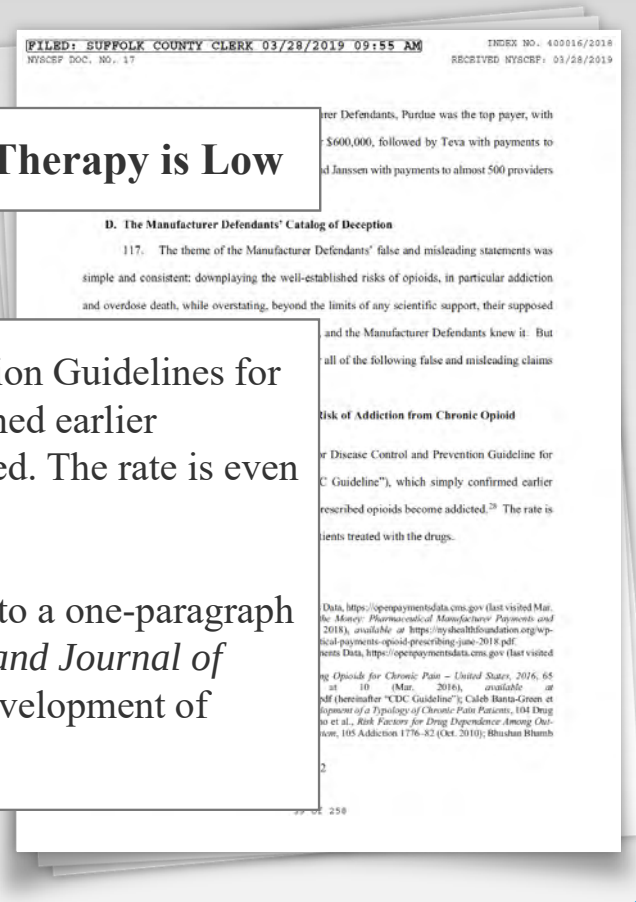
1. Misrepresentation #1: The Risk of Addiction from Chronic Opioid Therapy is Low

NY AG FAC, p. 32

118. According to the 2016 Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain (the "CDC Guideline"), which simply confirmed earlier scientific findings, up to 26% of people who are prescribed opioids becomes addicted. The rate is even worse—up to 40%—among chronic pain patients treated with the drugs.

119. To upend this hard reality, the Manufacturer Defendants turned to a one-paragraph letter to the editor from Dr. Hershel Jick and Jane Porter published in the *New England Journal of Medicine* ("NEJM") in 1980 (the "Porter/Jick letter"), which concluded that "the development of addiction is rare in medical patients with no history of addiction." . . . .

NY AG FAC ¶¶118-19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NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

rer Defendants, Purdue was the top payer, with
$600,000, followed by Teva with payments to
d Janssen with payments to almost 500 providers

D. The Manufacturer Defendants' Catalog of Deception

117. The theme of the Manufacturer Defendants' false and misleading statements was simple and consistent: downplaying the well-established risks of opioids, in particular addiction and overdose death, while overstating, beyond the limits of any scientific support, their supposed and the Manufacturer Defendants knew it. But all of the following false and misleading claims

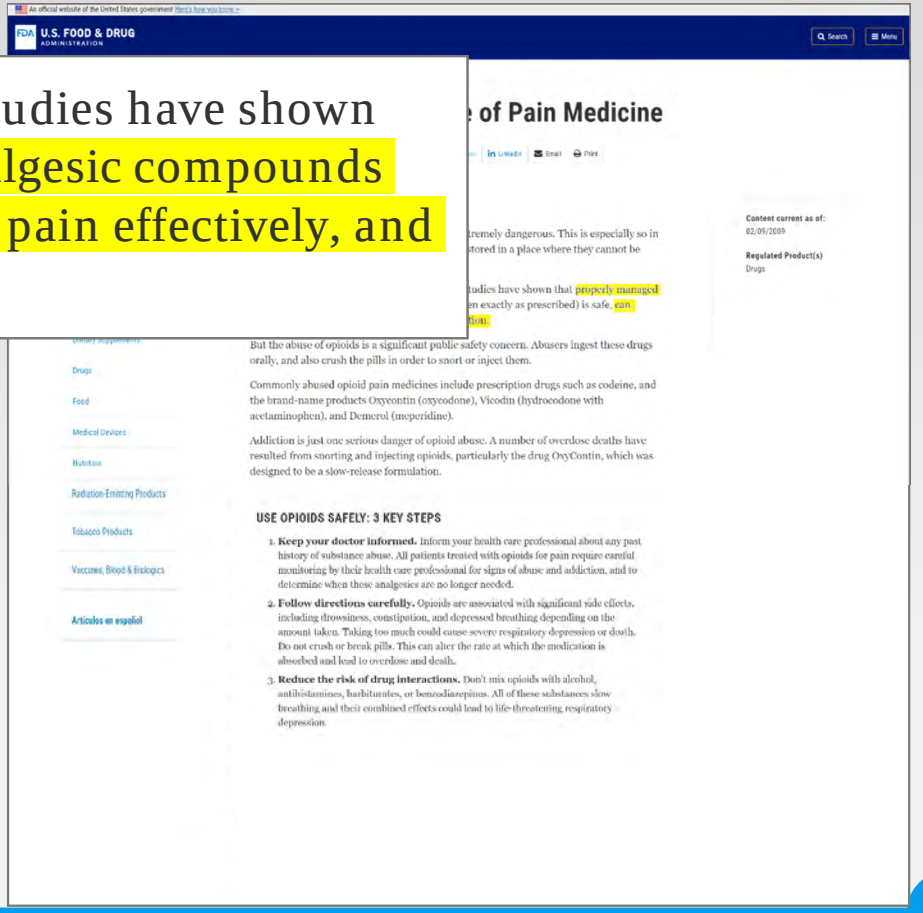
Risk of Addiction from Chronic Opioid

r Disease Control and Prevention Guideline for
C Guideline"), which simply confirmed earlier
rescribed opioids become addicted.[28] The rate is
ients treated with the drugs.

FDA: Medically-Managed Use of Opioids "Rarely Causes Addiction"

According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction.

https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine
(last updated Feb. 9, 2009)



U.S. FOOD & DRUG ADMINISTRATION

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of Pain Medicine

Content current as of: 02/09/2009

Regulated Product(s) Drugs

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Medical Devices
Nutrition
Radiation-Emitting Products
Tobacco Products
Vaccines, Blood & Biologics
Articulos en español

But the abuse of opioids is a significant public safety concern. Abusers ingest these drugs orally, and also crush the pills in order to snort or inject them.

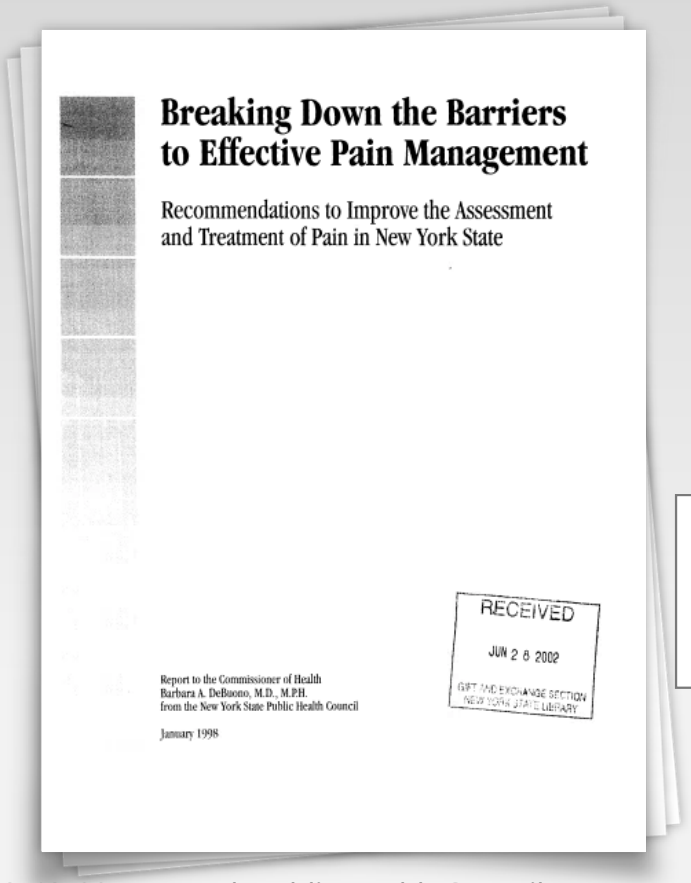
Commonly abused opioid pain medicines include prescription drugs such as codeine, and the brand-name products Oxycontin (oxycodone), Vicodin (hydrocodone with acetaminophen), and Demerol (meperidine).

Addiction is just one serious danger of opioid abuse. A number of overdose deaths have resulted from snorting and injecting opioids, particularly the drug OxyContin, which was designed to be a slow-release formulation.

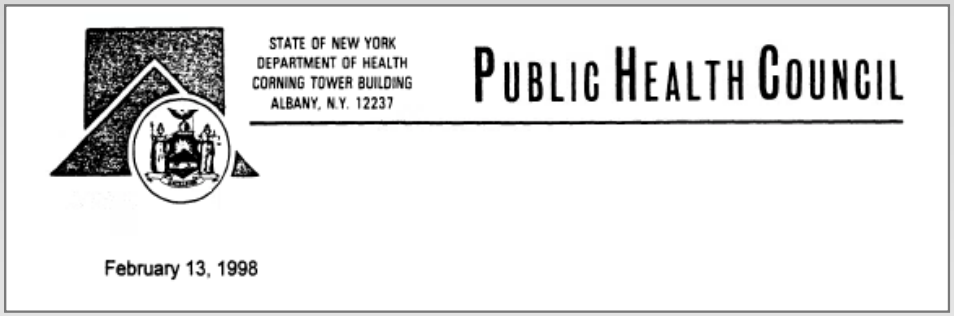
USE OPIOIDS SAFELY: 3 KEY STEPS

1. **Keep your doctor informed.** Inform your health care professional about any past history of substance abuse. All patients treated with opioids for pain require careful monitoring by their health care professional for signs of abuse and addiction, and to determine when these analgesics are no longer needed.
2. **Follow directions carefully.** Opioids are associated with significant side effects, including drowsiness, constipation, and depressed breathing depending on the amount taken. Taking too much could cause severe respiratory depression or death. Do not crush or break pills. This can alter the rate at which the medication is absorbed and lead to overdose and death.
3. **Reduce the risk of drug interactions.** Don't mix opioids with alcohol, antihistamines, barbiturates, or benzodiazepines. All of these substances slow breathing and their combined effects could lead to life-threatening respiratory depression.

New York Public Health Council in 1998: Medically-Managed Use of Opioids "Rarely Causes Addiction"



2/13/98 New York Public Health Council Report



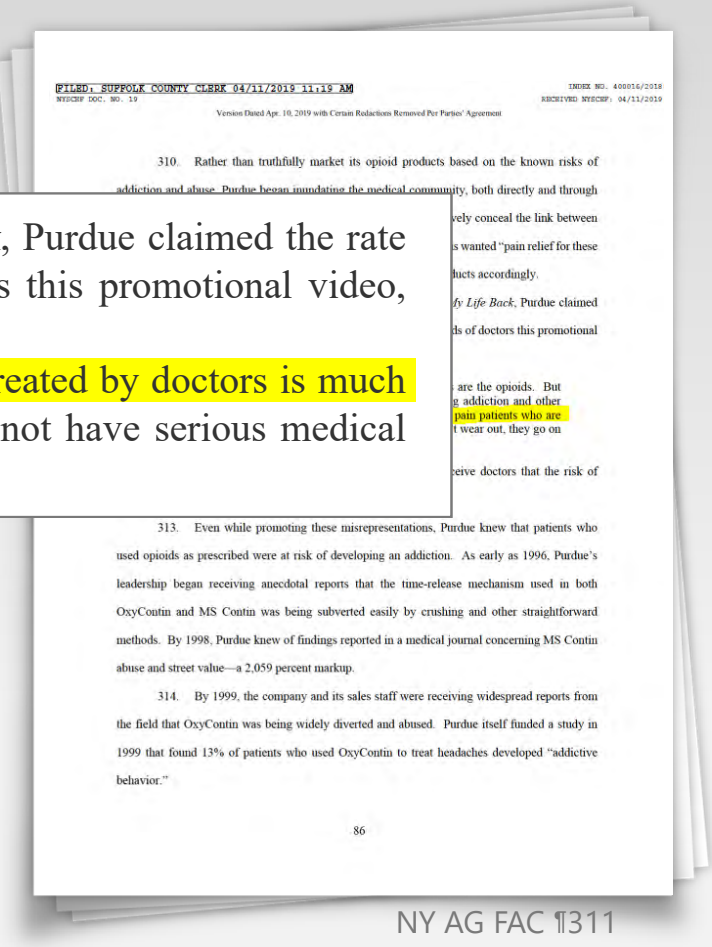
In 1998, the New York Public Health Council stated:

> "**Unfortunately, the public does not understand that opioid addiction when treating bona fide pain is rare**"

Alleged Misrepresentation in 1998 Video

311. For example, in its 1998 promotional video, *I Got My Life Back*, Purdue claimed the rate of addiction "is much less than 1%." Purdue mailed thousands of doctors this promotional video, where a physician asserts:

… Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects.



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Version Dated Apr. 10, 2019 with Certain Redactions Removed Per Parties' Agreement

310. Rather than truthfully market its opioid products based on the known risks of addiction and abuse, Purdue began inundating the medical community, both directly and through

311. For example, in its 1998 promotional video, *I Got My Life Back*, Purdue claimed

313. Even while promoting these misrepresentations, Purdue knew that patients who used opioids as prescribed were at risk of developing an addiction. As early as 1996, Purdue's leadership began receiving anecdotal reports that the time-release mechanism used in both OxyContin and MS Contin was being subverted easily by crushing and other straightforward methods. By 1998, Purdue knew of findings reported in a medical journal concerning MS Contin abuse and street value—a 2,059 percent markup.

314. By 1999, the company and its sales staff were receiving widespread reports from the field that OxyContin was being widely diverted and abused. Purdue itself funded a study in 1999 that found 13% of patients who used OxyContin to treat headaches developed "addictive behavior."

86

NY AG FAC ¶311

The New York Department of Public Health Was Saying Exactly the Same Thing at the Time

- **New York Health Department Task Force on Life and the Law Report — on New York Health Department website since 1994:**

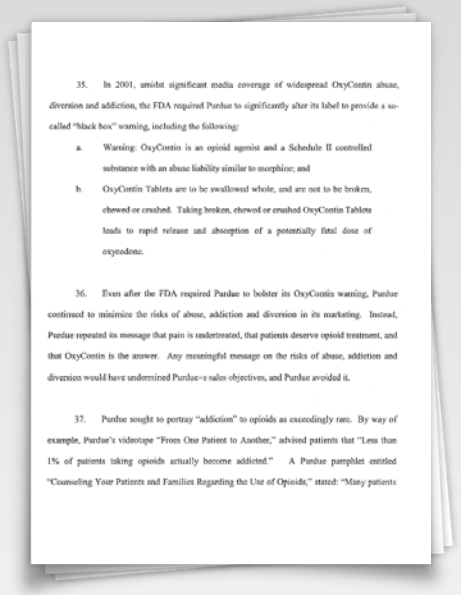
- "**Psychological dependence is extremely rare in patients receiving opioids or other medications for pain control**."
- "Studies also indicate that physicians and other health care professionals are excessively and unjustifiably concerned about the risk of addiction and respiratory depression, even though these responses to pain medication are extremely rare and can be prevented when treatment is appropriately monitored. In one study of 2,459 nurses, **only 24.8 percent knew that the rate of psychological dependence in patients treated with narcotic drugs for pain is less than one percent**"

https://www.health.ny.gov/regulations/task_force/reports_publications/when_death_is_sought/chap3.htm

This Alleged 1998 Misrepresentation Was Released in 2007

- **2007 Consent Judgments released these statements**

> 37. Purdue sought to portray "addiction" to opioids as exceedingly rare. By way of example, Purdue's videotape "From One Patient to Another," advised patients that "Less than 1% of patients taking opioids actually become addicted.



35. In 2001, amidst significant media coverage of widespread OxyContin abuse, diversion and addiction, the FDA required Purdue to significantly alter its label to provide a so-called "black box" warning, including the following:

a. Warning: OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine; and

b. OxyContin Tablets are to be swallowed whole, and are not to be broken, chewed or crushed. Taking broken, chewed or crushed OxyContin Tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone.

36. Even after the FDA required Purdue to bolster its OxyContin warning, Purdue continued to minimize the risks of abuse, addiction and diversion in its marketing. Instead, Purdue repeated its message that pain is undertreated, that patients deserve opioid treatment, and that OxyContin is the answer. Any meaningful message on the risks of abuse, addiction and diversion would have undermined Purdue-s sales objectives, and Purdue avoided it.

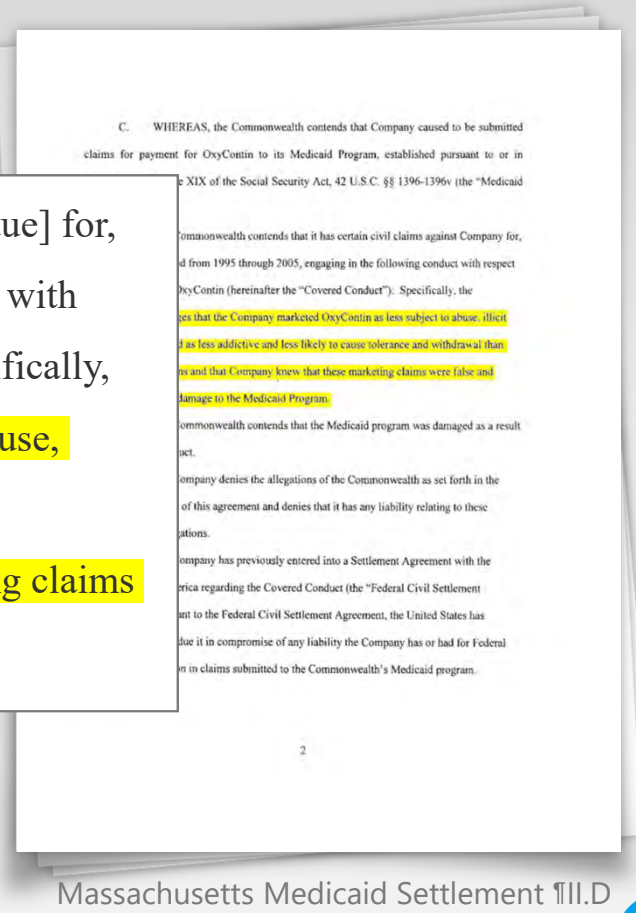
37. Purdue sought to portray "addiction" to opioids as exceedingly rare. By way of example, Purdue's videotape "From One Patient to Another," advised patients that "Less than 1% of patients taking opioids actually become addicted." A Purdue pamphlet entitled "Counseling Your Patients and Families Regarding the Use of Opioids," stated: "Many patients

2007 CT Complaint ¶37

This Alleged 1998 Misrepresentation Was Released in 2007

- **2007 Medicaid settlements released these statements**

D. The Commonwealth contends that it has certain civil claims against [Purdue] for, during the time period from 1995 through 2005, engaging in the following conduct with respect to the marketing of OxyContin (herein after the "Covered Conduct"): Specifically, the Commonwealth alleges that [Purdue] marketed OxyContin as less subject to abuse, illicit use and diversion and as less addictive and less likely to cause tolerance and withdrawal than other pain medications and that [Purdue] knew that these marketing claims were false and misleading, causing damage to the Medicaid Program.


C. WHEREAS, the Commonwealth contends that Company caused to be submitted
claims for payment for OxyContin to its Medicaid Program, established pursuant to or in
e XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the "Medicaid
Commonwealth contends that it has certain civil claims against Company for,
d from 1995 through 2005, engaging in the following conduct with respect
OxyContin (hereinafter the "Covered Conduct"). Specifically, the
es that the Company marketed OxyContin as less subject to abuse, illicit
l as less addictive and less likely to cause tolerance and withdrawal than
s and that Company knew that these marketing claims were false and
damage to the Medicaid Program.
Commonwealth contends that the Medicaid program was damaged as a result
act.
ompany denies the allegations of the Commonwealth as set forth in the
of this agreement and denies that it has any liability relating to these
ations.
ompany has previously entered into a Settlement Agreement with the
erica regarding the Covered Conduct (the "Federal Civil Settlement
ant to the Federal Civil Settlement Agreement, the United States has
due it in compromise of any liability the Company has or had for Federal
n in claims submitted to the Commonwealth's Medicaid program.
2

Massachusetts Medicaid Settlement ¶II.D

Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

2. Misrepresentation #2: Signs of Addictive Behavior are "Pseudoaddiction," Potentially Requiring More Opioids

NY AG FAC, p. 34

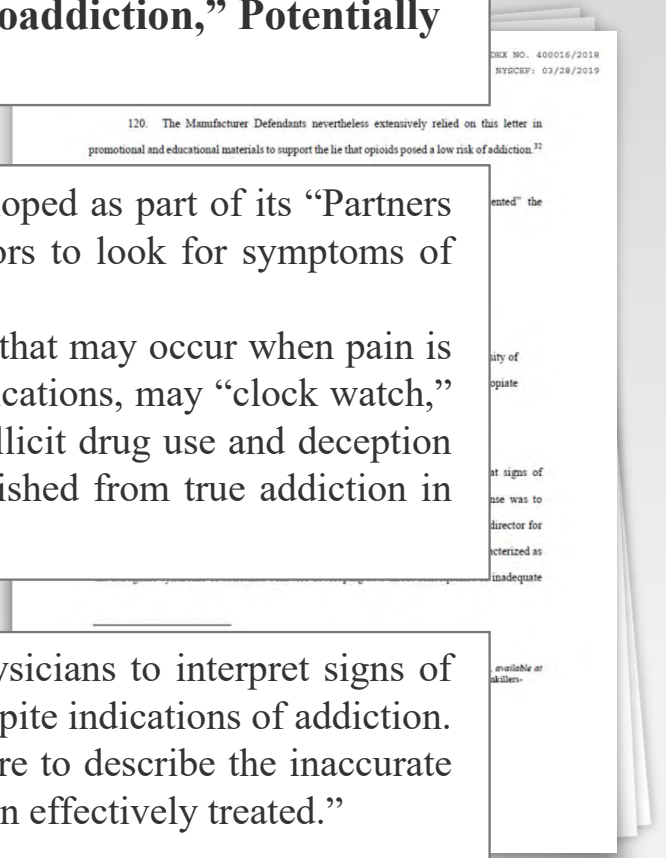
326. For example, Purdue widely distributed an unbranded pamphlet developed as part of its "Partners Against Pain" initiative, *Clinical Issues in Opioid Prescribing*, which urged doctors to look for symptoms of "pseudoaddiction:"

[Pseudoaddiction is a] term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug-seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

NY AG FAC ¶326

328. Purdue's other widely-distributed materials similarly encouraged physicians to interpret signs of addiction as under-treatment of pain and urged them to treat pain "aggressively" despite indications of addiction. One pamphlet . . . claimed: "The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated."

NY AG FAC ¶328



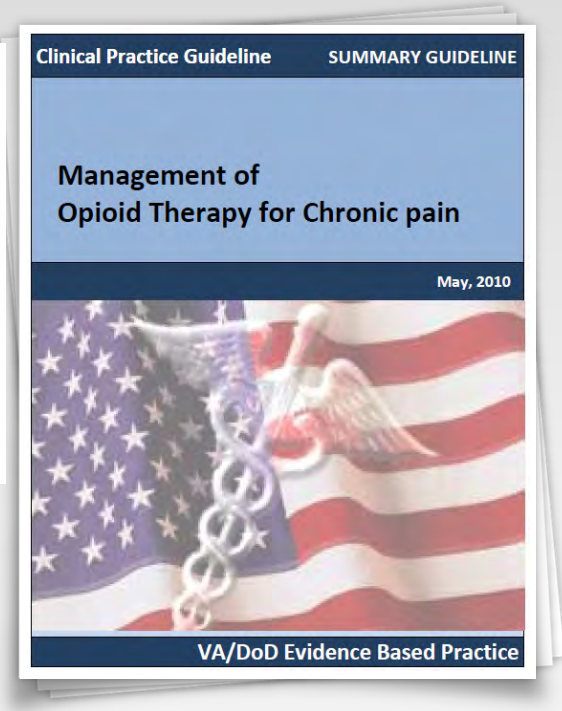
Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

1. The Federal Government Recognizes Pseudoaddiction

Pseudoaddiction

Pseudoaddiction describes patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem to be inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain pain relief. In contrast to true addiction, in pseudoaddiction the behaviors resolve when the pain is effectively treated (Definitions, 2001). Misunderstanding of this phenomenon may lead the clinician to inappropriately stigmatize the patient with the label 'addict.' In the setting of unrelieved pain, the request for increases in drug dose requires careful assessment, renewed efforts to manage pain, and avoidance of stigmatizing labels. Distinguishing addiction from pseudoaddiction can be difficult and often takes time and multiple patient encounters.

VA/Dept. of Defense, Clinical Practice Guideline,
Management of Opioid Therapy for Chronic Pain 13 (May 2010)



https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf

Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

2. The FDA-Approved Label for OxyContin Describes Pseudoaddiction

> Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control. Most chronic pain patients limit their intake of opioids to achieve a balance between the benefits of the drug and dose-limiting side effects.

1995 OxyContin Label, p. 2, (PDD150170001)

> Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.

April 2013 OxyContin Label, p. 18, (PPLPC003000060503)

> Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.

September 2018 OxyContin Label, p. 28, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf

Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

3. The FDA-Approved Label for Percodan Discusses Pseudoaddiction

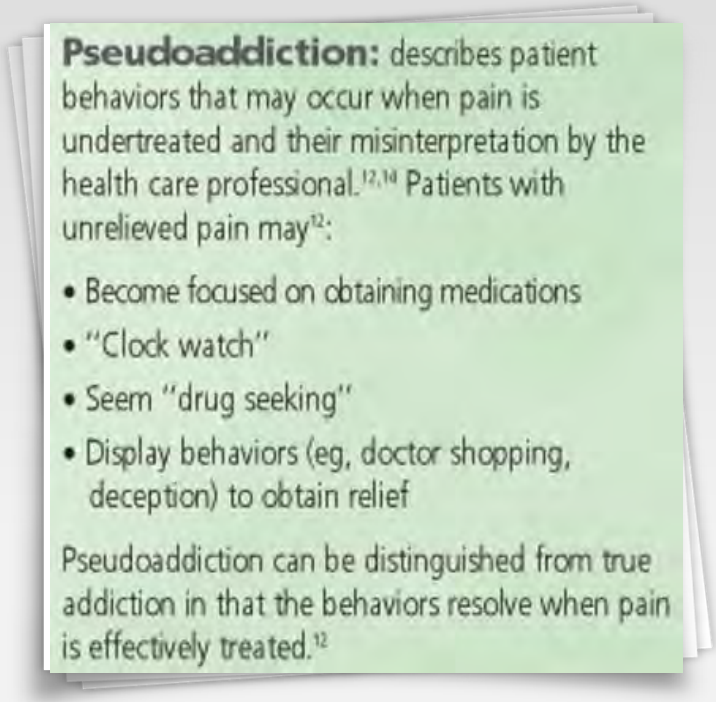
> Pseudoaddiction refers to pain relief seeking behavior of patients whose pain is poorly managed. It is considered an iatrogenic effect of ineffective pain management. The health care provider must assess continuously the psychological and clinical condition of a pain patient in order to distinguish addiction from pseudoaddiction and thus, be able to treat the pain adequately.

June 2010 Percodan Label, p. 17, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/07337slr029_percodan_lbl.pdf

Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

4. The States Approved Educating HCPs About Pseudoaddiction

- ¶15 of the Consent Judgments required that Purdue provide all HCPs educational information about detecting and preventing abuse and diversion for 10 years (2007-2017)
- Purdue sent the materials to all Consent Judgment States on August 6, 2007 to ensure their consent (PPLPUCC004238887)
- The materials discussed pseudoaddiction at length
- Every state acquiesced — none objected



Pseudoaddiction: describes patient behaviors that may occur when pain is undertreated and their misinterpretation by the health care professional.[12,14] Patients with unrelieved pain may[12]:

- Become focused on obtaining medications
- "Clock watch"
- Seem "drug seeking"
- Display behaviors (eg, doctor shopping, deception) to obtain relief

Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.[12]

Providing Relief, Preventing Abuse, PPLP003275282 at -288

Alleged Misrepresentation No. 2:
Signs of Addictive Behavior May Be "Pseudoaddiction"

5. Scientific Literature Acknowledges Pseudoaddiction

Green & Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, CURRENT ADDICTION REPORTS at 310-317 (2015)

In a survey of medical literature, **224 papers were identified that discussed pseudoaddiction. Only 4 contended that it "remains untested and uncharacterized as an objectively confirmable diagnosis"** and **2 contended it was a "social rather than biological construct."**


Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature

Scientific consensus is represented by 218 articles accepting the concept, not 6 questioning it

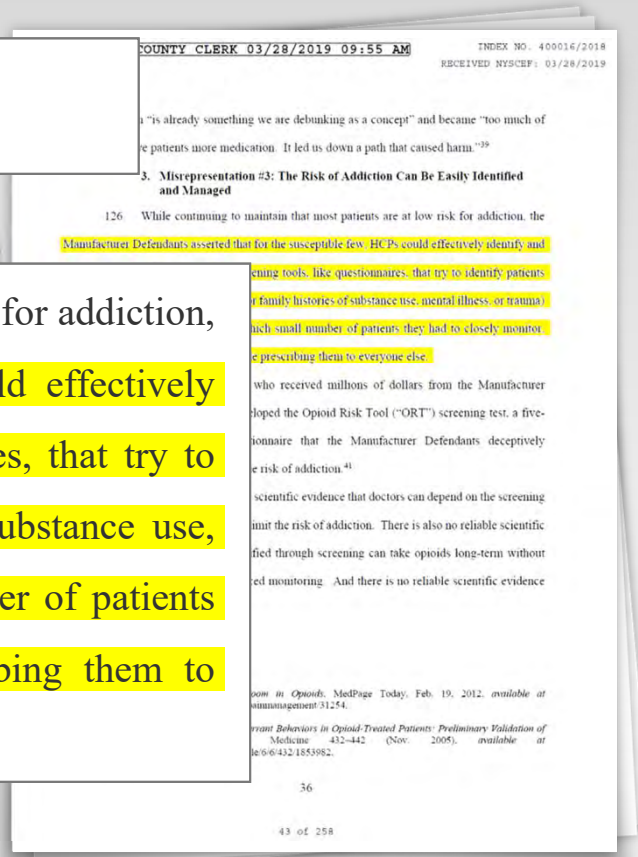
Alleged Misrepresentation No. 3:
Risk of Addiction Can Be Easily Identified And Managed

3. Misrepresentation #3: The Risk of Addiction Can Be Easily Identified and Managed

NY AG FAC, p. 36

126. While continuing to maintain that most patients are at low risk for addiction, the Manufacturer Defendants asserted that for the susceptible few, HCPs could effectively identify and manage the risk. They promoted screening tools, like questionnaires, that try to identify patients with addiction risks (such as personal or family histories of substance use, mental illness, or trauma) to make HCPs feel like they knew which small number of patients they had to closely monitor, thereby making them more comfortable prescribing them to everyone else.

NY AG FAC ¶126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3. Misrepresentation #3: The Risk of Addiction Can Be Easily Identified and Managed

126 While continuing to maintain that most patients are at low risk for addiction, the

Manufacturer Defendants asserted that for the susceptible few, HCPs could effectively identify and

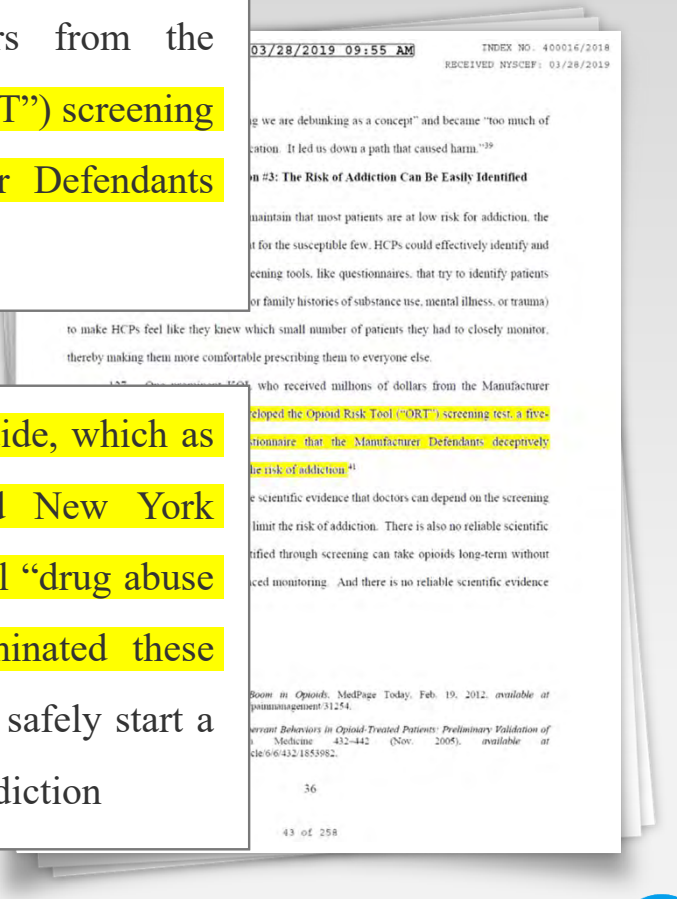
Alleged Misrepresentation No. 3:
Risk of Addiction Can Be Easily Identified And Managed

127. One prominent KOL who received millions of dollars from the Manufacturer Defendants, Dr. Lynn Webster developed the Opioid Risk Tool ("ORT") screening test, a five-question *self-reported* patient questionnaire that the Manufacturer Defendants deceptively represented could accurately predict the risk of addiction.

NY AG FAC ¶127

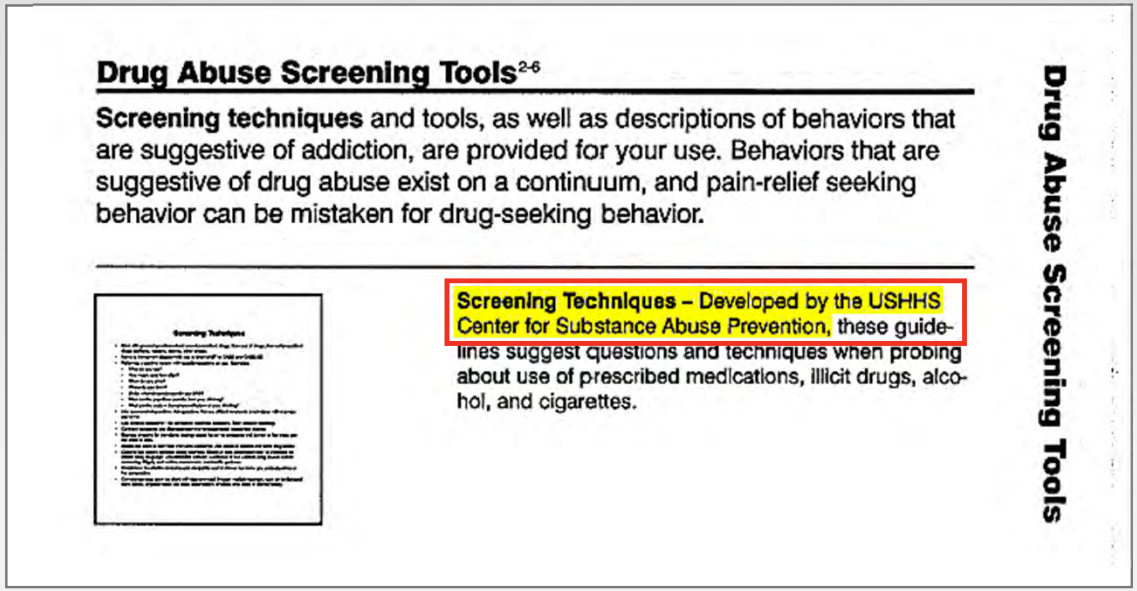
318. For example, Purdue distributed APF's Treatment Options guide, which as noted above, touted "opioid agreements." Purdue's detailers also provided New York prescribers a Partners Against Pain "Pain Management Kit" that contained several "drug abuse screening tools," including the "Opioid Risk Tool." Purdue actively disseminated these materials to misleadingly give providers a false sense of security that they could safely start a course of opioids with patients and effectively manage those with a high risk of addiction

NY AG FAC ¶318



Alleged Misrepresentation No. 3:
Risk of Addiction Can Be Easily Identified And Managed

- NYAG attacks screening tools developed by the U.S. Government

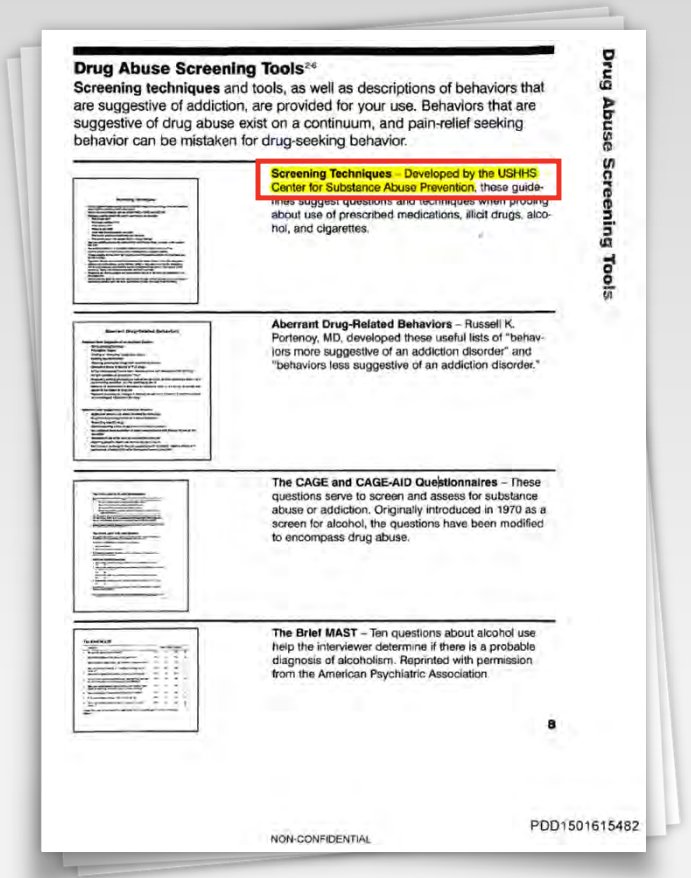


Drug Abuse Screening Tools[2-6]

Screening techniques and tools, as well as descriptions of behaviors that are suggestive of addiction, are provided for your use. Behaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.

Screening Techniques – Developed by the USHHS Center for Substance Abuse Prevention, these guidelines suggest questions and techniques when probing about use of prescribed medications, illicit drugs, alcohol, and cigarettes.

Drug Abuse Screening Tools



Drug Abuse Screening Tools[2-6]

Screening techniques and tools, as well as descriptions of behaviors that are suggestive of addiction, are provided for your use. Behaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.

Screening Techniques – Developed by the USHHS Center for Substance Abuse Prevention, these guidelines suggest questions and techniques when probing about use of prescribed medications, illicit drugs, alcohol, and cigarettes.

Aberrant Drug-Related Behaviors – Russell K. Portenoy, MD, developed these useful lists of "behaviors more suggestive of an addiction disorder" and "behaviors less suggestive of an addiction disorder."

The CAGE and CAGE-AID Questionnaires – These questions serve to screen and assess for substance abuse or addiction. Originally introduced in 1970 as a screen for alcohol, the questions have been modified to encompass drug abuse.

The Brief MAST – Ten questions about alcohol use help the interviewer determine if there is a probable diagnosis of alcoholism. Reprinted with permission from the American Psychiatric Association

8

Drug Abuse Screening Tools

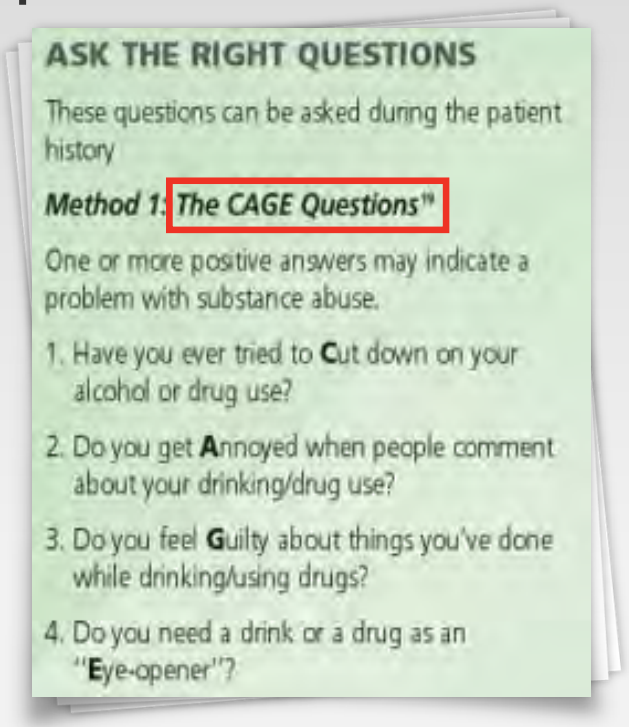
PDD1501615482

NON-CONFIDENTIAL

PARTNERS AGAINST PAIN, *Pain Management Kit* (2003) (PDD1501615472)

Alleged Misrepresentation No. 3:
Risk of Addiction Can Be Easily Identified And Managed

- **NYAG attacks advocating screening tools the States agreed that Purdue could use to educate HCPs — the CAGE questionnaire**
  - ¶15 of the Consent Judgments required that Purdue provide all HCPs educational information about detecting and preventing abuse and diversion for 10 years (2007-2017)
  - Purdue sent the materials to all Consent Judgment States on August 6, 2007 to ensure their consent (PPLPUCC004238887)
  - The materials recommended the CAGE questionnaire
  - Every state acquiesced—none objected



ASK THE RIGHT QUESTIONS

These questions can be asked during the patient history

***Method 1: The CAGE Questions*[19]**

One or more positive answers may indicate a problem with substance abuse.

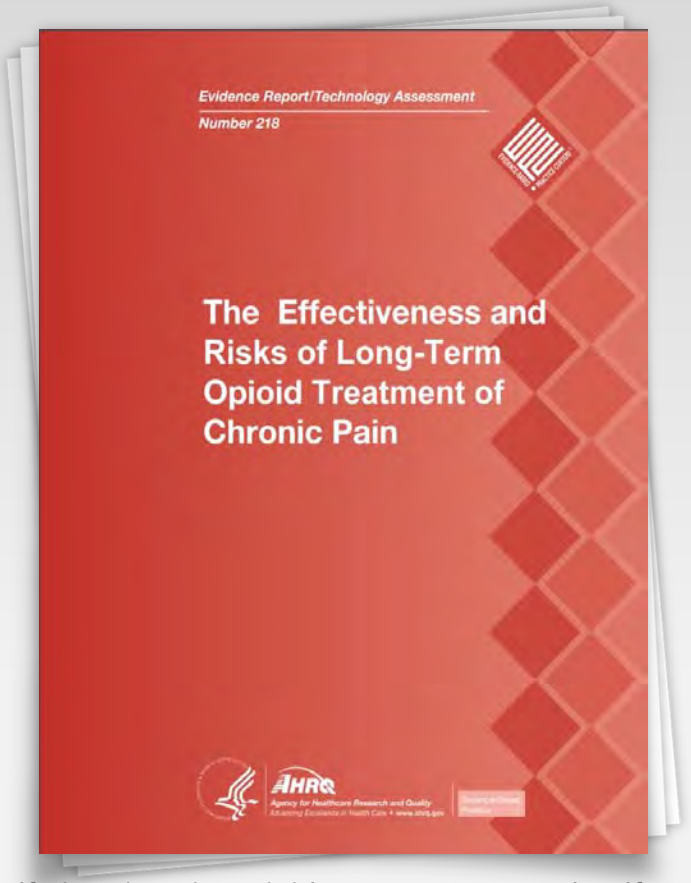
1. Have you ever tried to **C**ut down on your alcohol or drug use?
2. Do you get **A**nnoyed when people comment about your drinking/drug use?
3. Do you feel **G**uilty about things you've done while drinking/using drugs?
4. Do you need a drink or a drug as an "**E**ye-opener"?

Providing Relief, Preventing Abuse, PPLP003275282 at -292

Alleged Misrepresentation No. 3:
Risk of Addiction Can Be Easily Identified And Managed

- **NYAG relies on one 2014 study to claim risk assessment tools are deceptive** NY AG FAC ¶128 n.42
  - **The cited study did not determine that risk assessment tools were deceptive**
  - **It reviewed 4 studies that "examined the accuracy of instruments for predicting risk of opioid overdose, addiction, abuse or misuse."**
  - **It concluded that "[e]vidence … remains limited on the utility of opioid risk assessment instruments"**

See Roger Chou, et al., *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, EVIDENCE REP./TECH. ASSESSMENT NO. 218, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEP'T OF HEALTH AND HUMAN SERVS., at ES-12, ES-20, ES-25 (2014)



https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf

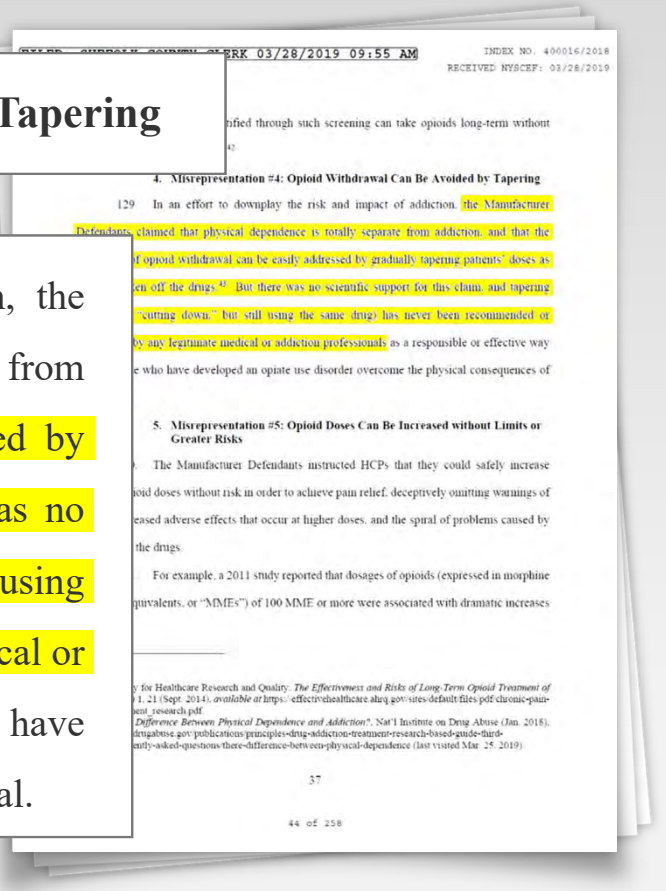
Alleged Misrepresentation No. 4:
Opioid Withdrawal Can Be Avoided by Tapering

4. Misrepresentation #4: Opioid Withdrawal Can Be Avoided by Tapering

NY AG FAC, p. 37

129. In an effort to downplay the risk and impact of addiction, the Manufacturer Defendants claimed that physical dependence is totally separate from addiction, and that the symptoms of opioid withdrawal can be easily addressed by gradually tapering patients' doses as they are taken off the drugs. But there was no scientific support for this claim, and tapering (essentially "cutting down," but still using the same drug) has never been recommended or recognized by any legitimate medical or addiction professionals as a responsible or effective way to help those who have developed an opiate use disorder overcome the physical consequences of withdrawal.

NY AG FAC ¶129



Tapering Is Identified As Useful to Avoid Precipitating Withdrawal on OxyContin's FDA-Approved Label

… it may be appropriate to taper the OxyContin dose, rather than abruptly discontinue it, due to the risk of precipitating withdrawal symptoms…

1995 OxyContin Label, p. 2, (PDD150170001)

When discontinuing OxyContin, gradually taper the dose *[see Dosage and Administration (2.4)]*. Do not abruptly discontinue OxyContin.

Apr. 2013 OxyContin Label, p. 10, (PPLPC003000060503)

When the patient no longer requires therapy with OXYCONTIN, taper the dosage gradually, by 25% to 50% every 2 to 4 days, while monitoring for signs and symptoms of withdrawal. If a patient develops these signs or symptoms, raise the dose to the previous level and taper more slowly, either by increasing the interval between decreases, decreasing the amount of change in dose, or both. Do not abruptly discontinue OXYCONTIN [*see Warnings and Precautions (5.14), Drug Abuse and Dependence (9.3)]*.

Sept. 2018 OxyContin Label, p. 10, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf

Federal Law Requires Drug Promotion Be Consistent with the FDA Label

21 C.F.R. §201.100(d)(1)

Requires labeling to be "consistent with and not contrary to such approved and permitted labeling"

21 U.S.C. §321(m)

Defines "labeling" to include all "written, printed, or graphic matter" that accompanies the drug

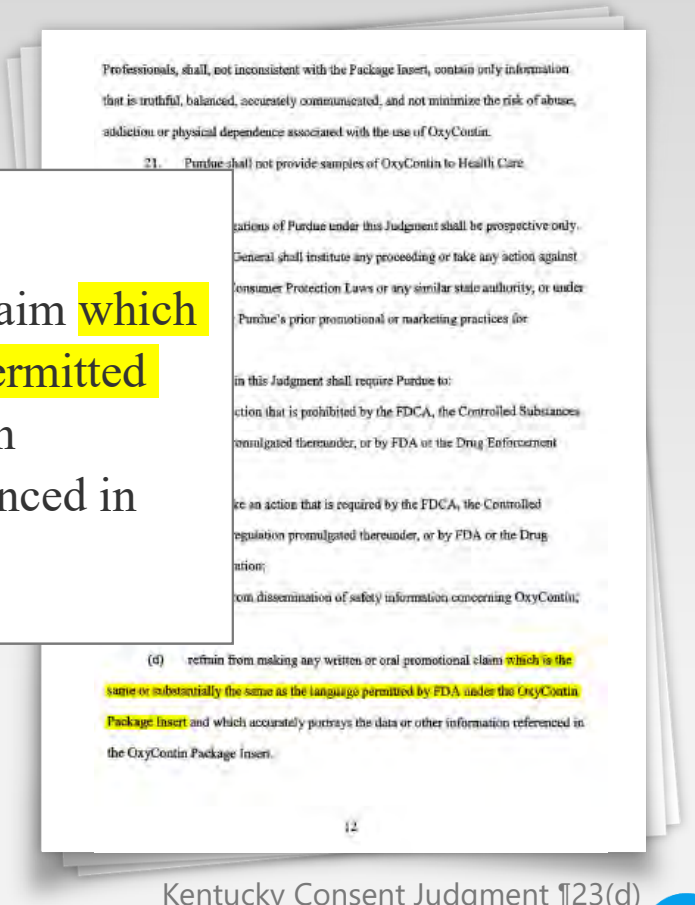
21 C.F.R. §202.1(l)(2)

Defines "labeling" to mean all materials "for use by medical practitioners … containing drug information … disseminated by or on behalf of [the] manufacturer"

Consent Judgments Permitted Marketing Consistent with the FDA-Approved Label

23. Nothing in this Judgment shall require Purdue to: …

(d) refrain from making any written or oral promotional claim which is the same or substantially the same as the language permitted by FDA under the OxyContin Package Insert and which accurately portrays the data or other information referenced in the OxyContin Package Insert.


Professionals, shall, not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.

21. Purdue shall not provide samples of OxyContin to Health Care

ations of Purdue under this Judgment shall be prospective only. General shall institute any proceeding or take any action against Consumer Protection Laws or any similar state authority, or under Purdue's prior promotional or marketing practices for

in this Judgment shall require Purdue to:
ction that is prohibited by the FDCA, the Controlled Substances promulgated thereunder, or by FDA or the Drug Enforcement

ke an action that is required by the FDCA, the Controlled regulation promulgated thereunder, or by FDA or the Drug ation;
om dissemination of safety information concerning OxyContin;

(d) refrain from making any written or oral promotional claim which is the same or substantially the same as the language permitted by FDA under the OxyContin Package Insert and which accurately portrays the data or other information referenced in the OxyContin Package Insert.

12

Kentucky Consent Judgment ¶23(d)

Consent Judgments Barred Promotion Inconsistent with the FDA-Approved Label

19-23649-rdd Doc 2251-3 Filed 01/11/21 Entered 01/11/21 23:33:24 03 Suppl.
Leventhal Ex. 003 Pg 2 of 25

RECEIVED
MAY 03 2007
FRANKLIN CIRCUIT COURT

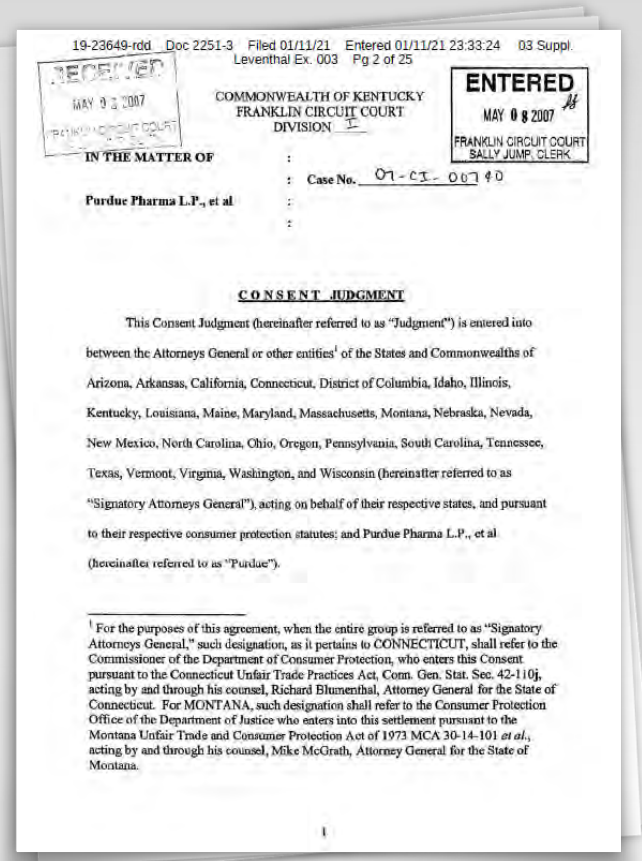
COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION I

ENTERED
MAY 08 2007
FRANKLIN CIRCUIT COURT
SALLY JUMP, CLERK

IN THE MATTER OF :
: Case No. 07-CI-00740
Purdue Pharma L.P., et al :
:

CONSENT JUDGMENT

3. In the promotion and marketing of OxyContin, Purdue shall not market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the "Indication and Usage" section of the Package Insert for OxyContin. . . .



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CONSENT JUDGMENT

This Consent Judgment (hereinafter referred to as "Judgment") is entered into between the Attorneys General or other entities[1] of the States and Commonwealths of Arizona, Arkansas, California, Connecticut, District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and pursuant to their respective consumer protection statutes; and Purdue Pharma L.P., et al (hereinafter referred to as "Purdue").

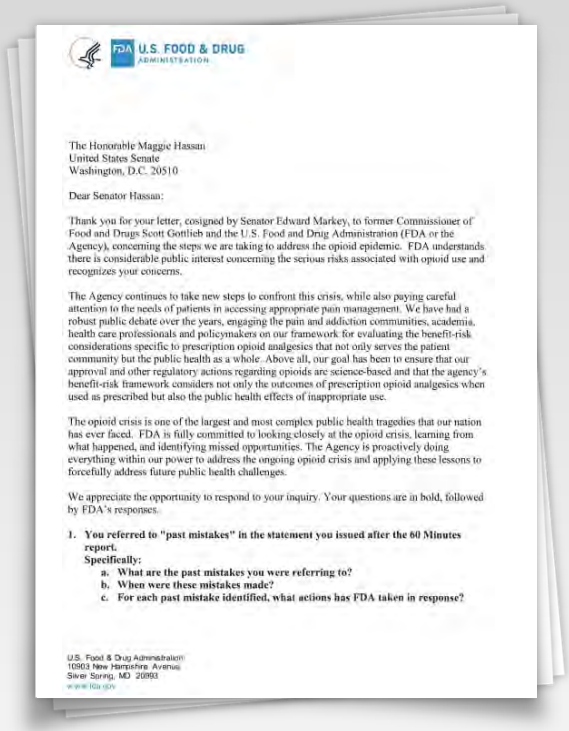
[1] For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Consent pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. For MONTANA, such designation shall refer to the Consumer Protection Office of the Department of Justice who enters into this settlement pursuant to the Montana Unfair Trade and Consumer Protection Act of 1973 MCA 30-14-101 *et al.*, acting by and through his counsel, Mike McGrath, Attorney General for the State of Montana.

Kentucky Consent Judgment ¶3

U.S. Government Still Recognizes Usefulness of Tapering

2020 FDA Letter to Senator Maggie Hassan:

- "[T]he HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics was published to further clarify **the need to judiciously provide individualized therapy, including slow tapering of opioids** … as well as recognition that there may be some patients who are unable to taper or discontinue opioid analgesic therapy." (Pages 13-14)



U.S. FOOD & DRUG ADMINISTRATION

The Honorable Maggie Hassan
United States Senate
Washington, D.C. 20510

Dear Senator Hassan:

Thank you for your letter, cosigned by Senator Edward Markey, to former Commissioner of Food and Drugs Scott Gottlieb and the U.S. Food and Drug Administration (FDA or the Agency), concerning the steps we are taking to address the opioid epidemic. FDA understands there is considerable public interest concerning the serious risks associated with opioid use and recognizes your concerns.

The Agency continues to take new steps to confront this crisis, while also paying careful attention to the needs of patients in accessing appropriate pain management. We have had a robust public debate over the years, engaging the pain and addiction communities, academia, health care professionals and policymakers on our framework for evaluating the benefit-risk considerations specific to prescription opioid analgesics that not only serves the patient community but the public health as a whole. Above all, our goal has been to ensure that our approval and other regulatory actions regarding opioids are science-based and that the agency's benefit-risk framework considers not only the outcomes of prescription opioid analgesics when used as prescribed but also the public health effects of inappropriate use.

The opioid crisis is one of the largest and most complex public health tragedies that our nation has ever faced. FDA is fully committed to looking closely at the opioid crisis, learning from what happened, and identifying missed opportunities. The Agency is proactively doing everything within our power to address the ongoing opioid crisis and applying these lessons to forcefully address future public health challenges.

We appreciate the opportunity to respond to your inquiry. Your questions are in bold, followed by FDA's responses.

1. **You referred to "past mistakes" in the statement you issued after the 60 Minutes report.**
   Specifically:
   a. **What are the past mistakes you were referring to?**
   b. **When were these mistakes made?**
   c. **For each past mistake identified, what actions has FDA taken in response?**

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

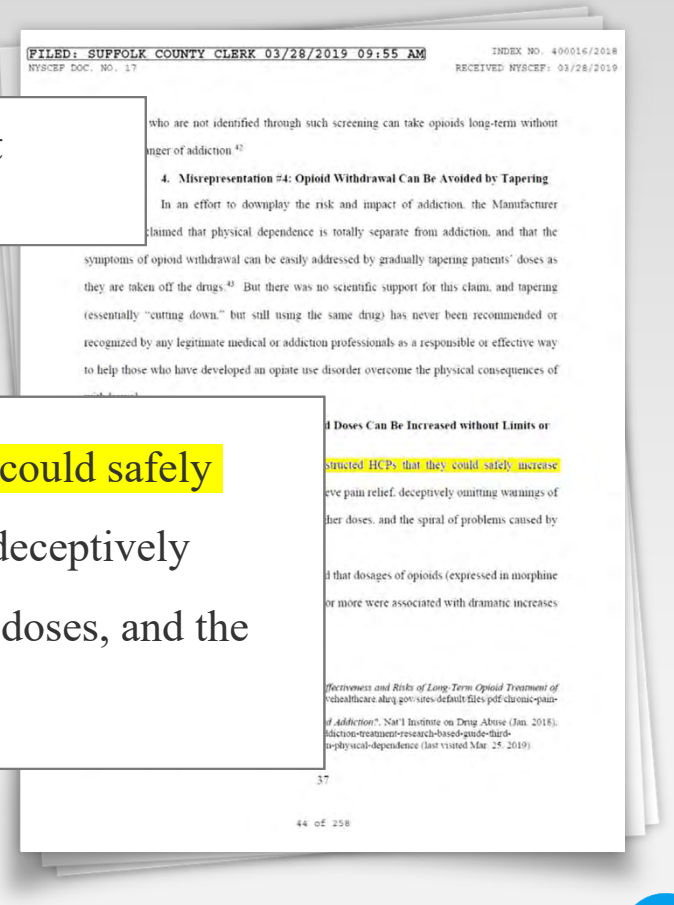
Alleged Misrepresentation No. 5:
Opioid Doses Can Be Increased without Limit or Greater Risk

5. Misrepresentation #5: Opioid Doses Can Be Increased without Limits or Greater Risks

NY AG FAC, p. 37

130. The Manufacturer Defendants instructed HCPs that they could safely increase patients' opioid doses without risk in order to achieve pain relief, deceptively omitting warnings of known, increased adverse effects that occur at higher doses, and the spiral of problems caused by tolerance to the drugs.

NY AG FAC ¶130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NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

who are not identified through such screening can take opioids long-term without anger of addiction.[42]

4. Misrepresentation #4: Opioid Withdrawal Can Be Avoided by Tapering

In an effort to downplay the risk and impact of addiction, the Manufacturer claimed that physical dependence is totally separate from addiction, and that the symptoms of opioid withdrawal can be easily addressed by gradually tapering patients' doses as they are taken off the drugs.[43] But there was no scientific support for this claim, and tapering (essentially "cutting down," but still using the same drug) has never been recommended or recognized by any legitimate medical or addiction professionals as a responsible or effective way to help those who have developed an opiate use disorder overcome the physical consequences of

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d that dosages of opioids (expressed in morphine

or more were associated with dramatic increases

ffectiveness and Risks of Long-Term Opioid Treatment of
vehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-

d Addiction?, Nat'l Institute on Drug Abuse (Jan. 2018),
ddiction-treatment-research-based-guide-third-
n-physical-dependence (last visited Mar. 25, 2019).

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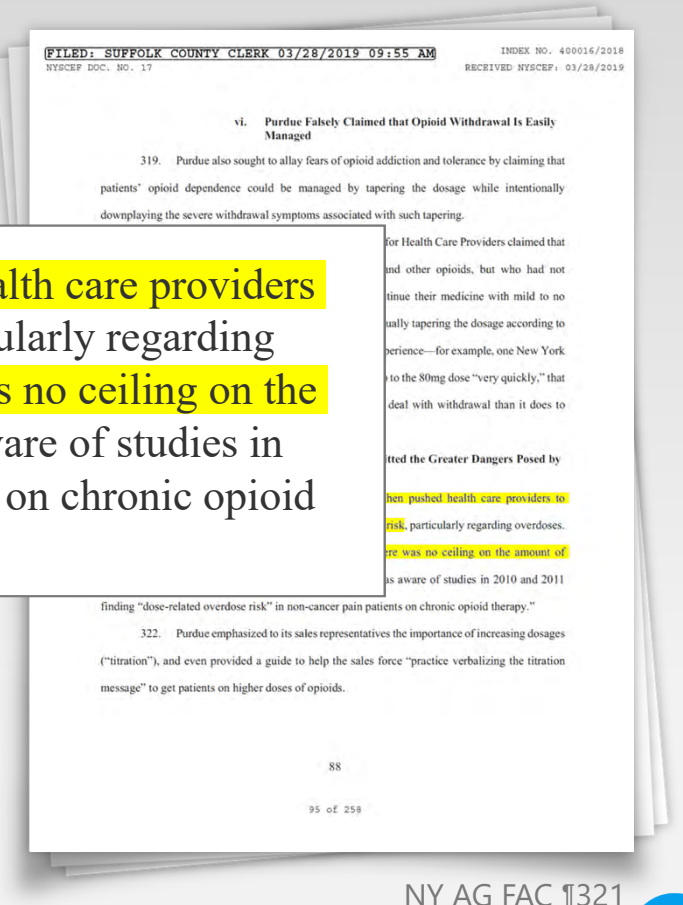
Alleged Misrepresentation No. 5:
Opioid Doses Can Be Increased without Limit or Greater Risk

Allegation: "No Ceiling" Statements Are Deceptive

321. Once patients started on opioids, Purdue then pushed health care providers to increase the dosages prescribed while omitting the increased risk, particularly regarding overdoses. Purdue trained its detailers to reassure prescribers that there was no ceiling on the amount of OxyContin a patient could be prescribed, even though it was aware of studies in 2010 and 2011 finding "dose-related overdose risk" in non-cancer patients on chronic opioid therapy."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NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

vi. Purdue Falsely Claimed that Opioid Withdrawal Is Easily Managed

319. Purdue also sought to allay fears of opioid addiction and tolerance by claiming that patients' opioid dependence could be managed by tapering the dosage while intentionally downplaying the severe withdrawal symptoms associated with such tapering.

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322. Purdue emphasized to its sales representatives the importance of increasing dosages ("titration"), and even provided a guide to help the sales force "practice verbalizing the titration message" to get patients on higher doses of opioids.

88

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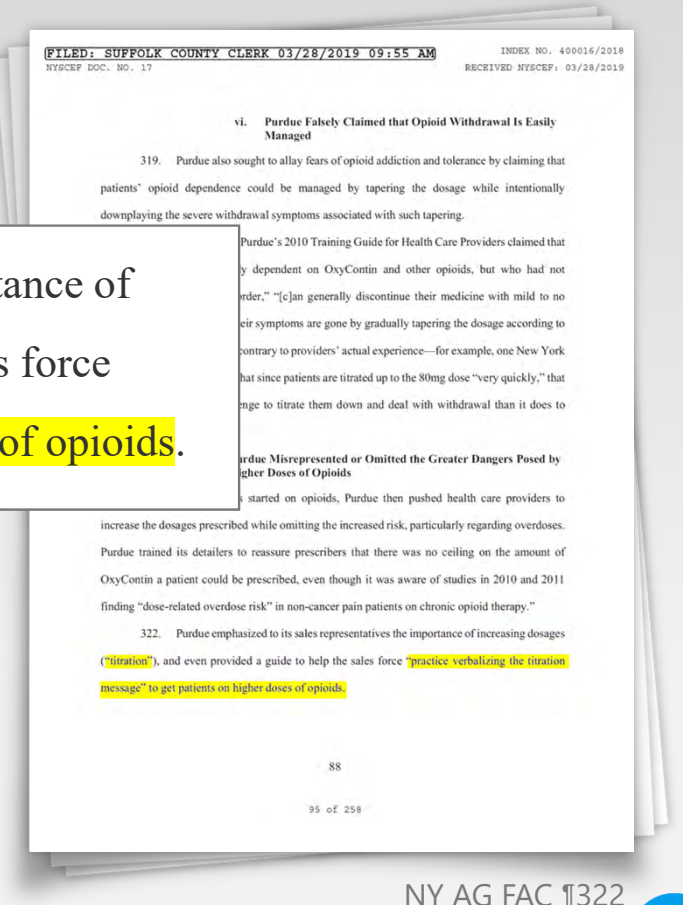
NY AG FAC ¶321

Alleged Misrepresentation No. 5:
Opioid Doses Can Be Increased without Limit or Greater Risk

Allegation: Emphasizing Titration Is Deceptive

322. Purdue emphasized to its sales representatives the importance of increasing dosages ("titration"), and even provided a guide to help the sales force "practice verbalizing the titration message" to get patients on higher doses of opioids.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Purdue's 2010 Training Guide for Health Care Providers claimed that

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88

95 of 258

NY AG FAC ¶322

The FDA-Approved OxyContin Label States There Is No Ceiling Effect

1995 FDA-Approved OxyContin Label:

12.1 Mechanism of Action

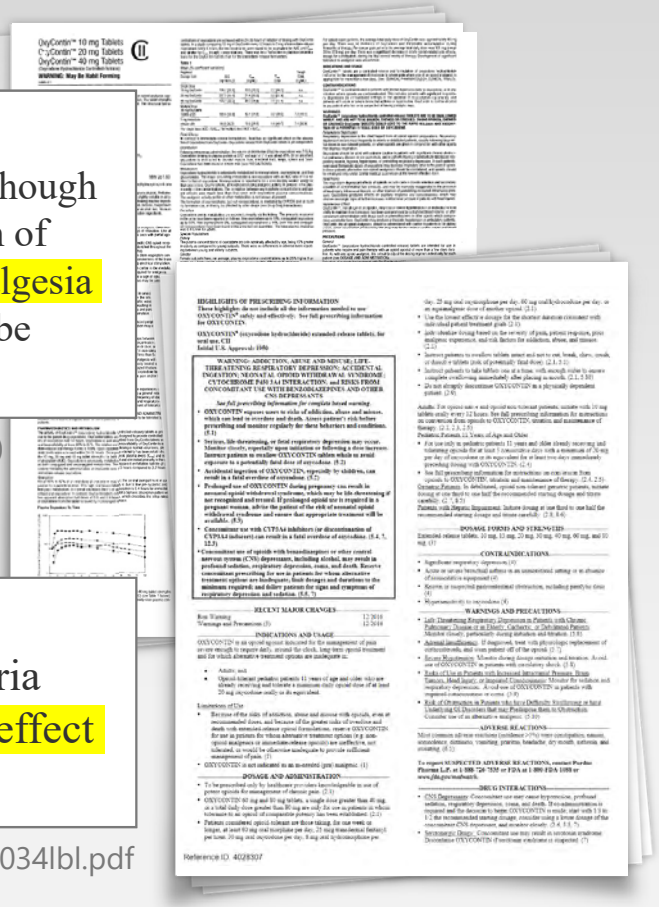
Oxycodone is a full opioid agonist and is relatively selective for the mu receptor, although it can bind to other opioid receptors at higher doses. The principal therapeutic action of oxycodone is analgesia. Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone. Clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory and CNS depression.

1995 OxyContin Label, p. 1, (PDD150170001)

2016 FDA-Approved OxyContin Label:

Oxycodone is a pure agonist opioid whose principal therapeutic action is analgesia. Other therapeutic effects of oxycodone include anxiolysis, euphoria and feelings of relaxation. Like all pure opioid agonists, there is no ceiling effect to analgesia, such as is seen with partial agonists or non-opioid analgesics.

2016 OxyContin Label, p. 33, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

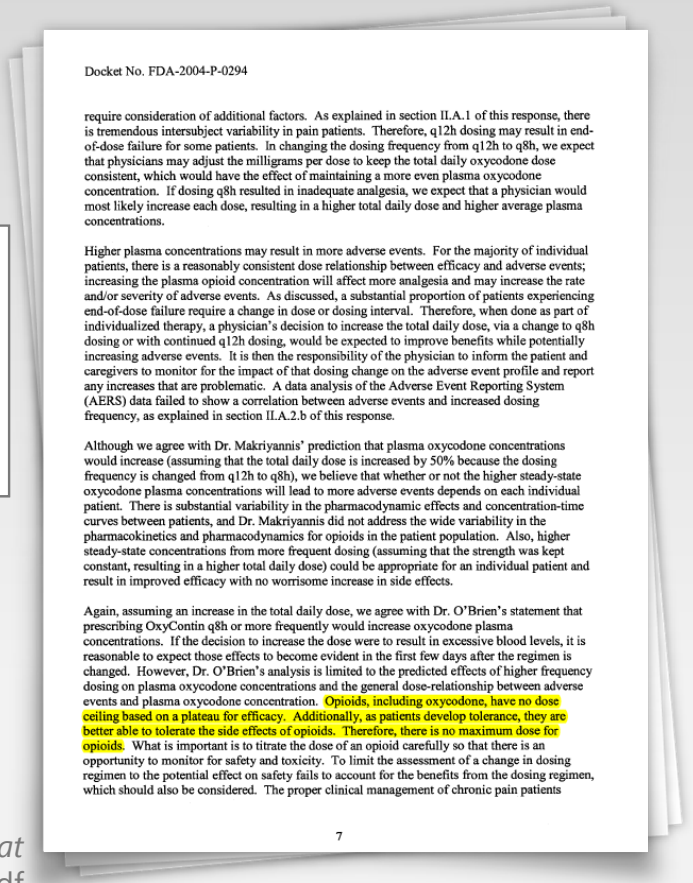


FDA Has Consistently Reaffirmed There Is No Ceiling Effect Or Maximum Dose For Opioids

FDA Letter to AG Richard Blumenthal (Sept. 9, 2008)

FDA Docket No. FDA-2004-P-0294, at p. 7

> **Opioids, including oxycodone, have no dose ceiling based on a plateau for efficiency**. Additionally, as patients develop tolerance, they are better able to tolerate the side effects of opioids. **Therefore, there is no maximum dose for opioids.**



Docket No. FDA-2004-P-0294

require consideration of additional factors. As explained in section II.A.1 of this response, there is tremendous intersubject variability in pain patients. Therefore, q12h dosing may result in end-of-dose failure for some patients. In changing the dosing frequency from q12h to q8h, we expect that physicians may adjust the milligrams per dose to keep the total daily oxycodone dose consistent, which would have the effect of maintaining a more even plasma oxycodone concentration. If dosing q8h resulted in inadequate analgesia, we expect that a physician would most likely increase each dose, resulting in a higher total daily dose and higher average plasma concentrations.

Higher plasma concentrations may result in more adverse events. For the majority of individual patients, there is a reasonably consistent dose relationship between efficacy and adverse events; increasing the plasma opioid concentration will affect more analgesia and may increase the rate and/or severity of adverse events. As discussed, a substantial proportion of patients experiencing end-of-dose failure require a change in dose or dosing interval. Therefore, when done as part of individualized therapy, a physician's decision to increase the total daily dose, via a change to q8h dosing or with continued q12h dosing, would be expected to improve benefits while potentially increasing adverse events. It is then the responsibility of the physician to inform the patient and caregivers to monitor for the impact of that dosing change on the adverse event profile and report any increases that are problematic. A data analysis of the Adverse Event Reporting System (AERS) data failed to show a correlation between adverse events and increased dosing frequency, as explained in section II.A.2.b of this response.

Although we agree with Dr. Makriyannis' prediction that plasma oxycodone concentrations would increase (assuming that the total daily dose is increased by 50% because the dosing frequency is changed from q12h to q8h), we believe that whether or not the higher steady-state oxycodone plasma concentrations will lead to more adverse events depends on each individual patient. There is substantial variability in the pharmacodynamic effects and concentration-time curves between patients, and Dr. Makriyannis did not address the wide variability in the pharmacokinetics and pharmacodynamics for opioids in the patient population. Also, higher steady-state concentrations from more frequent dosing (assuming that the strength was kept constant, resulting in a higher total daily dose) could be appropriate for an individual patient and result in improved efficacy with no worrisome increase in side effects.

Again, assuming an increase in the total daily dose, we agree with Dr. O'Brien's statement that prescribing OxyContin q8h or more frequently would increase oxycodone plasma concentrations. If the decision to increase the dose were to result in excessive blood levels, it is reasonable to expect those effects to become evident in the first few days after the regimen is changed. However, Dr. O'Brien's analysis is limited to the predicted effects of higher frequency dosing on plasma oxycodone concentrations and the general dose-relationship between adverse events and plasma oxycodone concentration. Opioids, including oxycodone, have no dose ceiling based on a plateau for efficacy. Additionally, as patients develop tolerance, they are better able to tolerate the side effects of opioids. Therefore, there is no maximum dose for opioids. What is important is to titrate the dose of an opioid carefully so that there is an opportunity to monitor for safety and toxicity. To limit the assessment of a change in dosing regimen to the potential effect on safety fails to account for the benefits from the dosing regimen, which should also be considered. The proper clinical management of chronic pain patients

7

FDA Docket No. FDA-2004-P-0294, at p. 7, *available at* https://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf

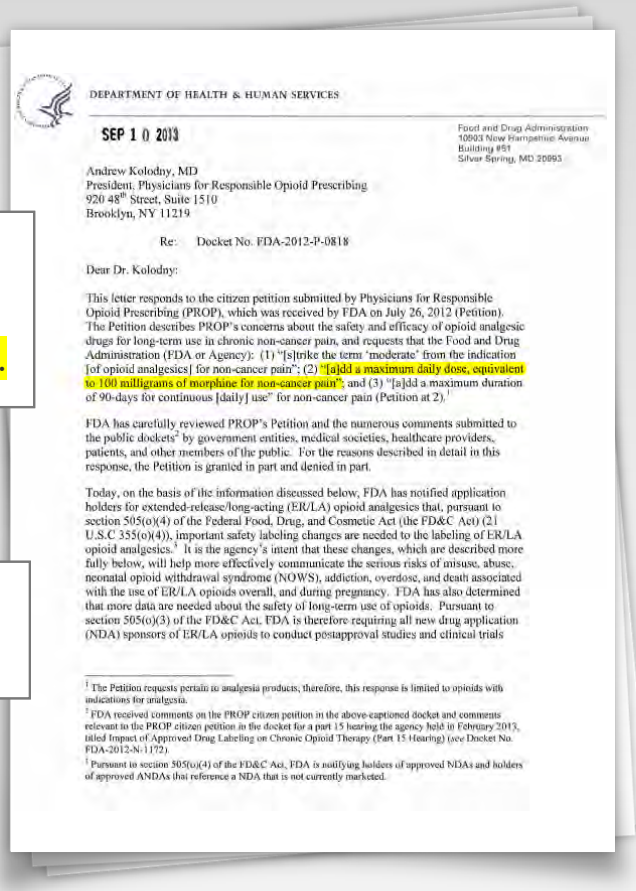
FDA Rejected a Maximum Daily Dose for OxyContin in 2013

In 2013 Physicians for Responsible Opioid Prescribing ("PROP") Petition asked the FDA to:

Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain . . . [because t]hree large observational studies published in 2010 and 2011 found dose-related overdose risk in CNCP patients on [chronic opioid therapy].

The FDA refused because:

… the scientific literature does not support establishing a maximum recommended daily dose of 100 mg MED.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 1 0 2013

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

Andrew Kolodny, MD
President, Physicians for Responsible Opioid Prescribing
920 48th Street, Suite 1510
Brooklyn, NY 11219

Re: Docket No. FDA-2012-P-0818

Dear Dr. Kolodny:

This letter responds to the citizen petition submitted by Physicians for Responsible Opioid Prescribing (PROP), which was received by FDA on July 26, 2012 (Petition). The Petition describes PROP's concerns about the safety and efficacy of opioid analgesic drugs for long-term use in chronic non-cancer pain, and requests that the Food and Drug Administration (FDA or Agency): (1) "[s]trike the term 'moderate' from the indication [of opioid analgesics] for non-cancer pain"; (2) "[a]dd a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain"; and (3) "[a]dd a maximum duration of 90-days for continuous [daily] use" for non-cancer pain (Petition at 2).[1]

FDA has carefully reviewed PROP's Petition and the numerous comments submitted to the public dockets[2] by government entities, medical societies, healthcare providers, patients, and other members of the public. For the reasons described in detail in this response, the Petition is granted in part and denied in part.

Today, on the basis of the information discussed below, FDA has notified application holders for extended-release/long-acting (ER/LA) opioid analgesics that, pursuant to section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C 355(o)(4)), important safety labeling changes are needed to the labeling of ER/LA opioid analgesics.[3] It is the agency's intent that these changes, which are described more fully below, will help more effectively communicate the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death associated with the use of ER/LA opioids overall, and during pregnancy. FDA has also determined that more data are needed about the safety of long-term use of opioids. Pursuant to section 505(o)(3) of the FD&C Act, FDA is therefore requiring all new drug application (NDA) sponsors of ER/LA opioids to conduct postapproval studies and clinical trials

[1] The Petition requests pertain to analgesia products, therefore, this response is limited to opioids with indications for analgesia.

[2] FDA received comments on the PROP citizen petition in the above-captioned docket and comments relevant to the PROP citizen petition in the docket for a part 15 hearing the agency held in February 2013, titled Impact of Approved Drug Labeling on Chronic Opioid Therapy (Part 15 Hearing) (see Docket No. FDA-2012-N-1172).

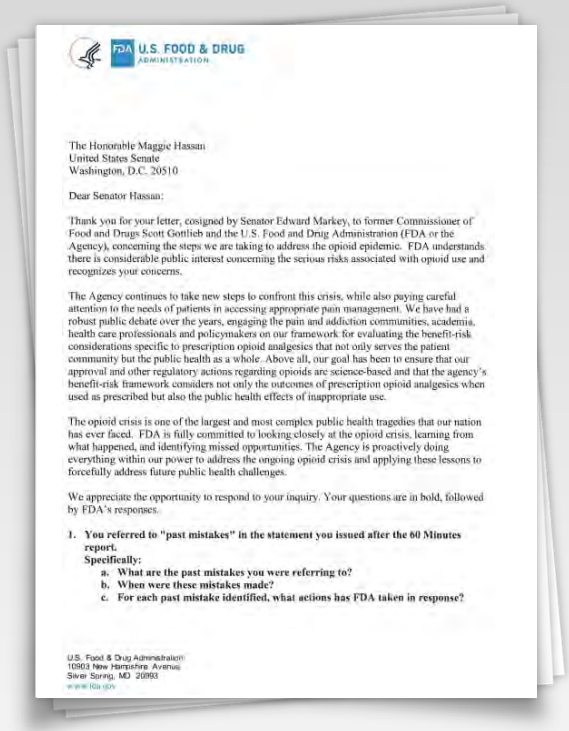
[3] Pursuant to section 505(o)(4) of the FD&C Act, FDA is notifying holders of approved NDAs and holders of approved ANDAs that reference a NDA that is not currently marketed.

9/10/13 2013 PROP Letter, pp. 1, 12, *available at* http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

FDA Still Rejects A Maximum Dose for Opioids

2020 FDA Letter to Senator Maggie Hassan:

- "[T]he data do not suggest a threshold [dose] below which opioid use is 'safe' and above which it is 'too risky.'" (Page 13)



U.S. FOOD & DRUG ADMINISTRATION

The Honorable Maggie Hassan
United States Senate
Washington, D.C. 20510

Dear Senator Hassan:

Thank you for your letter, cosigned by Senator Edward Markey, to former Commissioner of Food and Drugs Scott Gottlieb and the U.S. Food and Drug Administration (FDA or the Agency), concerning the steps we are taking to address the opioid epidemic. FDA understands there is considerable public interest concerning the serious risks associated with opioid use and recognizes your concerns.

The Agency continues to take new steps to confront this crisis, while also paying careful attention to the needs of patients in accessing appropriate pain management. We have had a robust public debate over the years, engaging the pain and addiction communities, academia, health care professionals and policymakers on our framework for evaluating the benefit-risk considerations specific to prescription opioid analgesics that not only serves the patient community but the public health as a whole. Above all, our goal has been to ensure that our approval and other regulatory actions regarding opioids are science-based and that the agency's benefit-risk framework considers not only the outcomes of prescription opioid analgesics when used as prescribed but also the public health effects of inappropriate use.

The opioid crisis is one of the largest and most complex public health tragedies that our nation has ever faced. FDA is fully committed to looking closely at the opioid crisis, learning from what happened, and identifying missed opportunities. The Agency is proactively doing everything within our power to address the ongoing opioid crisis and applying these lessons to forcefully address future public health challenges.

We appreciate the opportunity to respond to your inquiry. Your questions are in bold, followed by FDA's responses.

1. **You referred to "past mistakes" in the statement you issued after the 60 Minutes report.**
   Specifically:
   a. **What are the past mistakes you were referring to?**
   b. **When were these mistakes made?**
   c. **For each past mistake identified, what actions has FDA taken in response?**

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

Individualized Titration As Optimal Way to Find Lowest Effective Dose Is Explained in the OxyContin Label

1995 OxyContin Label:

As with all opioids, the minimum effective plasma concentration tor analgesia will vary widely among patients, especially among patients who have been previously treated with potent agonist opioids. As a result, patients need to be treated with individualized titration of dosage to the desired effect. The minimum effective analgesic concentration of oxycodone for any individual patient may increase with repeated dosing due to an increase in pain and/or the development of tolerance.

1995 OxyContin Label, p. 1, (PDD150170001)

2013 OxyContin Label:

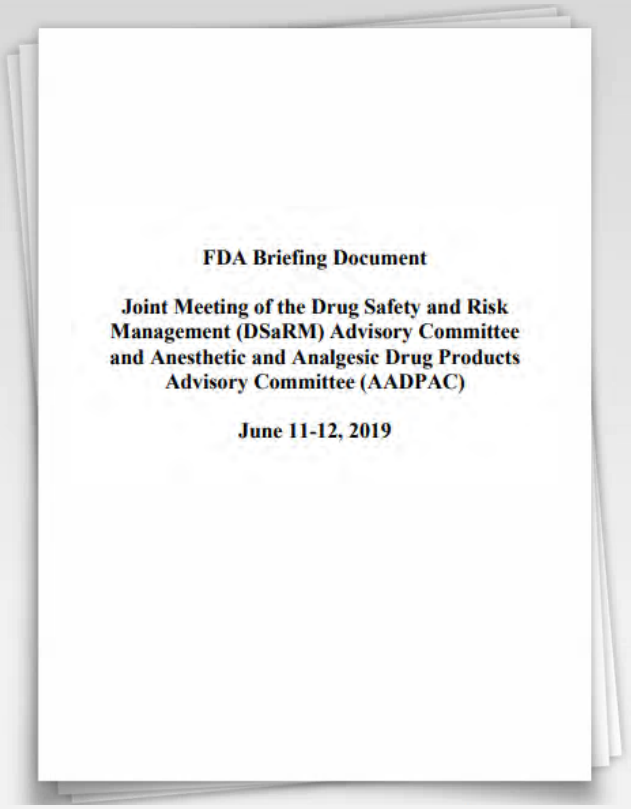
Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving OxyContin to assess the maintenance of pain control and the relative incidence of adverse reactions. During chronic therapy, especially for non-cancer-related pain (or pain associated with other terminal illnesses), periodically reassess the continued need for the use of opioid analgesics.

April 2013 OxyContin Label, p. 7, (PPLPC003000060503)

Individualized Titration As Optimal Way to Find Lowest Effective Dose Is Explained in the OxyContin Label

FDA Briefing Book for June 11-12, 2019 Joint Meeting of the Drug Safety and Risk Mgmt. Advisory Comm. and Anesthetic and Analgesic Drug Products Advisory Comm.:

- "**With the consideration of individual variability, the clinician may individually titrate the [opioid] to a dose that provides adequate analgesia and minimizes adverse reactions based on the patient's response.**" (Page 14)
- "**The general approach is to initiate opioid treatment with a low dose and individually titrate to a tolerable dose that provides adequate analgesia.'"** (Page 14)



https://www.fda.gov/media/127780/download

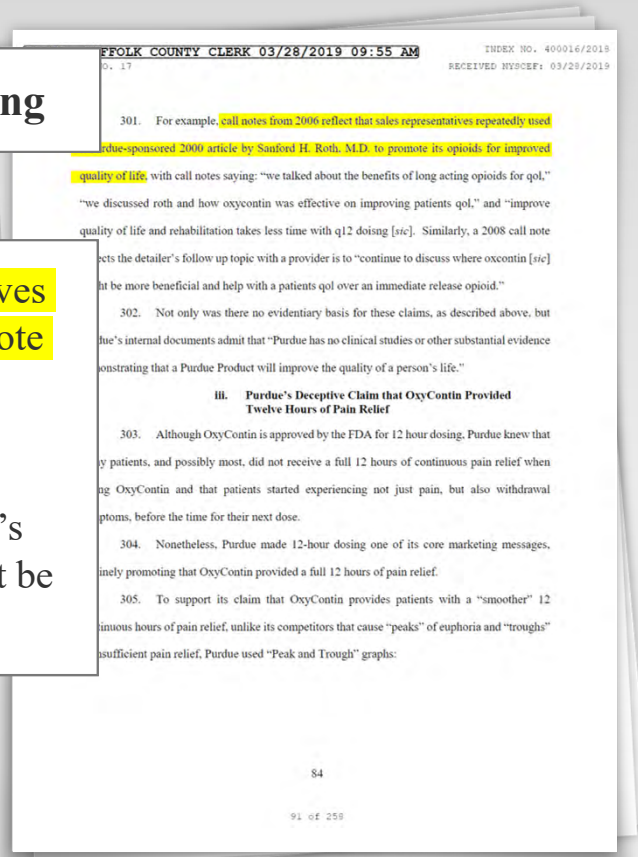
Alleged Misrepresentation No. 6:
Long-Term Opioid Use Improves Functioning

6. Misrepresentation #6: Long-Term Opioid Use Improves Functioning

NY AG FAC, p. 38

301. For example, call notes from 2006 reflect that sales representatives repeatedly used a Purdue-sponsored 2000 article by Sanford H. Roth, M.D. to promote its opioids for improved quality of life, with call notes saying: "we talked about the benefits of long acting opioids for qol," "we discussed roth and how oxycontin was effective on improving patients qol," and "improve quality of life and rehabilitation takes less time with q12 doisng [sic]. Similarly, a 2008 call note reflects the detailer's follow up topic with a provider is to "continue to discuss where oxcontin [sic] might be more beneficial and help with a patients qol over an immediate release opioid.".

NY AG FAC ¶301


FFOLK COUNTY CLERK 03/28/2019 09:55 AM INDEX NO. 400016/2018
O. 17 RECEIVED NYSCEF: 03/28/2019

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302. Not only was there no evidentiary basis for these claims, as described above, but lue's internal documents admit that "Purdue has no clinical studies or other substantial evidence onstrating that a Purdue Product will improve the quality of a person's life."

iii. Purdue's Deceptive Claim that OxyContin Provided Twelve Hours of Pain Relief

303. Although OxyContin is approved by the FDA for 12 hour dosing, Purdue knew that y patients, and possibly most, did not receive a full 12 hours of continuous pain relief when ng OxyContin and that patients started experiencing not just pain, but also withdrawal ptoms, before the time for their next dose.

304. Nonetheless, Purdue made 12-hour dosing one of its core marketing messages, inely promoting that OxyContin provided a full 12 hours of pain relief.

305. To support its claim that OxyContin provides patients with a "smoother" 12 inuous hours of pain relief, unlike its competitors that cause "peaks" of euphoria and "troughs" nsufficient pain relief, Purdue used "Peak and Trough" graphs:

84

91 of 258

- Purdue expressly prohibited quality of life claims

Purdue Expressly Prohibited Quality of Life Claims

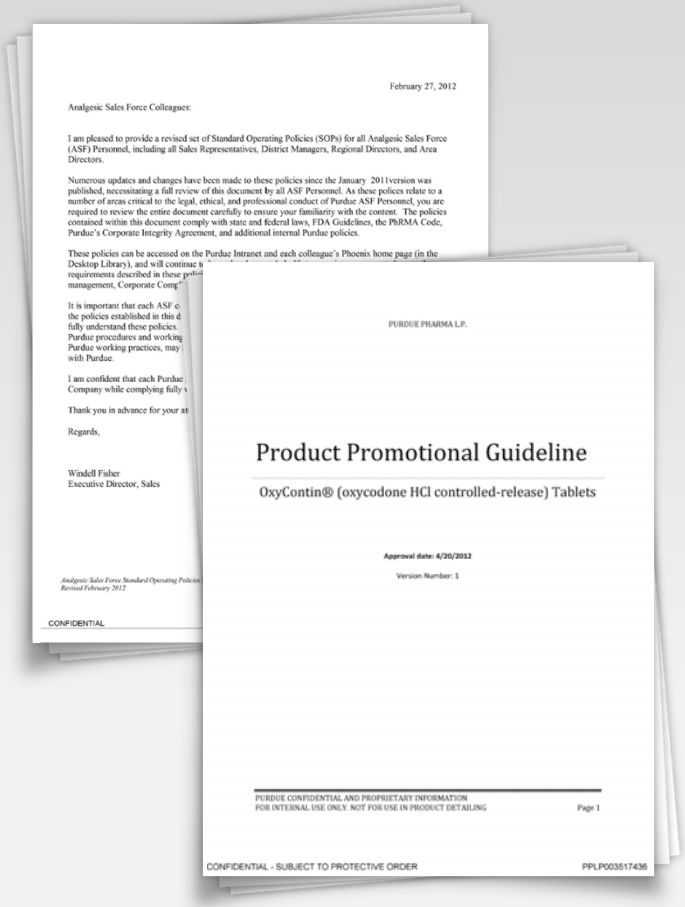
Quality of Life and Convenience Claims

Quality of life and convenience claims may be explicit or implied; both are to be avoided. All claims must be consistent with product labeling and Company Approved Material. As Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life or that taking a Purdue Product is more convenient than an alternative product, such claims cannot be made. Likewise, it is impermissible to ask a question of the customer that causes him/her to make a quality of life conclusion about a Purdue product.

5.0 TOPICS PRECLUDED FROM PROMOTION

The following topics are specifically excluded from promotional materials at this time.

- Efficacy claims or representations that suggest or imply that OxyContin is indicated for acute or mild chronic pain (or any other type of pain beyond moderate to severe chronic pain), pediatric patients, or pregnant women.
- Comparative efficacy or safety claims (e.g., "like all opioids…", "more effective than…").
- Any claim that suggests or implies that OxyContin can be used in pediatric patients.
- Pharmacoeconomic (PE) claims are not substantiated by competent and reliable scientific studies.
- Quality of Life (QoL) claims (e.g., improvements in functionality or sleep), including visual representations or pictorials that are not substantiated by patient reported outcomes (PROs) validated tools.



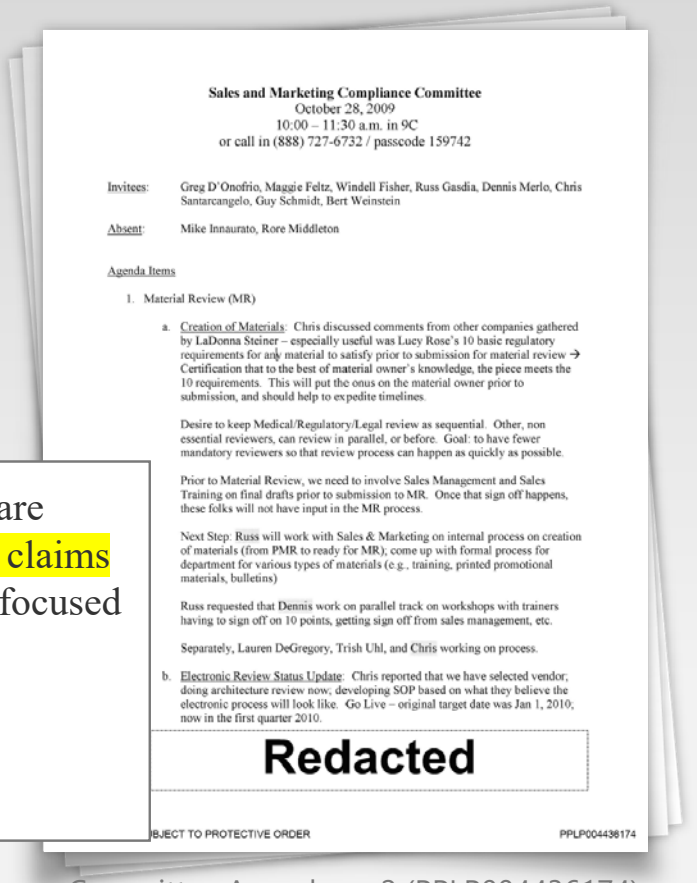
2/27/12 SOP for Analgesic Sales Force, p. 14 (PPLPC014000164042); 4/20/2012 Product Promotional Guidelines, p. 13 (PPLP003517436)

Purdue Retrained Or Disciplined Employees Who Made Quality of Life Claims

Sales and Marketing Compliance Committee
October 28, 2009
10:00 – 11:30 a.m. in 9C
or call in (888) 727-6732 / passcode 159742

2. Call Note Reviews: Litigation Support is thru July on key word searches; they are working to catch up on call note searches. Biggest issue = sleep and quality of life claims ➡ we trained on this issue in April and again in June 2009. This issue seems to be focused particularly in February timeframe.

Going forward, we will get reports on a monthly basis per Bert's agreement with Mike Panagrossi.



Sales and Marketing Compliance Committee
October 28, 2009
10:00 – 11:30 a.m. in 9C
or call in (888) 727-6732 / passcode 159742

Invitees: Greg D'Onofrio, Maggie Feltz, Windell Fisher, Russ Gasdia, Dennis Merlo, Chris Santarcangelo, Guy Schmidt, Bert Weinstein

Absent: Mike Innaurato, Rore Middleton

Agenda Items

1. Material Review (MR)

a. Creation of Materials: Chris discussed comments from other companies gathered by LaDonna Steiner – especially useful was Lucy Rose's 10 basic regulatory requirements for any material to satisfy prior to submission for material review → Certification that to the best of material owner's knowledge, the piece meets the 10 requirements. This will put the onus on the material owner prior to submission, and should help to expedite timelines.

Desire to keep Medical/Regulatory/Legal review as sequential. Other, non essential reviewers, can review in parallel, or before. Goal: to have fewer mandatory reviewers so that review process can happen as quickly as possible.

Prior to Material Review, we need to involve Sales Management and Sales Training on final drafts prior to submission to MR. Once that sign off happens, these folks will not have input in the MR process.

Next Step: Russ will work with Sales & Marketing on internal process on creation of materials (from PMR to ready for MR); come up with formal process for department for various types of materials (e.g., training, printed promotional materials, bulletins)

Russ requested that Dennis work on parallel track on workshops with trainers having to sign off on 10 points, getting sign off from sales management, etc.

Separately, Lauren DeGregory, Trish Uhl, and Chris working on process.

b. Electronic Review Status Update: Chris reported that we have selected vendor; doing architecture review now; developing SOP based on what they believe the electronic process will look like. Go Live – original target date was Jan 1, 2010; now in the first quarter 2010.

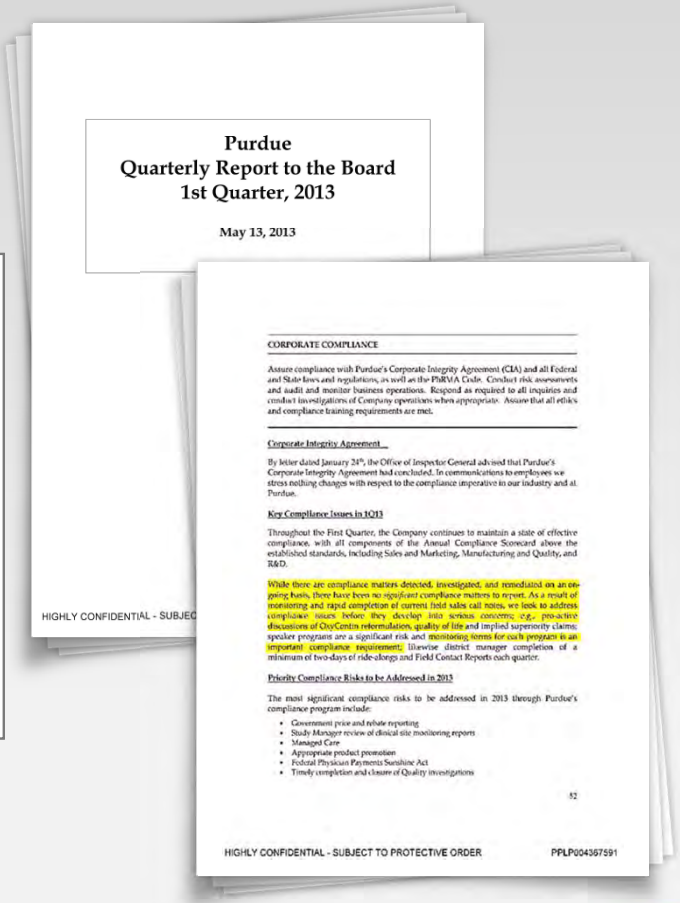
Redacted

BJECT TO PROTECTIVE ORDER PPLP004436174

10/28/09 Sales and Marketing Compliance Committee Agenda, p. 2 (PPLP004436174)

Board Was Informed Compliance Department Monitored And Remediated Quality of Life Claims

While there are compliance matters detected, investigated, and remediated on an ongoing basis, there have been no significant compliance matters to report. As a result of monitoring and rapid completion of current field sales call notes, **we look to address compliance issues before they develop into serious concerns; e.g.,** pro-active discussions of OxyContin reformulation, **quality of life** and implied superiority claims; speaker programs are a significant risk and monitoring forms for each program is an important compliance requirement; likewise district manager completion of a minimum of two-days of ride-alongs and Field Contact Reports each quarter.



Purdue
Quarterly Report to the Board
1st Quarter, 2013

May 13, 2013

CORPORATE COMPLIANCE

Assure compliance with Purdue's Corporate Integrity Agreement (CIA) and all Federal and State laws and regulations, as well as the PMWA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

Corporate Integrity Agreement

By letter dated January 24th, the Office of Inspector General advised that Purdue's Corporate Integrity Agreement had concluded. In communications to employees we stress nothing changes with respect to the compliance imperative in our industry and at Purdue.

Key Compliance Issues in 1Q13

Throughout the First Quarter, the Company continues to maintain a state of effective compliance, with all components of the Annual Compliance Scorecard above the established standards, including Sales and Marketing, Manufacturing and Quality, and R&D.

While there are compliance matters detected, investigated, and remediated on an ongoing basis, there have been no significant compliance matters to report. As a result of monitoring and rapid completion of current field sales call notes, we look to address compliance issues before they develop into serious concerns; e.g., pro-active discussions of OxyContin reformulation, quality of life and implied superiority claims; speaker programs are a significant risk and monitoring forms for each program is an important compliance requirement; likewise district manager completion of a minimum of two-days of ride-alongs and Field Contact Reports each quarter.

Priority Compliance Risks to be Addressed in 2013

The most significant compliance risks to be addressed in 2013 through Purdue's compliance program include:

- Government price and rebate reporting
- Study Manager review of clinical site monitoring reports
- Managed Care
- Appropriate product promotion
- Federal Physician Payments Sunshine Act
- Timely completion and closure of Quality investigations

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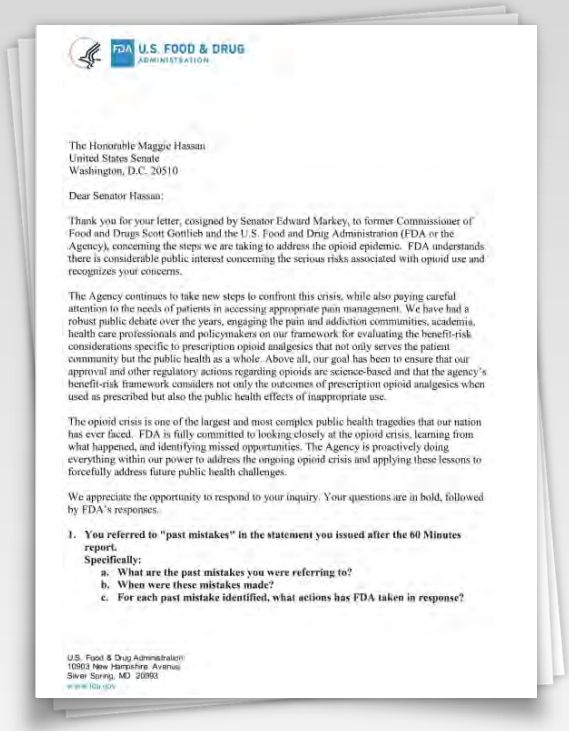
HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER PPLP004367591

May 2013 Board Report, p. 52 (PPLP004367540)

FDA Has Always Approved Long-Term Use of OxyContin

2020 FDA Letter to Senator Maggie Hassan:

- **"Chronic or long-term use (in appropriate situations), with no maximum duration, was always part of the approved use of OxyContin.'"** (Page 4)



U.S. FOOD & DRUG ADMINISTRATION

The Honorable Maggie Hassan
United States Senate
Washington, D.C. 20510

Dear Senator Hassan:

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The Agency continues to take new steps to confront this crisis, while also paying careful attention to the needs of patients in accessing appropriate pain management. We have had a robust public debate over the years, engaging the pain and addiction communities, academia, health care professionals and policymakers on our framework for evaluating the benefit-risk considerations specific to prescription opioid analgesics that not only serves the patient community but the public health as a whole. Above all, our goal has been to ensure that our approval and other regulatory actions regarding opioids are science-based and that the agency's benefit-risk framework considers not only the outcomes of prescription opioid analgesics when used as prescribed but also the public health effects of inappropriate use.

The opioid crisis is one of the largest and most complex public health tragedies that our nation has ever faced. FDA is fully committed to looking closely at the opioid crisis, learning from what happened, and identifying missed opportunities. The Agency is proactively doing everything within our power to address the ongoing opioid crisis and applying these lessons to forcefully address future public health challenges.

We appreciate the opportunity to respond to your inquiry. Your questions are in bold, followed by FDA's responses.

1. **You referred to "past mistakes" in the statement you issued after the 60 Minutes report.**
   Specifically:
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   b. **When were these mistakes made?**
   c. **For each past mistake identified, what actions has FDA taken in response?**

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

Alleged Misrepresentation No. 7:
Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

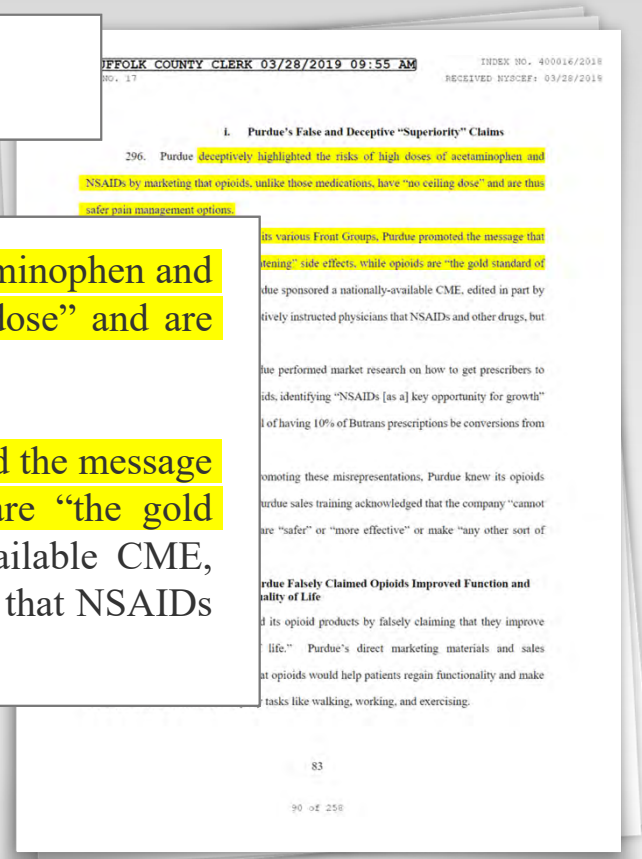
7. Misrepresentation #7: Alternative Forms of Pain Relief Pose Greater Risks than Opioids

NY AG FAC, p. 41

296. Purdue deceptively highlighted the risks of high doses of acetaminophen and NSAIDs by marketing that opioids, unlike those medications, have "no ceiling dose" and are thus safer pain management options.

297. Directly and through its various Front Groups, Purdue promoted the message that NSAIDs and Tylenol have "life-threatening" side effects, while opioids are "the gold standard of pain medications." For example, Purdue sponsored a nationally-available CME, edited in part by KOL Dr. Russell Portenoy, that deceptively instructed physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

NY AG FAC ¶¶296-97



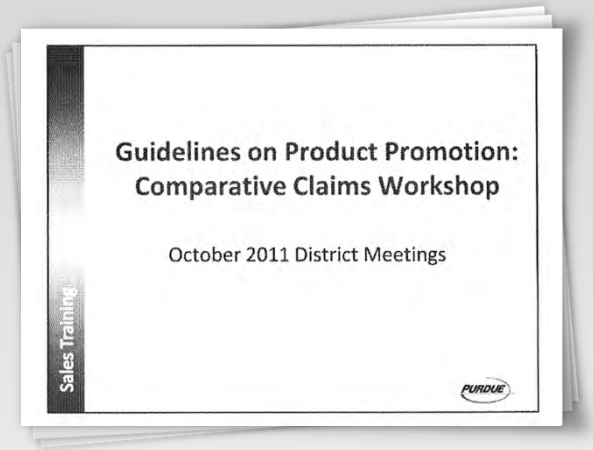
- Purdue expressly prohibited quality of life claims

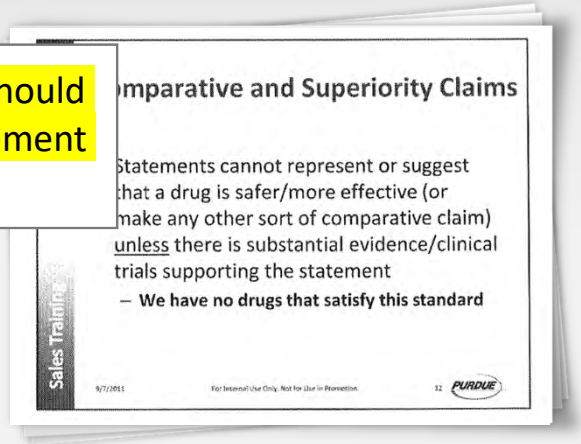
Purdue Prohibited Comparative Claims

Statements cannot represent or suggest that a drug is safer/more effective (or make any other sort of comparative claim) unless there is substantial evidence/clinical trials supporting the statement — We have no drugs that satisfy this standard

Be careful not to IMPLY superiority in your discussions with HCPs

What If It Is the HCP Who Is Making These Statements? . . . When this happens, what should you do? . . . There are circumstances where it is necessary to respond to the HCP's statement (e.g., when failure to do so might leave a misimpression about our products





10/11 Guidelines on Product Promotion: Comparative Claims Workshop (PPLP003439475)

Purdue Prohibited Comparative Claims

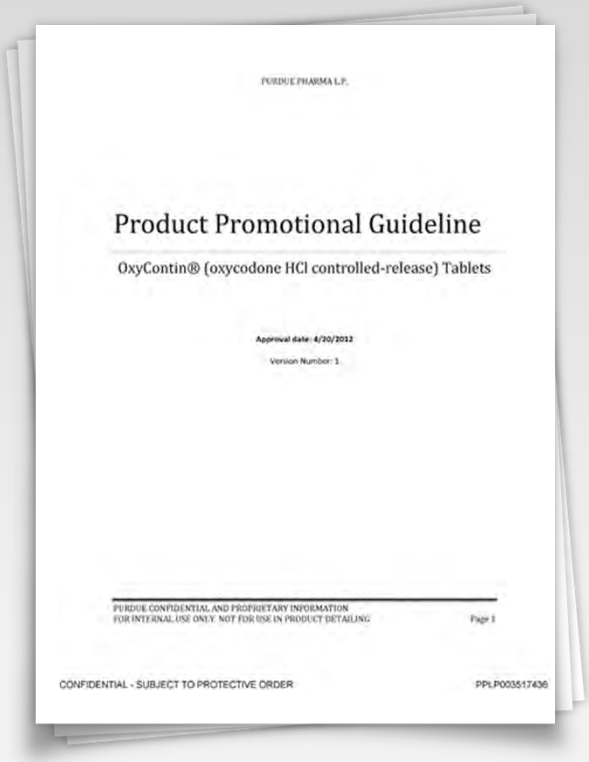
Product Promotional Guidelines (Apr. 20, 2012)**:**

- "**Care should be taken to avoid any comparative claims to other productions or classes of drugs.**" (Page 4)

***

"**5.0 TOPICS PRECLUDED FROM PROMOTION**"

- "**Comparative efficacy or safety claims**" (Page 13)


PURDUE PHARMA L.P.

Product Promotional Guideline

OxyContin® (oxycodone HCl controlled-release) Tablets

Approval date: 4/20/2012

Version Number: 1

PURDUE CONFIDENTIAL AND PROPRIETARY INFORMATION
FOR INTERNAL USE ONLY. NOT FOR USE IN PRODUCT DETAILING

Page 1

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP003517436

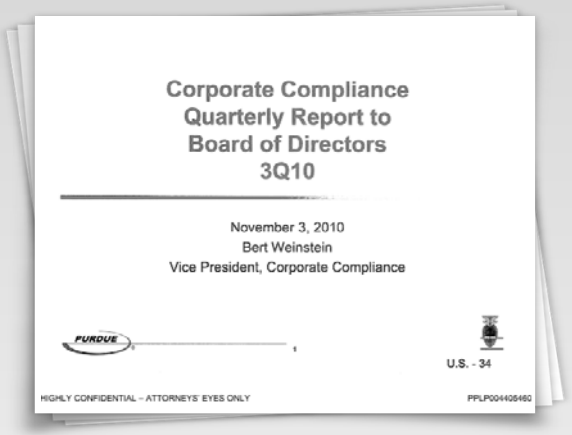
4/20/2012 Product Promotional Guidelines, pp. 4, 13 (PPLP003517436)

Board Was Advised Comparative Claims Were Monitored And Remediated

- Routine review of call notes revealed references that suggested potential comparative claims of superiority of Purdue products relative to competitors. Compliance conducted a broader review of all call notes entered after training on comparative claims in June 2009. A total of 75 potentially problematic notes were identified. Interviews were held with responsible sales representatives, and district managers who had reviewed, but not commented on those call notes.

- Follow up discipline included: termination of one representative for multiple compliance violations, **probation** for a second representative, and **written warning letters** for an additional 16 representatives. One manager received a written warning letter, and a second was provided with verbal coaching.

- **Additional procedures have been put in place**, to ensure that any training on promotional issues that a representative misses will be provided when the representative returns from leave (or joins the company if a new employee).


Corporate Compliance
Quarterly Report to
Board of Directors
3Q10

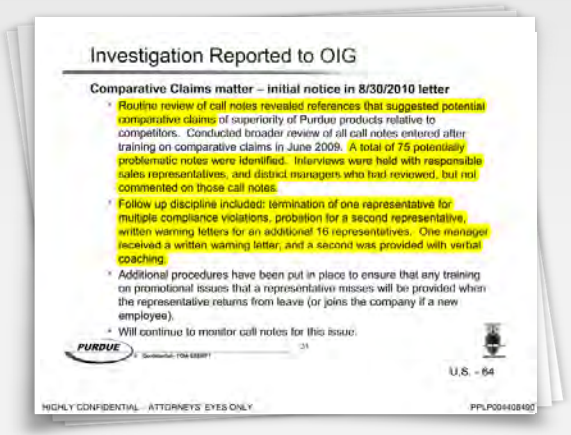
November 3, 2010
Bert Weinstein
Vice President, Corporate Compliance

PURDUE

U.S. - 34

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY

PPLP004405460


Investigation Reported to OIG

Comparative Claims matter – initial notice in 8/30/2010 letter

- Routine review of call notes revealed references that suggested potential comparative claims of superiority of Purdue products relative to competitors. Conducted broader review of all call notes entered after training on comparative claims in June 2009. A total of 75 potentially problematic notes were identified. Interviews were held with responsible sales representatives, and district managers who had reviewed, but not commented on those call notes.
- Follow up discipline included: termination of one representative for multiple compliance violations, probation for a second representative, written warning letters for an additional 16 representatives. One manager received a written warning letter, and a second was provided with verbal coaching.
- Additional procedures have been put in place to ensure that any training on promotional issues that a representative misses will be provided when the representative returns from leave (or joins the company if a new employee).
- Will continue to monitor call notes for this issue.

PURDUE

U.S. - 64

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY

PPLP004408490

3Q2010 Quarterly Compliance Report at slide 31 (PPLP004405460, -490)

Alleged Misrepresentation No. 8:
Extended-Release Drugs Provide 12 Or More Hours of Pain Relief

8. Misrepresentation #8: Extended-Release Drugs Provide Twelve or More Hours of Pain Relief

146. The Manufacturer Defendants misled doctors and patients about the original selling point of their "revolutionary" extended-release ("ER") opioids, making the knowingly false claim that such drugs would provide 12 or more hours of pain relief for most patients. This claim provided the basis for the Manufacturer Defendants' patents and their efforts to differentiate themselves from competitors, and facilitated their false claims that ER drugs have a more even, stable release mechanism that avoids peaks and valleys, and therefore the rush that fosters misuse and addiction.

147. The active ingredient in the Manufacturer Defendants' ER opioids does not enter the body at a linear rate. OxyContin, for example, works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief. As a result, in many patients, OxyContin does not last for the twelve hours promised. …

NY AG FAC p.43, ¶¶146-47

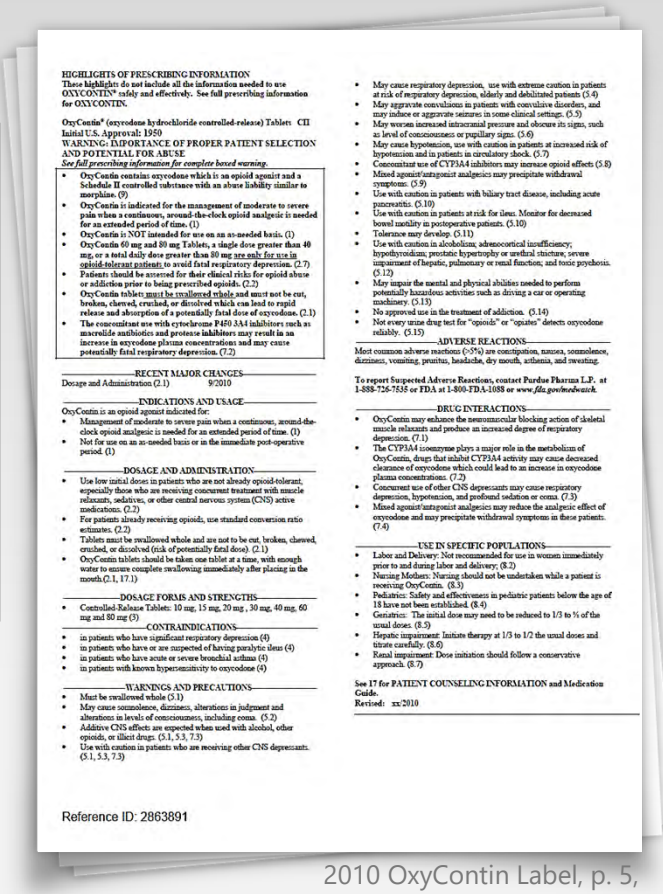
The FDA Approved OxyContin As A 12-Hour Drug

FDA-approved label:

2.2 Initiating Therapy with OxyContin

* * *

Experience indicates a reasonable starting dose of OxyContin for patients who are taking non-opioid analgesics and require continuous around-the-clock therapy for an extended period of time is 10 mg every 12 hours. Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions while maintaining an every-twelve-hour dosing regimen.



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OXYCONTIN® safely and effectively. See full prescribing information for OXYCONTIN.

OxyContin® (oxycodone hydrochloride controlled-release) Tablets CII
Initial U.S. Approval: 1950
WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE
See full prescribing information for complete boxed warning.

- OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (9)
- OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)
- OxyContin is NOT intended for use on an as-needed basis. (1)
- OxyContin 60 mg and 80 mg Tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in opioid-tolerant patients to avoid fatal respiratory depression. (2.7)
- Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. (2.2)
- OxyContin tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved which can lead to rapid release and absorption of a potentially fatal dose of oxycodone. (2.1)
- The concomitant use with cytochrome P450 3A4 inhibitors such as macrolide antibiotics and protease inhibitors may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. (7.2)

RECENT MAJOR CHANGES
Dosage and Administration (2.1) 9/2010

INDICATIONS AND USAGE
OxyContin is an opioid agonist indicated for:

- Management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)
- Not for use on an as-needed basis or in the immediate post-operative period. (1)

DOSAGE AND ADMINISTRATION

- Use low initial doses in patients who are not already opioid-tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other central nervous system (CNS) active medications. (2.2)
- For patients already receiving opioids, use standard conversion ratio estimates. (2.2)
- Tablets must be swallowed whole and are not to be cut, broken, chewed, crushed, or dissolved (risk of potentially fatal dose). (2.1)
- OxyContin tablets should be taken one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.(2.1, 17.1)

DOSAGE FORMS AND STRENGTHS

- Controlled-Release Tablets: 10 mg, 15 mg, 20 mg , 30 mg, 40 mg, 60 mg and 80 mg (3)

CONTRAINDICATIONS

- in patients who have significant respiratory depression (4)
- in patients who have or are suspected of having paralytic ileus (4)
- in patients who have acute or severe bronchial asthma (4)
- in patients with known hypersensitivity to oxycodone (4)

WARNINGS AND PRECAUTIONS

- Must be swallowed whole (5.1)
- May cause somnolence, dizziness, alterations in judgment and alterations in levels of consciousness, including coma. (5.2)
- Additive CNS effects are expected when used with alcohol, other opioids, or illicit drugs. (5.1, 5.3, 7.3)
- Use with caution in patients who are receiving other CNS depressants. (5.1, 5.3, 7.3)
- May cause respiratory depression, use with extreme caution in patients at risk of respiratory depression, elderly and debilitated patients (5.4)
- May aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. (5.5)
- May worsen increased intracranial pressure and obscure its signs, such as level of consciousness or pupillary signs. (5.6)
- May cause hypotension, use with caution in patients at increased risk of hypotension and in patients in circulatory shock. (5.7)
- Concomitant use of CYP3A4 inhibitors may increase opioid effects (5.8)
- Mixed agonist/antagonist analgesics may precipitate withdrawal symptoms. (5.9)
- Use with caution in patients with biliary tract disease, including acute pancreatitis. (5.10)
- Use with caution in patients at risk for ileus. Monitor for decreased bowel motility in postoperative patients. (5.10)
- Tolerance may develop. (5.11)
- Use with caution in alcoholism; adrenocortical insufficiency; hypothyroidism; prostatic hypertrophy or urethral stricture; severe impairment of hepatic, pulmonary or renal function; and toxic psychosis. (5.12)
- May impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. (5.13)
- No approved use in the treatment of addiction. (5.14)
- Not every urine drug test for "opioids" or "opiates" detects oxycodone reliably. (5.15)

ADVERSE REACTIONS
Most common adverse reactions (>5%) are constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, asthenia, and sweating.

To report Suspected Adverse Reactions, contact Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

- OxyContin may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression. (7.1)
- The CYP3A4 isoenzyme plays a major role in the metabolism of OxyContin, drugs that inhibit CYP3A4 activity may cause decreased clearance of oxycodone which could lead to an increase in oxycodone plasma concentrations. (7.2)
- Concurrent use of other CNS depressants may cause respiratory depression, hypotension, and profound sedation or coma. (7.3)
- Mixed agonist/antagonist analgesics may reduce the analgesic effect of oxycodone and may precipitate withdrawal symptoms in these patients. (7.4)

USE IN SPECIFIC POPULATIONS

- Labor and Delivery: Not recommended for use in women immediately prior to and during labor and delivery; (8.2)
- Nursing Mothers: Nursing should not be undertaken while a patient is receiving OxyContin. (8.3)
- Pediatrics: Safety and effectiveness in pediatric patients below the age of 18 have not been established. (8.4)
- Geriatrics: The initial dose may need to be reduced to 1/3 to ½ of the usual doses. (8.5)
- Hepatic impairment: Initiate therapy at 1/3 to 1/2 the usual doses and titrate carefully. (8.6)
- Renal impairment: Dose initiation should follow a conservative approach. (8.7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.
Revised: xx/2010

Reference ID: 2863891

2010 OxyContin Label, p. 5, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf.

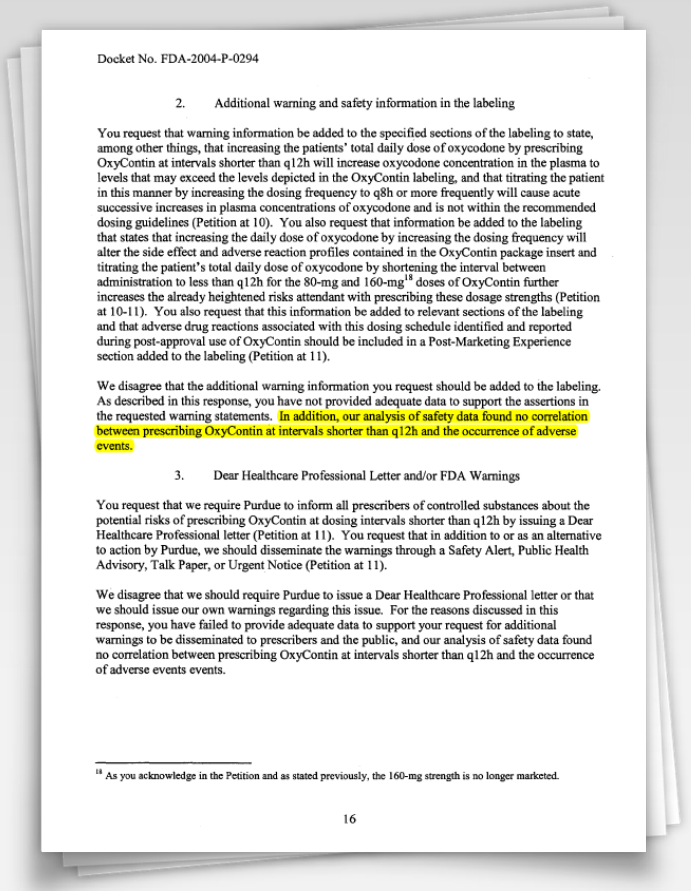
Purdue is therefore required to market OxyContin as a 12-hour drug (21 C.F.R. §201.100(d)(1); Consent Judgments ¶3)

FDA Found Dosing OxyContin More Often Than 12 Hours Was Not Associated with Adverse Events

FDA Letter to AG Richard Blumenthal (Sept. 9, 2008)

FDA Docket No. FDA-2004-P-0294, at p. 16

> **[O]ur analysis of safety data found no correlation between prescribing OxyContin at intervals shorter than q12h and the occurrence of adverse events.**



Docket No. FDA-2004-P-0294

2. Additional warning and safety information in the labeling

You request that warning information be added to the specified sections of the labeling to state, among other things, that increasing the patients' total daily dose of oxycodone by prescribing OxyContin at intervals shorter than q12h will increase oxycodone concentration in the plasma to levels that may exceed the levels depicted in the OxyContin labeling, and that titrating the patient in this manner by increasing the dosing frequency to q8h or more frequently will cause acute successive increases in plasma concentrations of oxycodone and is not within the recommended dosing guidelines (Petition at 10). You also request that information be added to the labeling that states that increasing the daily dose of oxycodone by increasing the dosing frequency will alter the side effect and adverse reaction profiles contained in the OxyContin package insert and titrating the patient's total daily dose of oxycodone by shortening the interval between administration to less than q12h for the 80-mg and 160-mg[18] doses of OxyContin further increases the already heightened risks attendant with prescribing these dosage strengths (Petition at 10-11). You also request that this information be added to relevant sections of the labeling and that adverse drug reactions associated with this dosing schedule identified and reported during post-approval use of OxyContin should be included in a Post-Marketing Experience section added to the labeling (Petition at 11).

We disagree that the additional warning information you request should be added to the labeling. As described in this response, you have not provided adequate data to support the assertions in the requested warning statements. In addition, our analysis of safety data found no correlation between prescribing OxyContin at intervals shorter than q12h and the occurrence of adverse events.

3. Dear Healthcare Professional Letter and/or FDA Warnings

You request that we require Purdue to inform all prescribers of controlled substances about the potential risks of prescribing OxyContin at dosing intervals shorter than q12h by issuing a Dear Healthcare Professional letter (Petition at 11). You request that in addition to or as an alternative to action by Purdue, we should disseminate the warnings through a Safety Alert, Public Health Advisory, Talk Paper, or Urgent Notice (Petition at 11).

We disagree that we should require Purdue to issue a Dear Healthcare Professional letter or that we should issue our own warnings regarding this issue. For the reasons discussed in this response, you have failed to provide adequate data to support your request for additional warnings to be disseminated to prescribers and the public, and our analysis of safety data found no correlation between prescribing OxyContin at intervals shorter than q12h and the occurrence of adverse events events.

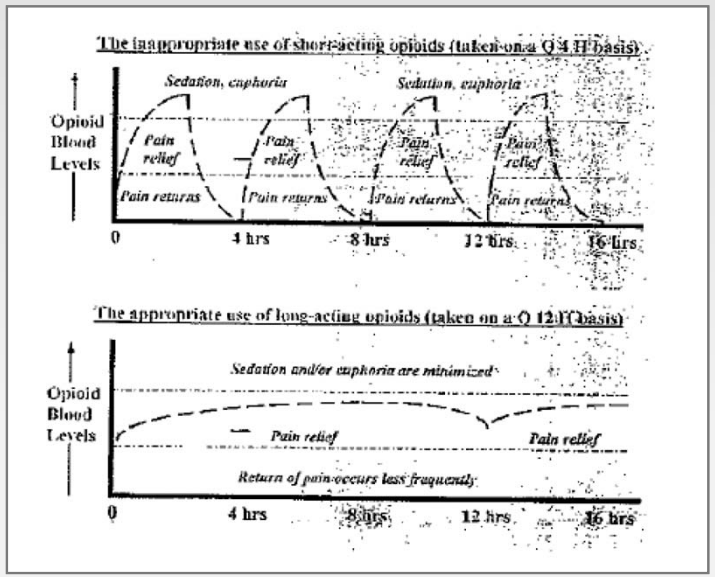
[18] As you acknowledge in the Petition and as stated previously, the 160-mg strength is no longer marketed.

16

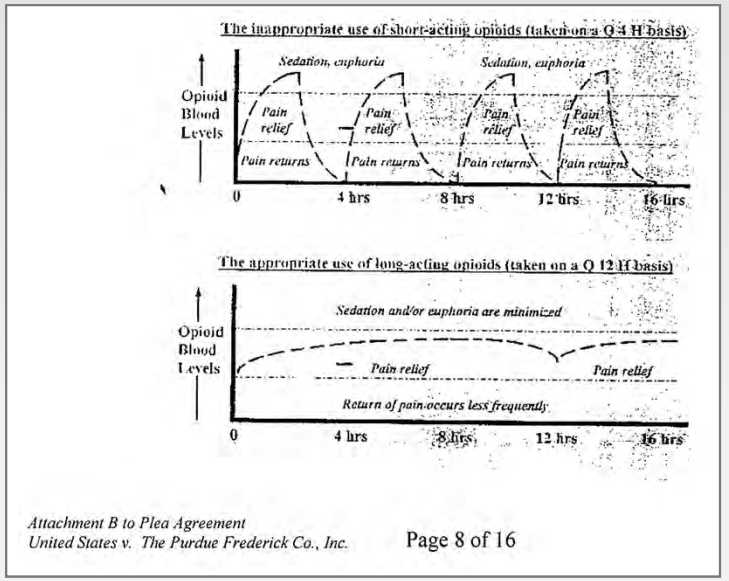
FDA Docket No. FDA-2004-P-0294, at p. 16, *available at available at* https://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf; *see also id.* at p.18

1998 Dosing Misrepresentations Are 23 Years' Old and Released

- NY AG's only example of Purdue overstating the dosing period is a graph from a 1998 training manual
- Purdue publicly admitted those graphs were deceptive when it pled guilty in 2007
- No evidence of post-2007 repetition



NY AG FAC, p. 85



Agreed Statement of Facts ¶¶25, 26, *United States v. Purdue Frederick Co.*, No. 1:07-cr-29 (JPJ) (W.D. Va. May 10, 2007)

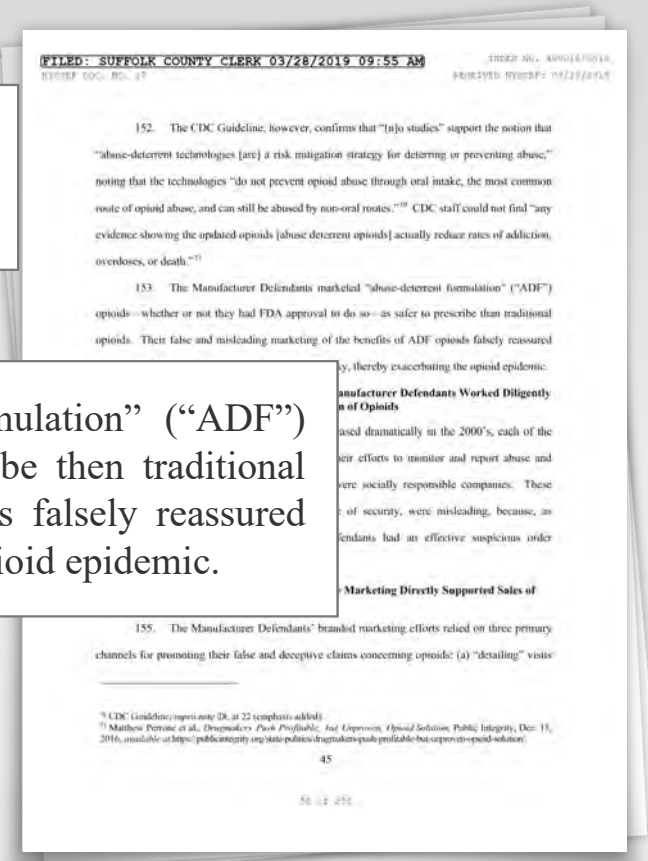
Alleged Misrepresentation No. 9:
OxyContin's 2010 Reformulation Successfully Deters Abuse

9. Misrepresentation #9: Newly-Developed but More Expensive Formulations of Opioids Successfully Deter Abuse

NY AG FAC p. 44

153. The Manufacturer Defendants marketed "abuse-deterrent formulation" ("ADF") opioids—whether or not they had FDA approval to do so—as safer to prescribe then traditional opioids. Their false and misleading marketing of the benefits of ADF opioids falsely reassured prescribers that prescribing such opioids was not risky, thereby exacerbating the opioid epidemic.

NY AG FAC ¶153


FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM

152. The CDC Guideline, however, confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[70] CDC staff could not find "any evidence showing the updated opioids [abuse deterrent opioids] actually reduce rates of addiction, overdoses, or death."[71]

153. The Manufacturer Defendants marketed "abuse-deterrent formulation" ("ADF") opioids—whether or not they had FDA approval to do so—as safer to prescribe than traditional opioids. Their false and misleading marketing of the benefits of ADF opioids falsely reassured

anufacturer Defendants Worked Diligently
n of Opioids

Marketing Directly Supported Sales of

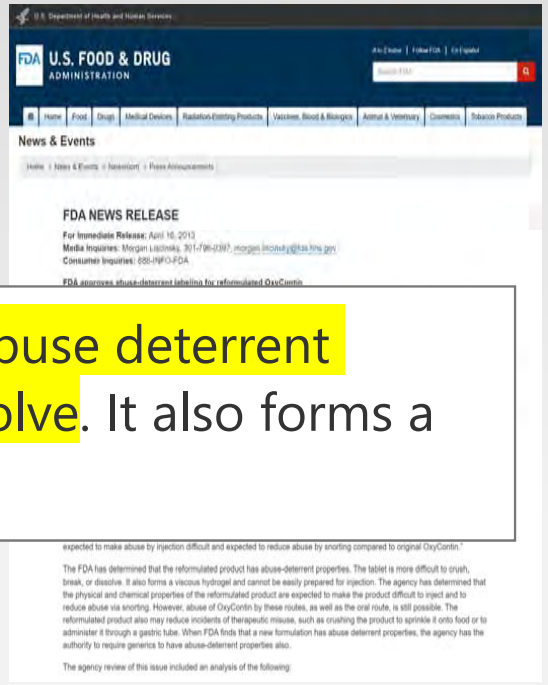
155. The Manufacturer Defendants' branded marketing efforts relied on three primary channels for promoting their false and deceptive claims concerning opioids: (a) "detailing" visits

45

Alleged Misrepresentation No. 9:
OxyContin's 2010 Reformulation Successfully Deters Abuse

1. **The only alleged misrepresentation is the abuse-deterrent language on the FDA-approved label**

2. **FDA determined reformulated OxyContin has abuse deterrent properties**


U.S. FOOD & DRUG ADMINISTRATION

News & Events

FDA NEWS RELEASE

For Immediate Release: April 16, 2013

Media Inquiries: Morgan Liscinsky, 301-796-0397, morgan.liscinsky@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA approves abuse-deterrent labeling for reformulated OxyContin

expected to make abuse by injection difficult and expected to reduce abuse by snorting compared to original OxyContin."

The FDA has determined that the reformulated product has abuse-deterrent properties. The tablet is more difficult to crush, break, or dissolve. It also forms a viscous hydrogel and cannot be easily prepared for injection. The agency has determined that the physical and chemical properties of the reformulated product are expected to make the product difficult to inject and to reduce abuse via snorting. However, abuse of OxyContin by these routes, as well as the oral route, is still possible. The reformulated product also may reduce incidents of therapeutic misuse, such as crushing the product to sprinkle it onto food or to administer it through a gastric tube. When FDA finds that a new formulation has abuse deterrent properties, the agency has the authority to require generics to have abuse-deterrent properties also.

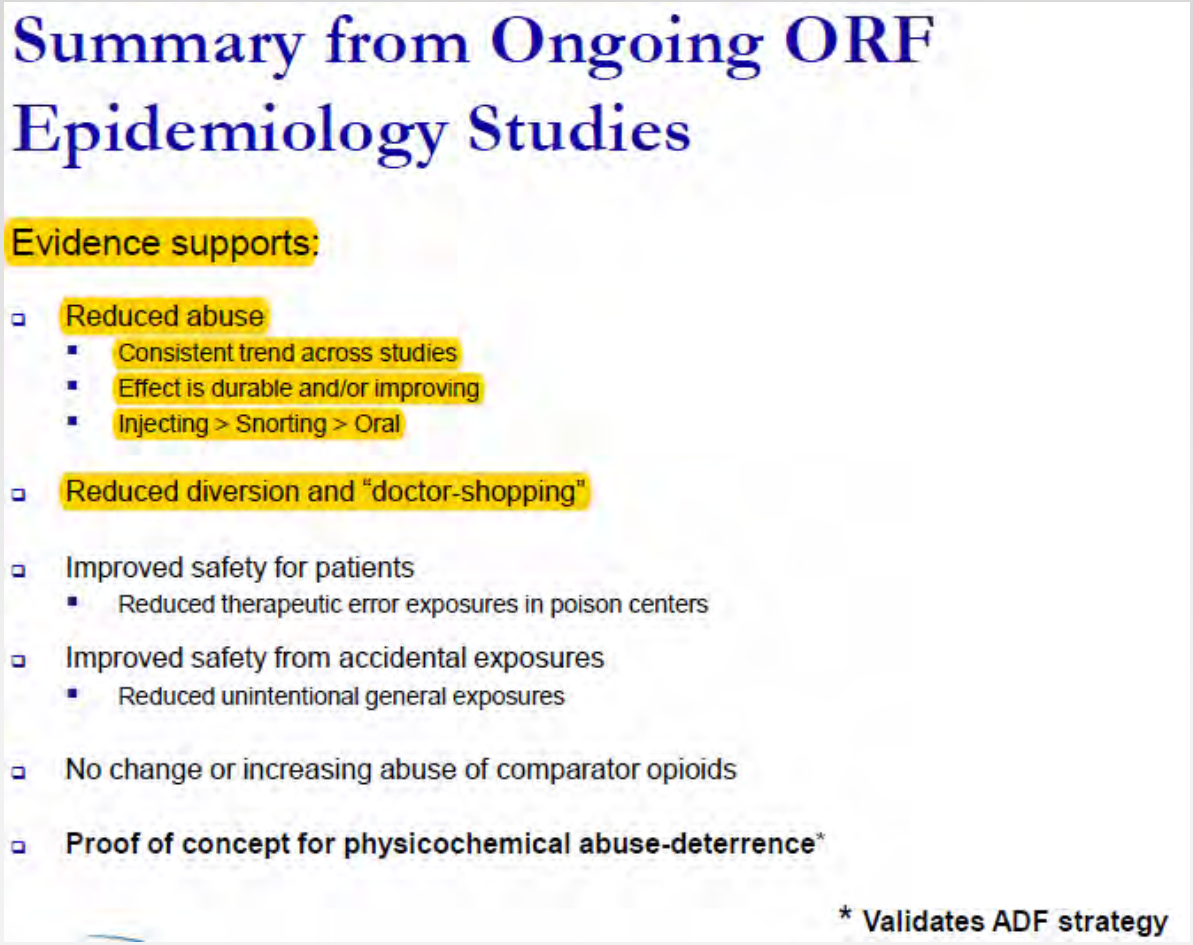
The agency review of this issue included an analysis of the following:

> The FDA has determined that the reformulated product has abuse deterrent properties. The tablet is more difficult to crush, break, or dissolve. It also forms a viscous hydrogel and cannot be easily prepared for injection. The agency has determined that the physical and chemical properties of the reformulated product are expected to make the product difficult to inject and to reduce abuse via snorting. However, abuse of OxyContin by these routes, as well as the oral route, is still possible. The reformulated product also may reduce incidents of therapeutic misuse, such as crushing the product to sprinkle it onto food or to administer it through a gastric tube. When FDA finds that a new formulation has abuse deterrent properties, the agency has the authority to require generics to have abuse-deterrent properties also.

April 16, 2013 FDA Press Release

https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm

Evidence Establishes That Abuse-Deterrent OxyContin Succeeded in Reducing Abuse



Summary from Ongoing ORF Epidemiology Studies

Evidence supports:

- Reduced abuse
  - Consistent trend across studies
  - Effect is durable and/or improving
  - Injecting > Snorting > Oral
- Reduced diversion and "doctor-shopping"
- Improved safety for patients
  - Reduced therapeutic error exposures in poison centers
- Improved safety from accidental exposures
  - Reduced unintentional general exposures
- No change or increasing abuse of comparator opioids
- **Proof of concept for physicochemical abuse-deterrence***

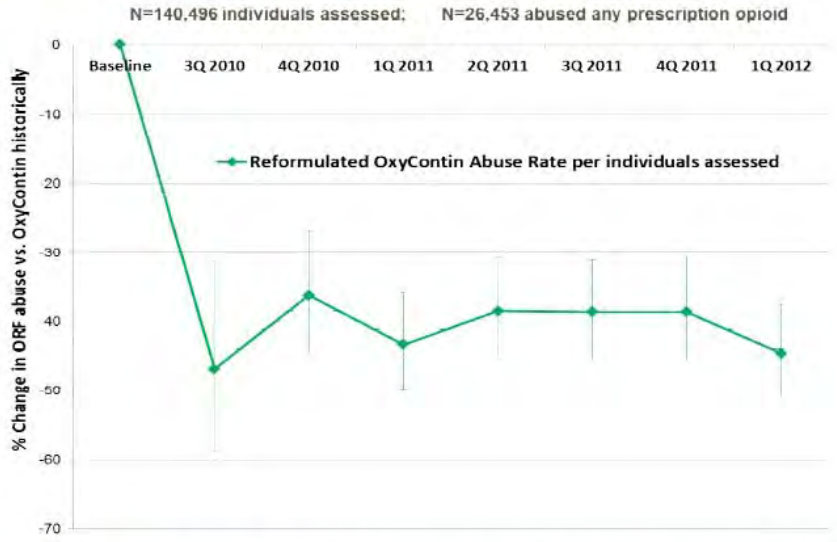
*** Validates ADF strategy**

PPLP004409195 (Nov. 3, 2012 Purdue Presentation to Beneficiaries)

Evidence Establishes That Abuse-Deterrent OxyContin Succeeded in Reducing Abuse

Abuse by Individuals Assessed for Substance Abuse Treatment

% Reduction from Baseline in NAVIPPRO® System
(Baseline is 14 months prior to ORF introduction)



95% confidence intervals shown; Baseline is average rate per individuals assessed over 14 months.

PURDUE

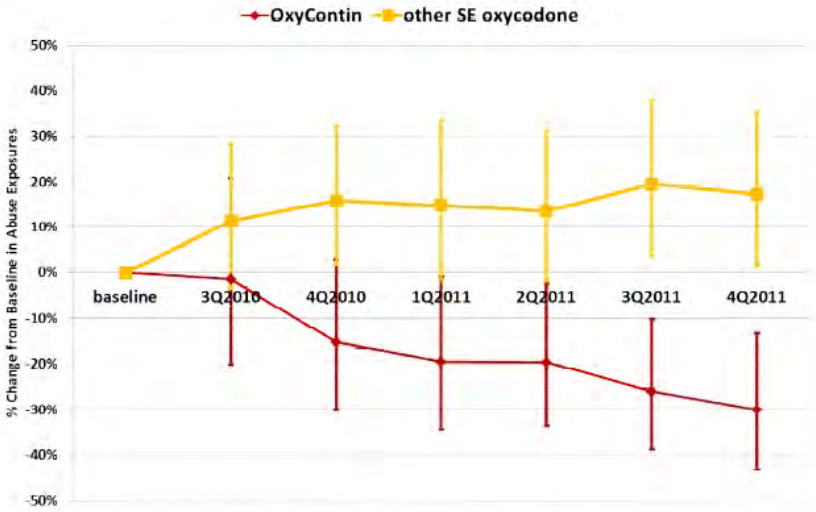
Confidential

PPLPC044000041897, -961 (Mar. 21, 2013 Presentation to Board)

Evidence Establishes That Abuse-Deterrent OxyContin Succeeded in Reducing Abuse

Poison Center Data from National Poison Data System

% Reduction from Baseline in Number of Intentional Abuse Exposures
(Baseline is 12 months prior to ORF introduction)



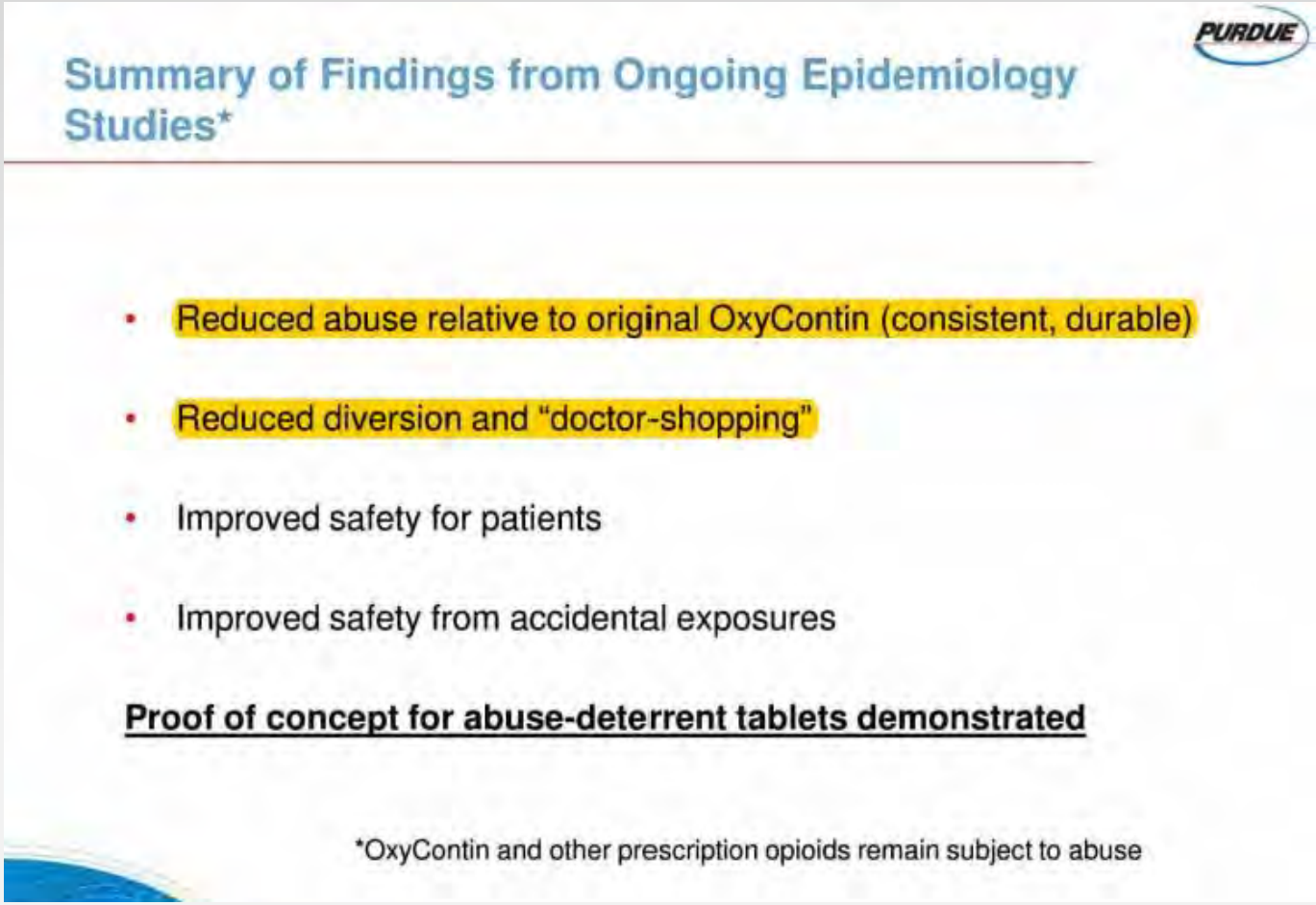
Source: National Poison Data System. Note: Baseline is average of 4 quarters from 3Q2009 to 2Q2010. 95% CI shown

PURDUE

Confidential

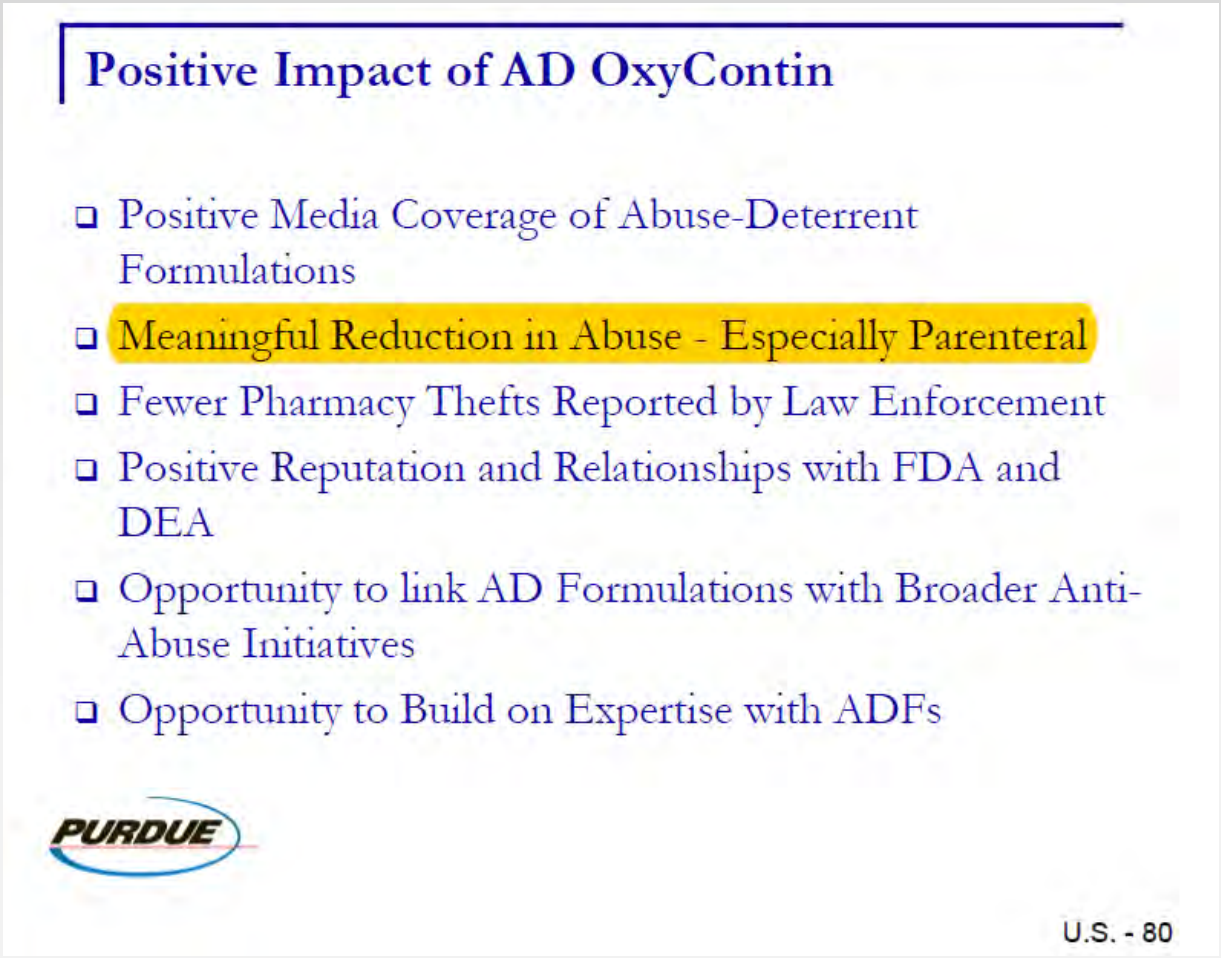
PPLPC044000041897, -962 (Mar. 21, 2013 Presentation to Board)

Evidence Establishes That Abuse-Deterrent OxyContin Succeeded in Reducing Abuse



PPLPC044000041968
(Mar. 21, 2013
Presentation to Board)

Evidence Establishes That Abuse-Deterrent OxyContin Succeeded in Reducing Abuse



PPLP004409860 (July 25, 2013 Presentation to Board)

FDA Still Encourages Development of Abuse-Deterrent Opioids

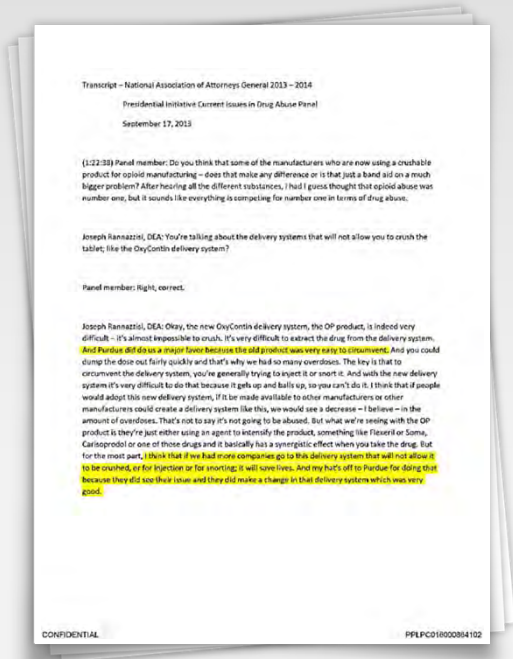
The FDA is encouraging the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse.

https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics

DEA Praised Abuse-Deterrent OxyContin, Encouraged Emulation

Quote from Jose Rannazzisi, former head of the DEA's Office of Diversion Control, at the National Association of Attorneys General in 2013:

Joseph Rannazzisi, DEA: Okay, the new OxyContin delivery system, the OP product, is indeed very difficult - it's almost impossible to crush. It's very difficult to extract the drug from the delivery system. And Purdue did do us a major favor because the old product was very easy to circumvent. And you could dump the dose out fairly quickly and that's why we had so many overdoses. The key is that to circumvent the delivery system, you're generally trying to inject it or snort it. And with the new delivery system it's very difficult to do that because it gels up and balls up, so you can't do it. I think that if people would adopt this new delivery system, if it be made available to other manufacturers or other manufacturers could create a delivery system like this, we would see a decrease - I believe - in the amount of overdoses. That's not to say it's not going to be abused. But what we're seeing with the OP product is they're just either using an agent to intensify the product, something like Flexeril or Soma, Carisoprodol or one of those drugs and it basically has a synergistic effect when you take the drug. But for the most part, I think that if we had more companies go to this delivery system that will not allow it to be crushed, or for injection or for snorting; it will save lives. And my hat's off to Purdue for doing that because they did see their issue and they did make a change in that delivery system which was very good.


Transcript – National Association of Attorneys General 2013 – 2014

Presidential Initiative Current Issues in Drug Abuse Panel

September 17, 2013

(1:22:33) Panel member: Do you think that some of the manufacturers who are now using a crushable product for opioid manufacturing – does that make any difference or is that just a band aid on a much bigger problem? After hearing all the different substances, I had I guess thought that opioid abuse was number one, but it sounds like everything is competing for number one in terms of drug abuse.

Joseph Rannazzisi, DEA: You're talking about the delivery systems that will not allow you to crush the tablet; like the OxyContin delivery system?

Panel member: Right, correct.

Joseph Rannazzisi, DEA: Okay, the new OxyContin delivery system, the OP product, is indeed very difficult – it's almost impossible to crush. It's very difficult to extract the drug from the delivery system. And Purdue did do us a major favor because the old product was very easy to circumvent. And you could dump the dose out fairly quickly and that's why we had so many overdoses. The key is that to circumvent the delivery system, you're generally trying to inject it or snort it. And with the new delivery system it's very difficult to do that because it gels up and balls up, so you can't do it. I think that if people would adopt this new delivery system, if it be made available to other manufacturers or other manufacturers could create a delivery system like this, we would see a decrease – I believe – in the amount of overdoses. That's not to say it's not going to be abused. But what we're seeing with the OP product is they're just either using an agent to intensify the product, something like Flexeril or Soma, Carisoprodol or one of those drugs and it basically has a synergistic effect when you take the drug. But for the most part, I think that if we had more companies go to this delivery system that will not allow it to be crushed, or for injection or for snorting; it will save lives. And my hat's off to Purdue for doing that because they did see their issue and they did make a change in that delivery system which was very good.

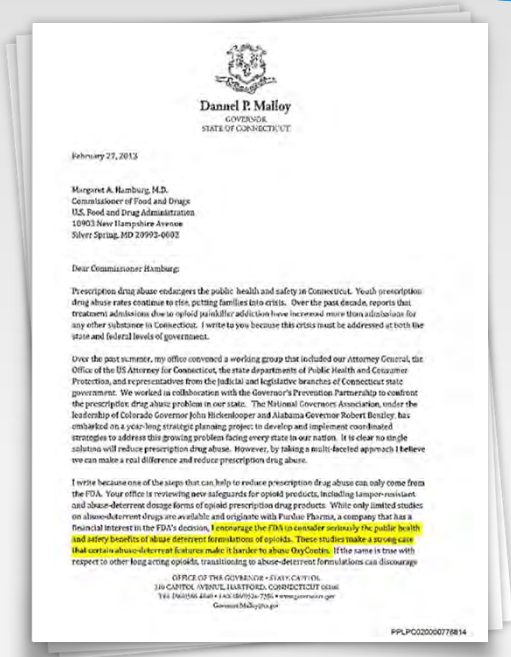
CONFIDENTIAL PPLPC018000884102

9/17/13 J. Rannazzisi, DEA (Presidential Initiative Current Issues In Drug Abuse Panel) (PPLPC018000884102)

Connecticut Governor Praised Abuse-Deterrent OxyContin, Encouraged Emulation

Dannel P. Malloy
GOVERNOR
STATE OF CONNECTICUT

I write because one of the steps that can help to reduce prescription drug abuse can only come from the FDA. Your office is reviewing new safeguards for opioid products, including tamper-resistant and abuse-deterrent dosage forms of opioid prescription drug products. While only limited studies on abuse-deterrent drugs are available and originate with Purdue Pharma, a company that has a financial interest in the FDA's decision, I encourage the FDA to consider seriously the public health and safety benefits of abuse deterrent formulations of opioids. These studies make a strong case that certain abuse-deterrent features make it harder to abuse OxyContin. If the same is true with respect to other long acting opioids, transitioning to abuse-deterrent formulations can discourage the abuse of extended release opioid prescription drugs while still making opioid drugs available to the patients who need them.


Dannel P. Malloy
GOVERNOR
STATE OF CONNECTICUT

February 27, 2013

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

Prescription drug abuse endangers the public health and safety in Connecticut. Youth prescription drug abuse rates continue to rise, putting families into crisis. Over the past decade, reports that treatment admissions due to opioid painkiller addiction have increased more than admissions for any other substance in Connecticut. I write to you because this crisis must be addressed at both the state and federal levels of government.

Over the past summer, my office convened a working group that included our Attorney General, the Office of the US Attorney for Connecticut, the state departments of Public Health and Consumer Protection, and representatives from the judicial and legislative branches of Connecticut state government. We worked in collaboration with the Governor's Prevention Partnership to confront the prescription drug abuse problem in our state. The National Governors Association, under the leadership of Colorado Governor John Hickenlooper and Alabama Governor Robert Bentley, has embarked on a year-long strategic planning project to develop and implement coordinated strategies to address this growing problem facing every state in our nation. It is clear no single solution will reduce prescription drug abuse. However, by taking a multi-faceted approach I believe we can make a real difference and reduce prescription drug abuse.

I write because one of the steps that can help to reduce prescription drug abuse can only come from the FDA. Your office is reviewing new safeguards for opioid products, including tamper-resistant and abuse-deterrent dosage forms of opioid prescription drug products. While only limited studies on abuse-deterrent drugs are available and originate with Purdue Pharma, a company that has a financial interest in the FDA's decision, I encourage the FDA to consider seriously the public health and safety benefits of abuse deterrent formulations of opioids. These studies make a strong case that certain abuse-deterrent features make it harder to abuse OxyContin. If the same is true with respect to other long acting opioids, transitioning to abuse-deterrent formulations can discourage

OFFICE OF THE GOVERNOR • STATE CAPITOL

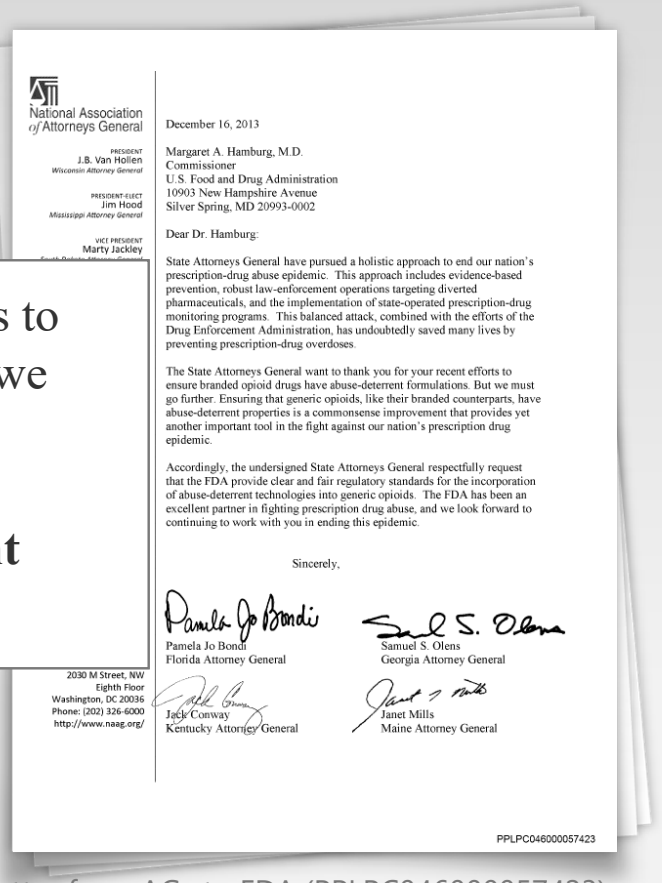
PPLPC020000776814

2/27/13 Letter from D. Malloy (PPLPC020000776814)

42 State AGs Encouraged Abuse-Deterrent Formulations

National Association of Attorneys General

The State Attorneys General want to thank you for your recent efforts to ensure branded opioid drugs have abuse-deterrent formulations. But we must go further. **Ensuring generic opioids, like their branded counterparts, have abuse-deterrent properties is a commonsense improvement that provides yet another important tool in the fight against our nation's prescription drug epidemic**.



National Association of Attorneys General

PRESIDENT
J.B. Van Hollen
Wisconsin Attorney General

PRESIDENT-ELECT
Jim Hood
Mississippi Attorney General

VICE PRESIDENT
Marty Jackley

2030 M Street, NW
Eighth Floor
Washington, DC 20036
Phone: (202) 326-6000
http://www.naag.org/

December 16, 2013

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

State Attorneys General have pursued a holistic approach to end our nation's prescription-drug abuse epidemic. This approach includes evidence-based prevention, robust law-enforcement operations targeting diverted pharmaceuticals, and the implementation of state-operated prescription-drug monitoring programs. This balanced attack, combined with the efforts of the Drug Enforcement Administration, has undoubtedly saved many lives by preventing prescription-drug overdoses.

The State Attorneys General want to thank you for your recent efforts to ensure branded opioid drugs have abuse-deterrent formulations. But we must go further. Ensuring that generic opioids, like their branded counterparts, have abuse-deterrent properties is a commonsense improvement that provides yet another important tool in the fight against our nation's prescription drug epidemic.

Accordingly, the undersigned State Attorneys General respectfully request that the FDA provide clear and fair regulatory standards for the incorporation of abuse-deterrent technologies into generic opioids. The FDA has been an excellent partner in fighting prescription drug abuse, and we look forward to continuing to work with you in ending this epidemic.

Sincerely,

Pamela Jo Bondi
Florida Attorney General

Samuel S. Olens
Georgia Attorney General

Jack Conway
Kentucky Attorney General

Janet Mills
Maine Attorney General

PPLPC046000057423

12/16/13 Letter from AGs to FDA (PPLPC046000057423)

42 State AGs Encouraged Abuse-Deterrent Formulations

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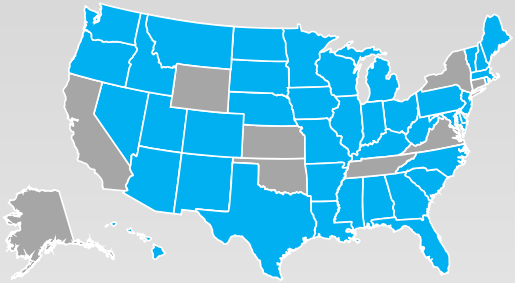

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Samuel S. Olens
Georgia Attorney General

Jack Conway
Kentucky Attorney General

Janet Mills
Maine Attorney General

Chris Koster
Missouri Attorney General

Luther Strange
Alabama Attorney General

Tom Horne
Arizona Attorney General

Dustin McDaniel
Arkansas Attorney General

John Suthers
Colorado Attorney General

Joseph R. "Beau" Biden III
Delaware Attorney General

Lenny Rapadas
Guam Attorney General

David Louie
Hawaii Attorney General

Lawrence Wasden
Idaho Attorney General

Lisa Madigan
Illinois Attorney General

Greg Zoeller
Indiana Attorney General

Tom Miller
Iowa Attorney General

James "Buddy" Caldwell
Louisiana Attorney General

Douglas F. Gansler
Maryland Attorney General

Martha Coakley
Massachusetts Attorney General

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Michigan Attorney General

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New Mexico Attorney General

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North Carolina Attorney General

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Vermont Attorney General

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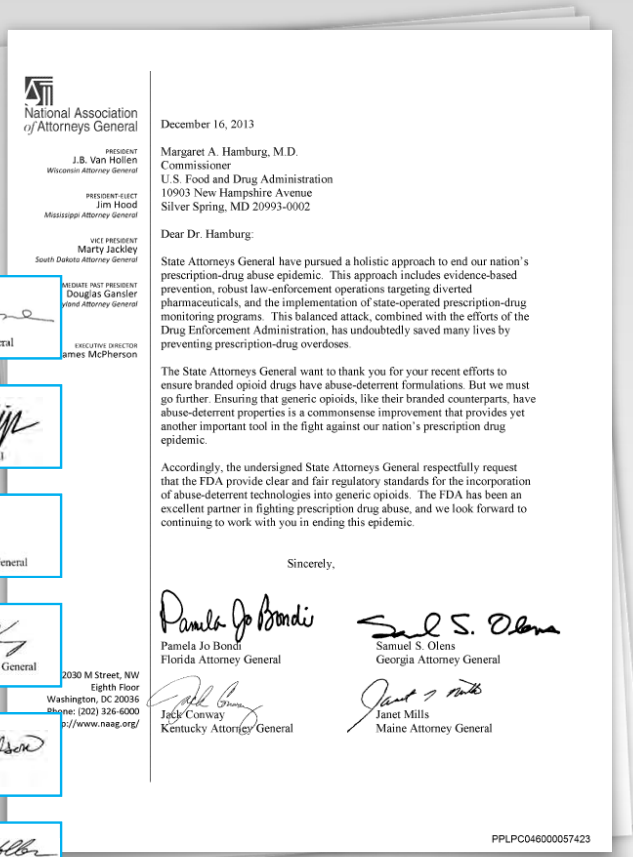
Washington Attorney General

Patrick Morrisey
West Virginia Attorney General

J.B. Van Hollen
Wisconsin Attorney General



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PPLPC046000057423

12/16/13 Letter from AGs to FDA (PPLPC046000057423)

FDA-Approved Label for Abuse-Deterrent OxyContin Discloses Continuing Risk of Addiction And Abuse

WARNING: ABUSE POTENTIAL, LIFE-THREATENING

RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

See full prescribing information for complete boxed warning.

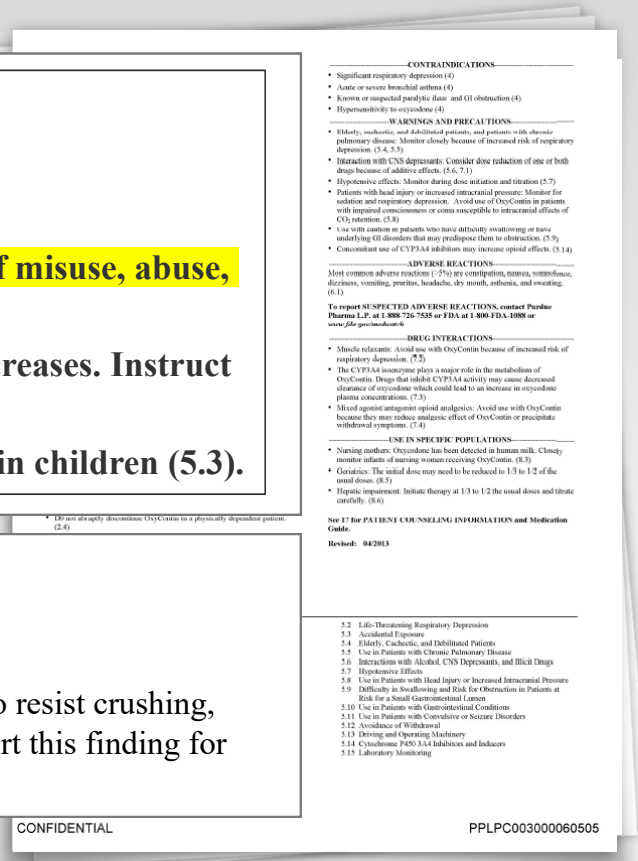
- **OxyContin contains oxycodone, a Schedule II controlled substance. Monitor for signs of misuse, abuse, and addiction during OxyContin therapy (5.1, 9).**
- **Fatal respiratory depression may occur, with highest risk at initiation and with dose increases. Instruct patients on proper administration of OxyContin tablets to reduce the risk (5.2).**
- **Accidental ingestion of OxyContin can result in fatal overdose of oxycodone, especially in children (5.3).**

Abuse Deterrence Studies

* * *

In Vitro Testing

Results support that, relative to original OxyContin, there is an increase in the ability of OxyContin to resist crushing, breaking, and dissolution using a variety of tools and solvents. The results of these studies also support this finding for OxyContin relative to an immediate-release oxycodone.


CONTRAINDICATIONS

WARNINGS AND PRECAUTIONS

ADVERSE REACTIONS

DRUG INTERACTIONS

USE IN SPECIFIC POPULATIONS

CONFIDENTIAL PPLPC003000060505

Apr. 2013 OxyContin Label, pp. 1, 18-19, (PPLPC003000060503)

FDA-Approved Label for Abuse-Deterrent OxyContin Discloses Continuing Risk of Addiction And Abuse

5.1 Abuse Potential

OxyContin contains oxycodone, an opioid agonist and a Schedule II controlled substance. Oxycodone can be abused in a manner similar to other opioid agonists legal or illicit. Opioid agonists are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing OxyContin in situations where there is concern about increased risks of misuse, abuse, or diversion. Concerns about abuse, addiction, and diversion should not, however, prevent the proper management of pain.

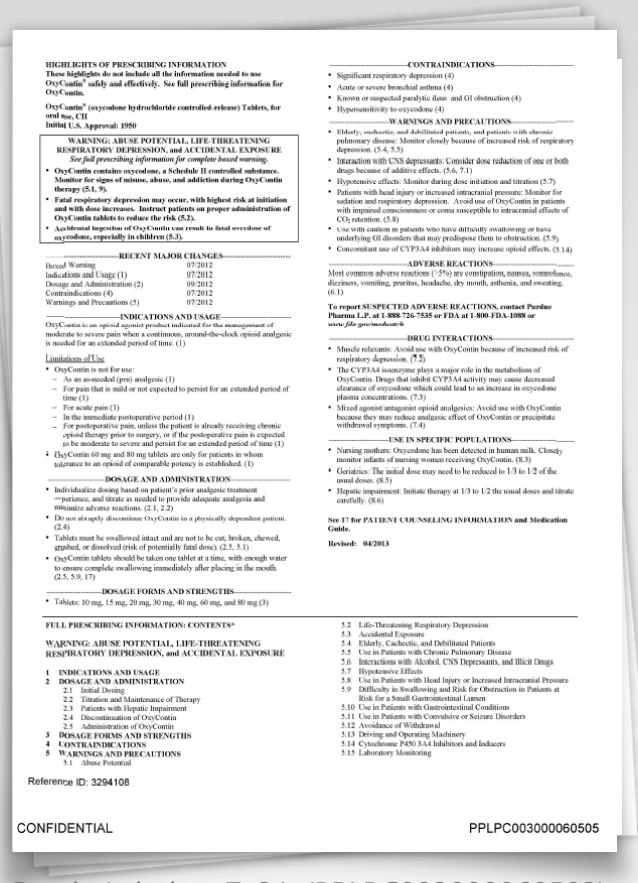
* * *

Misuse or abuse of OxyContin by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the opioid and pose a significant risk that could result in overdose and death [see Drug Abuse and Dependence (9) and Overdosage (10)].

Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product.

Summary

The in vitro data demonstrate that OXYCONTIN has physicochemical properties expected to make abuse via injection difficult. The data from the clinical study, along with support from the in vitro data, also indicate that **OXYCONTIN has physicochemical properties that are expected to reduce abuse via the intranasal route. However, abuse of OXYCONTIN by these routes, as well as by the oral route, is still possible.**



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OxyContin® safely and effectively. See full prescribing information for OxyContin.

OxyContin® (oxycodone hydrochloride controlled-release) Tablets, for oral use, CII

Initial U.S. Approval: 1950

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

See full prescribing information for complete boxed warning.

- **OxyContin contains oxycodone, a Schedule II controlled substance. Monitor for signs of misuse, abuse, and addiction during OxyContin therapy (5.1, 9).**
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RECENT MAJOR CHANGES

Boxed Warning	07/2012
Indications and Usage (1)	07/2012
Dosage and Administration (2)	09/2012
Contraindications (4)	07/2012
Warnings and Precautions (5)	07/2012

INDICATIONS AND USAGE

OxyContin is an opioid agonist product indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)

Limitations of Use

- OxyContin is not for use:
  - As an as-needed (prn) analgesic (1)
  - For pain that is mild or not expected to persist for an extended period of time (1)
  - For acute pain (1)
  - In the immediate postoperative period (1)
  - For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (1)
- OxyContin 60 mg and 80 mg tablets are only for patients in whom tolerance to an opioid of comparable potency is established. (1)

DOSAGE AND ADMINISTRATION

- Individualize dosing based on patient's prior analgesic treatment experience, and titrate as needed to provide adequate analgesia and minimize adverse reactions. (2.1, 2.2)
- Do not abruptly discontinue OxyContin in a physically dependent patient. (2.4)
- Tablets must be swallowed intact and are not to be cut, broken, chewed, crushed, or dissolved (risk of potentially fatal dose). (2.5, 5.1)
- OxyContin tablets should be taken one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth. (2.5, 5.9, 17)

DOSAGE FORMS AND STRENGTHS

- Tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg (3)

CONTRAINDICATIONS

- Significant respiratory depression (4)
- Acute or severe bronchial asthma (4)
- Known or suspected paralytic ileus and GI obstruction (4)
- Hypersensitivity to oxycodone (4)

WARNINGS AND PRECAUTIONS

- Elderly, cachectic, and debilitated patients, and patients with chronic pulmonary disease: Monitor closely because of increased risk of respiratory depression. (5.4, 5.5)
- Interaction with CNS depressants: Consider dose reduction of one or both drugs because of additive effects. (5.6, 7.1)
- Hypotensive effects: Monitor during dose initiation and titration (5.7)
- Patients with head injury or increased intracranial pressure: Monitor for sedation and respiratory depression. Avoid use of OxyContin in patients with impaired consciousness or coma susceptible to intracranial effects of CO_2 retention. (5.8)
- Use with caution in patients who have difficulty swallowing or have underlying GI disorders that may predispose them to obstruction. (5.9)
- Concomitant use of CYP3A4 inhibitors may increase opioid effects. (5.14)

ADVERSE REACTIONS

Most common adverse reactions (>5%) are constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, asthenia, and sweating. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

DRUG INTERACTIONS

- Muscle relaxants: Avoid use with OxyContin because of increased risk of respiratory depression. (7.2)
- The CYP3A4 isoenzyme plays a major role in the metabolism of OxyContin. Drugs that inhibit CYP3A4 activity may cause decreased clearance of oxycodone which could lead to an increase in oxycodone plasma concentrations. (7.3)
- Mixed agonist/antagonist opioid analgesics: Avoid use with OxyContin because they may reduce analgesic effect of OxyContin or precipitate withdrawal symptoms. (7.4)

USE IN SPECIFIC POPULATIONS

- Nursing mothers: Oxycodone has been detected in human milk. Closely monitor infants of nursing women receiving OxyContin. (8.3)
- Geriatrics: The initial dose may need to be reduced to 1/3 to 1/2 of the usual doses. (8.5)
- Hepatic impairment: Initiate therapy at 1/3 to 1/2 the usual doses and titrate carefully. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 04/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Initial Dosing
2.2 Titration and Maintenance of Therapy
2.3 Patients with Hepatic Impairment
2.4 Discontinuation of OxyContin
2.5 Administration of OxyContin
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Abuse Potential
5.2 Life-Threatening Respiratory Depression
5.3 Accidental Exposure
5.4 Elderly, Cachectic, and Debilitated Patients
5.5 Use in Patients with Chronic Pulmonary Disease
5.6 Interactions with Alcohol, CNS Depressants, and Illicit Drugs
5.7 Hypotensive Effects
5.8 Use in Patients with Head Injury or Increased Intracranial Pressure
5.9 Difficulty in Swallowing and Risk for Obstruction in Patients at Risk for a Small Gastrointestinal Lumen
5.10 Use in Patients with Gastrointestinal Conditions
5.11 Use in Patients with Convulsive or Seizure Disorders
5.12 Avoidance of Withdrawal
5.13 Driving and Operating Machinery
5.14 Cytochrome P450 3A4 Inhibitors and Inducers
5.15 Laboratory Monitoring

Reference ID: 3294108

CONFIDENTIAL PPLPC003000060505

Apr. 2013 OxyContin Label, p. 7, 21, (PPLPC003000060503)

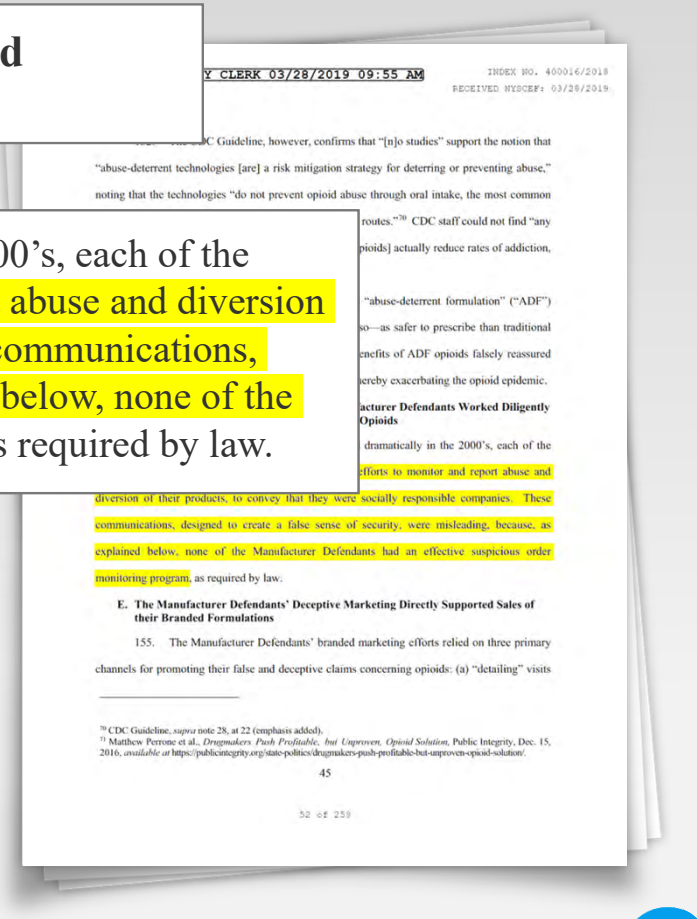
Alleged Misrepresentation No. 10: The Manufacturer Defendants Worked Diligently to Detect And Prevent Diversion of Opioids

10. Misrepresentation #10: The Manufacturer Defendants Worked Diligently to Detect and Prevent Diversion of Opioids

NY AG FAC p. 45

154. After the diversion of opioids increased dramatically in the 2000's, each of the Manufacturer Defendants extensively advertised their efforts to monitor and report abuse and diversion of their products, to convey that they were socially responsible companies. These communications, designed to create a false sense of security, were misleading because, as explained below, none of the Manufacturer Defendants had an effective suspicious order monitoring program, as required by law.

NY AG FAC ¶154



1. **Irrelevant: No marketing based on anti-diversion initiatives**
2. **Purdue spent hundreds of millions of dollars on anti-diversion initiatives**
   https://www.purduepharma.com/addressing-the-crisis/select-initiatives/

Purdue Spent Hundreds of Millions of Dollars on Anti-Diversion Initiatives

Previously available at https://www.purdueopioidinfo.com/app/uploads/2019/05/purdue-80-actions-taken-timeline-10.pdf

PURDUE

Timeline of Select Initiatives

2001

Purdue developed the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system to detect and study abuse, misuse, and diversion on a nationwide basis. Purdue transferred ownership of RADARS in 2006 to not-for-profit Denver Health and Hospital Authority's Rocky Mountain Poison and Drug Center. Purdue transferred the system to an independent third party which allowed pharmaceutical companies and government agencies to more readily access valuable data on opioid abuse and diversion.

2002

Purdue voluntarily developed a risk management plan (RiskMAP) in coordination with the FDA to help detect and prevent opioid abuse and diversion.

Purdue provided more than $4 million to develop "Painfully Obvious," a prescription drug abuse awareness program for pre-teens, parents, and middle school teachers.

Purdue began a program to provide tamper-resistant prescription pads at no cost to healthcare professionals. These prescription pads were ordered by more than 16,000 DEA-registered healthcare professionals.

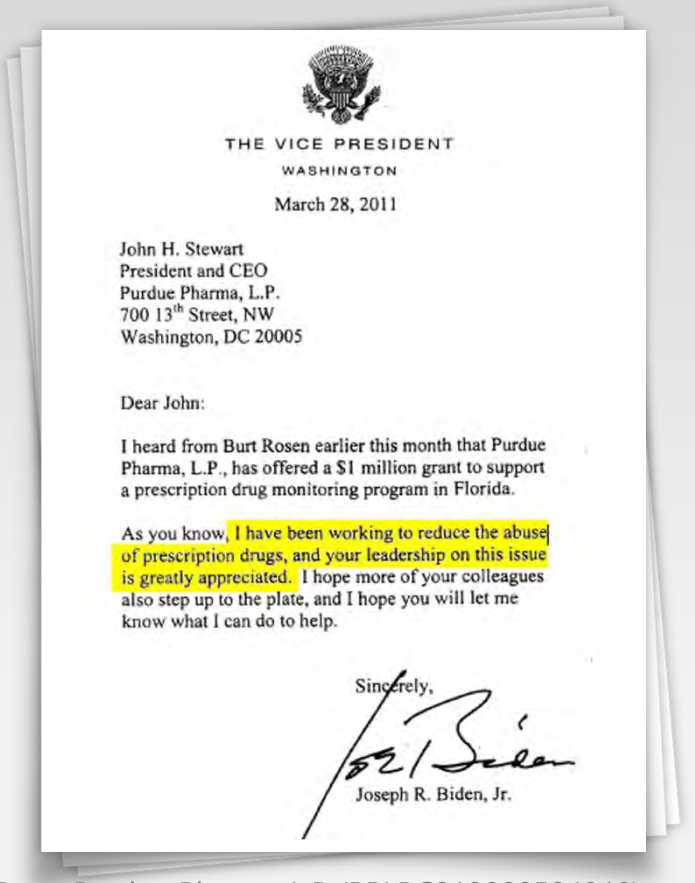
Purdue worked with The Governor's Prevention Partnership in

Vice President Biden Praised Purdue for Its Leadership on Anti-Abuse Efforts

THE VICE PRESIDENT
WASHINGTON
March 28, 2011

I heard from Burt Rosen earlier this month that Purdue Pharma, L.P., has offered a $1 million grant to support a prescription drug monitoring program in Florida.

As you know, I have been working to reduce the abuse of prescription drugs, and your leadership on this issue is greatly appreciated. I hope more of your colleagues also step up to the plate, and I hope you will let me know what I can do to help.



THE VICE PRESIDENT
WASHINGTON
March 28, 2011

John H. Stewart
President and CEO
Purdue Pharma, L.P.
700 13th Street, NW
Washington, DC 20005

Dear John:

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As you know, I have been working to reduce the abuse of prescription drugs, and your leadership on this issue is greatly appreciated. I hope more of your colleagues also step up to the plate, and I hope you will let me know what I can do to help.

Sincerely,

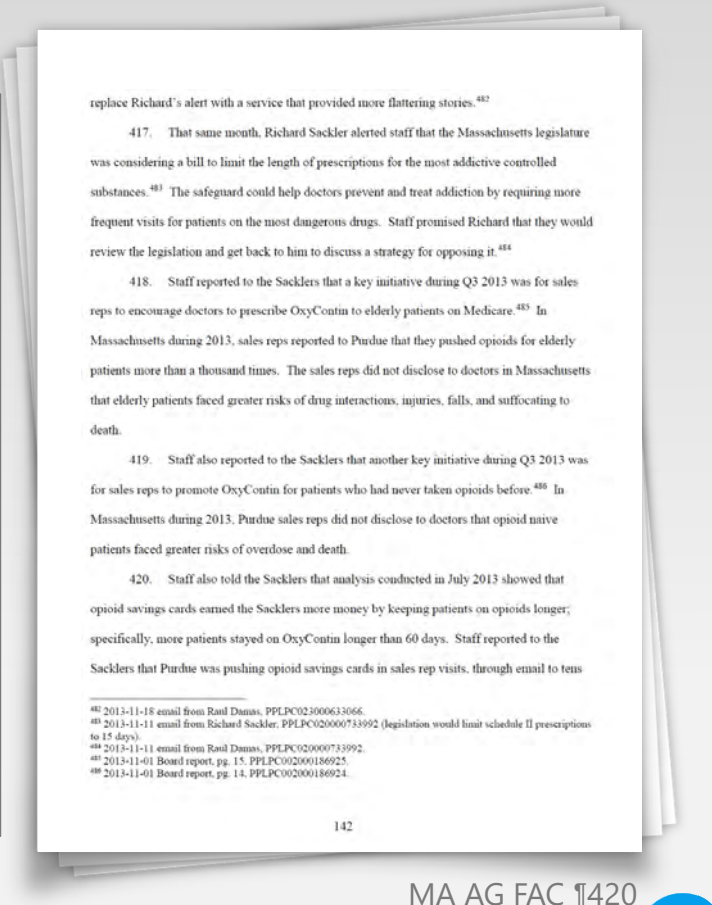
Joseph R. Biden, Jr.

3/28/11 Letter from Joe Biden, Vice President of the Untied States, to John H. Stewart, Pres., Purdue Pharma L.P. (PPLPC018000504018)

Allegation: Savings Cards Deceptively Kept Patients on Opioids Longer

Massachusetts AG Complaint ¶ 420:

420. Staff also told the Sacklers that analysis conducted in July 2013 showed that opioid savings cards earned the Sacklers more money by keeping patients on opioids longer; specifically, more patients stayed on OxyContin longer than 60 days. Staff reported to the Sacklers that Purdue was pushing opioid savings cards in sales rep visits, through email to tens of thousands of health care providers, and online. In Massachusetts during 2013, sales reps reported to Purdue that they promoted opioid savings cards to prescribers more than a thousand times. The sales reps did not tell doctors in Massachusetts that savings cards led patients to stay on opioids longer than 60 days, or that staying on opioids longer increased the risk of addiction and death.



replace Richard's alert with a service that provided more flattering stories.[482]

417. That same month, Richard Sackler alerted staff that the Massachusetts legislature was considering a bill to limit the length of prescriptions for the most addictive controlled substances.[483] The safeguard could help doctors prevent and treat addiction by requiring more frequent visits for patients on the most dangerous drugs. Staff promised Richard that they would review the legislation and get back to him to discuss a strategy for opposing it.[484]

418. Staff reported to the Sacklers that a key initiative during Q3 2013 was for sales reps to encourage doctors to prescribe OxyContin to elderly patients on Medicare.[485] In Massachusetts during 2013, sales reps reported to Purdue that they pushed opioids for elderly patients more than a thousand times. The sales reps did not disclose to doctors in Massachusetts that elderly patients faced greater risks of drug interactions, injuries, falls, and suffocating to death.

419. Staff also reported to the Sacklers that another key initiative during Q3 2013 was for sales reps to promote OxyContin for patients who had never taken opioids before.[486] In Massachusetts during 2013, Purdue sales reps did not disclose to doctors that opioid naive patients faced greater risks of overdose and death.

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[482] 2013-11-18 email from Raul Damas, PPLPC023000633066.
[483] 2013-11-11 email from Richard Sackler, PPLPC020000733992 (legislation would limit schedule II prescriptions to 15 days).
[484] 2013-11-11 email from Raul Damas, PPLPC020000733992.
[485] 2013-11-01 Board report, pg. 15, PPLPC002000186925.
[486] 2013-11-01 Board report, pg. 14, PPLPC002000186924.

142

MA AG FAC ¶420

Savings Cards Carried OxyContin's Black Box Warning

WARNING:
OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

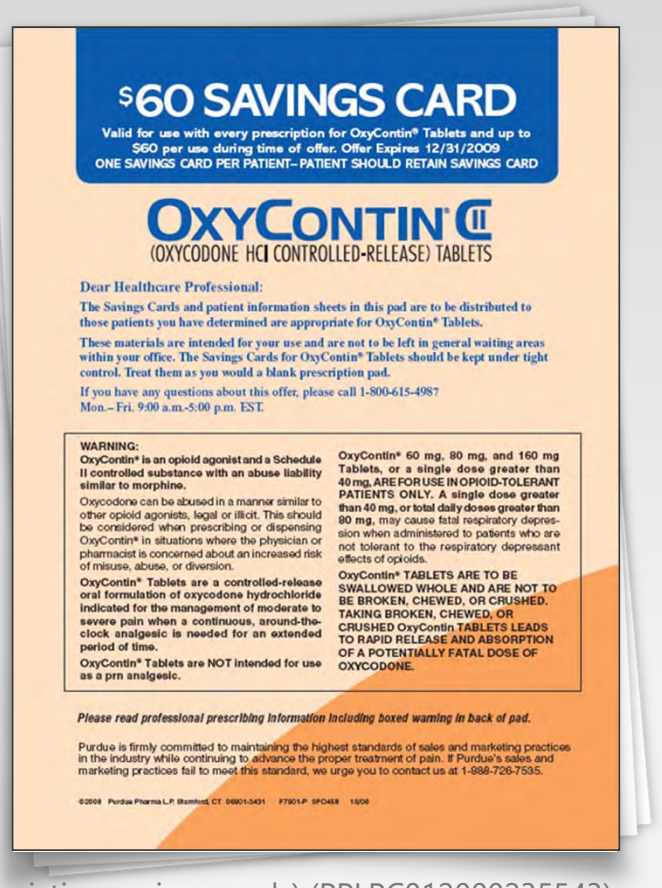
Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin® Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin® Tablets are NOT intended for use as a prn analgesic.

OxyContin® 60 mg, 80 mg, and 160 mg Tablets, or a single dose greater than 40 mg, ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. A single dose greater than 40 mg, or total daily doses greater than 80 mg, may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory depressant effects of opioids.

OxyContin® TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.



$60 SAVINGS CARD

Valid for use with every prescription for OxyContin® Tablets and up to $60 per use during time of offer. Offer Expires 12/31/2009
ONE SAVINGS CARD PER PATIENT–PATIENT SHOULD RETAIN SAVINGS CARD

OXYCONTIN® CII
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

Dear Healthcare Professional:

The Savings Cards and patient information sheets in this pad are to be distributed to those patients you have determined are appropriate for OxyContin® Tablets.

These materials are intended for your use and are not to be left in general waiting areas within your office. The Savings Cards for OxyContin® Tablets should be kept under tight control. Treat them as you would a blank prescription pad.

If you have any questions about this offer, please call 1-800-615-4987
Mon.–Fri. 9:00 a.m.-5:00 p.m. EST.

WARNING:
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Please read professional prescribing information including boxed warning in back of pad.

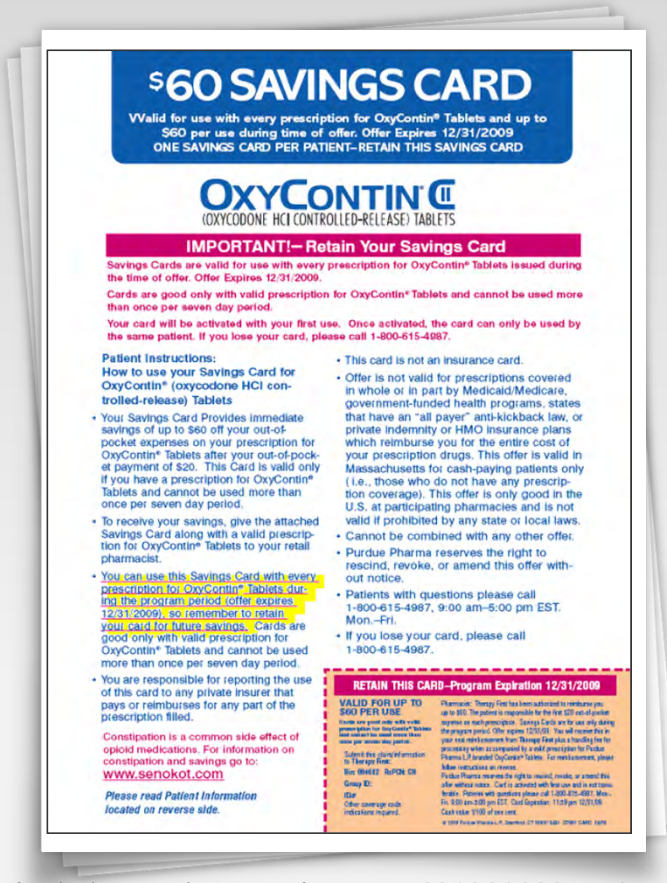
Purdue is firmly committed to maintaining the highest standards of sales and marketing practices in the industry while continuing to advance the proper treatment of pain. If Purdue's sales and marketing practices fail to meet this standard, we urge you to contact us at 1-888-726-7535.

©2008 Purdue Pharma L.P. Stamford, CT 06901-3431 F7901-P 6PO459 10/08

Board Presentation, p. 14 (depicting savings cards) (PPLPC012000235543)

Savings Cards Could Be Used Only With A Prescription

- To receive your savings, give the attached Savings Card along with a valid prescription for OxyContin® Tablets to your retail pharmacist.
- You can use this Savings Card with every prescription for OxyContin® Tablets during the program period (offer expires 12/31/2009), so remember to retain your card for future savings. Cards are good only with valid prescription for OxyContin® Tablets and cannot be used more than once per seven day period.



- **There is nothing deceptive about a savings card**

Board Presentation, p. 14 (depicting savings cards) (PPLPC012000235543)

Preemption

The Three Preemption Doctrines

State law is preempted if:

1. It is impossible to comply with both state and federal law ("Impossibility Preemption")

   Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1678–79 (2019)
   (state law failure to warn claims might be preempted if the FDA would have rejected the proposed warnings)

2. It conflicts with the federal regulatory scheme created by Congress ("Conflict Preemption")

   Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–51 (2001)
   (state law claims that defendant committed fraud on the FDA were preempted)

3. It "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," or otherwise conflicts with federal law ("Obstacle Preemption")

   Hines v. Davidowitz, 312 U.S. 52, 67 (1941)

Federal Law Requires Drug Promotion Be Consistent with the FDA-Approved Label

21 C.F.R. §201.100(d)(1)

Requires labeling to be "consistent with and not contrary to such approved and permitted labeling"

21 U.S.C. §321(m)

Defines "labeling" to include all "written, printed, or graphic matter" that accompanies the drug

21 C.F.R. §202.1(l)(2)

Defines "labeling" to mean all materials "for use by medical practitioners … containing drug information … disseminated by … [the] manufacturer"

Many Alleged Misrepresentations Are Consistent with the Label and Preempted — Impossibility Preemption

ALLEGATION	CORRESPONDING LABEL PROVISION
"No ceiling" NY AG FAC ¶¶321, 322	"Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone." October 2019 OxyContin Label, p. 35, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf
"Tapering . . . has never been recommended or recognized by any legitimate medical or addiction professionals" NY AG FAC ¶129	"When discontinuing OxyContin, gradually taper the dosage …." October 2019 OxyContin Label, p. 33, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf
"Signs of Addictive Behavior are Pseudoaddiction" NY AG FAC p. 34	"Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control." October 2019 OxyContin Label, p. 29, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf

The equivalent of the above appear in earlier labels

Claimants' Claims That Purdue Should Have Added Warnings Rejected By The FDA Are Preempted — Impossibility Preemption

State law failure to warn claims are preempted if (1) they are based on information known by the FDA at the time of approval, or (2) the FDA would have rejected the warning

Merck Sharp & Dohme Corp. v. Albrecht,
139 S. Ct. 1668, 1678–79 (2019)

State law failure to warn claims would be preempted if the FDA would have rejected the proposed warnings.

In re Celexa & Lexapro Mktg. & Sales Practices Litig.,
779 F.3d 34, 43 (1st Cir. 2015)

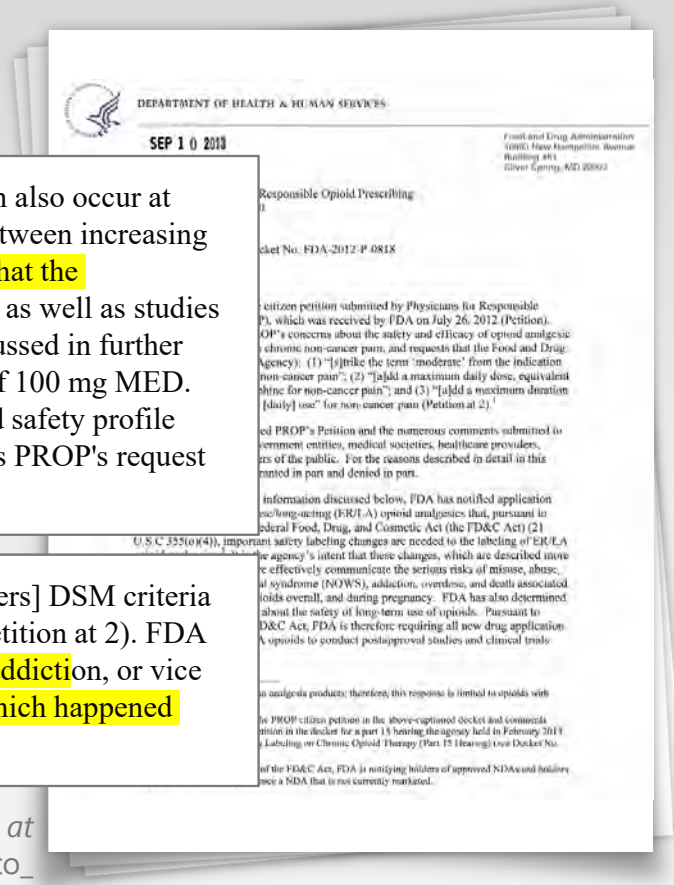
Preemption where alleged omission *"was known to the FDA at the time of the approval."*

Maze v. Bayer Healthcare Pharm. Inc.,
2019 WL 1062387, at *3 (E.D. Tenn. Mar. 6, 2019)

"[T]o impose state-law tort liability based on information known to the FDA at the time of approval is strictly prohibited under the Supremacy Clause and Wyeth."

In 2013, The FDA Expressly Rejected Warnings Claimants Seek

In 2013, FDA rejected PROP's request to impose a maximum dose or limit the duration of treatment


DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 1 0 2013

Responsible Opioid Prescribing

cket No. FDA-2012-P-0818

FDA agrees that adverse events and substance abuse of opioids occur at high doses-but adverse events can also occur at doses less than 100 mg MED. FDA also acknowledges that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events. However, the available information does not demonstrate that the relationship is necessarily a causal one. FDA has reviewed the studies cited in support of PROP's request, as well as studies cited in comments to the Petition docket and other studies described in the literature. For the reasons discussed in further detail below, the scientific literature does not support establishing a maximum recommended daily dose of 100 mg MED. Further, creating a maximum dose of 100 mg MED, or another dose ceiling, could imply a superior opioid safety profile under that set threshold, when there are no data to support such a conclusion. The Agency therefore denies PROP's request that opioid labeling specify a maximum daily dose.

The Petition also asserts that "[r]ecent surveys using [Diagnostic and Statistical Manual of Mental Disorders] DSM criteria found high rates of addiction in [chronic non-cancer pain] patients receiving [chronic opioid therapy]" (Petition at 2). FDA agrees with this assertion. However, the cited surveys did not suggest that chronic opioid therapy causes addiction, or vice versa. Both addiction and chronic opioid therapy were measured at one, point in time, so it is unknown which happened first: addiction or chronic opioid therapy.

9/10/13 2013 PROP Letter, pp. 12, 16, *available at* http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

FDA Implicitly Rejected Many Studies Claimants Rely on When It Approved the Reformulated OxyContin Label in 2010

- **Purdue could not unilaterally change label to address studies available to the FDA when the label was approved**
- **Most studies cited in the complaints were available when the FDA approved the reformulated OxyContin label in 2010**

21 C.F.R. §201.57(c)(6) and 21 C.F.R. §314.70(c)(6)

Only "newly acquired information" showing a "causal" relationship between the drug and a "clinically significant hazard" could justify a unilateral change. Which FDA can still reject.

FDA Implicitly Rejected Many Studies Claimants Rely on When It Approved the Reformulated OxyContin Label in 2010

Examples of old studies Claimants' failure-to-warn claims rely on:

- **2008:** Jeffrey Dersh et al., *Prescription Opioid Dependence is Associated with Poorer Outcomes in Disabling Spinal Disorders*, 33 SPINE 2219, 2219-27 (2008)
- **2002:** Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. & PRAC. PERSPS. 13, 13-20 (July 2002)
- **2009:** Caleb Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain—Development of a Typology of Chronic Pain Patients*, 104 DRUG ALCOHOL DEPENDENCE 34, 34-42 (2009).

Claimants' Fraud-on-the-FDA Claims Are Preempted — Conflict Preemption

Claimants' claims that the FDA should never have approved OxyContin for 12 hour dosing are fraud-on-the-FDA claims and are preempted

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–51 (2001)

- Under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350–51 (2001), **a claim that the FDA should not have approved a drug or medical device for a particular use or indication is preempted as a fraud-on-the-FDA claim**.
- The FDA approved OxyContin for 12 hour dosing.
  - It adhered to that decision in response to Connecticut AG's citizens petition.
- Claimants' claims that OxyContin should not have been approved for 12 hour dosing are essentially fraud-on-the-FDA claims and are therefore preempted.

Claimants' Claims That Science Approved by the FDA Is False Are Preempted — Obstacle Preemption

Wyeth v. Levine,
555 U.S. 555 (2009)

Merck Sharp & Dohme Corp. v. Albrecht,
139 S. Ct. 1668 (2019)

Wyeth v. Levine, 555 U.S. 555 (2009), and *Merck Sharp & Dohme Corp. v. Albrec*ht, 139 S. Ct. 1668 (2019), address ways in which state and federal laws can be **complementary**.

- But they are limited to "failure to warn claims" which complement the FDA's labelling requirements.

State law cannot **conflict** with federal law.

- A state law claim is preempted if it will "**frustrate** the achievement of congressional objectives." *Levine*, 555 U.S. at 581.
- State law is preempted if it "stands as an **obstacle** to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Claimants' Claims That Science Approved by the FDA Is False Are Preempted — Obstacle Preemption

- **Some of Claimants' claims pit federal and state law against each other:**
- **To prevail, Claimants must show that a statement that the federal regulator said is *true* and must appear on the label is in fact *false*. For example:**
  - The FDA label says that, as a scientific fact, OxyContin has **no ceiling dose**.
    - The NY AG's claim that, under state law, this statement is "false[]" is therefore preempted. *See* NY AG FAC ¶190.
  - The FDA label says that drug-seeking behavior **may not be a sign of addiction**.
    - The NY AG's claim that under state law it is false to say that drug seeking behavior may not be a sign of addiction is preempted. *See* NY AG FAC ¶¶325-29.

Those claims pose an obstacle to the federal scheme and are preempted.

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 5: Underlying Claims Against Purdue, Effect of Criminal Plea, Deceptive Marketing, Preemption

April 27, 2021

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 6: Causation, Statutory Consumer Fraud, Public Nuisance, Claims By Opioid Users And Their Families

April 27, 2021

Causation

Two Claimed Injuries

1. **Excess health care costs** for employees and others covered by governmental insurance plans or by Medicaid, **incurred by the Claimants as insurers and third-party payors** (consisting of reimbursed cost of prescribed opioids and costs of treatment for opioid addiction); and

2. **Expenses incurred by Claimants directly to combat the opioid epidemic**, including addiction treatment, emergency services, and law enforcement, criminal justice, social services, and through lost productivity.

See, e.g., NY Municipalities' Master Long Form Complaint ("MLFC") ¶¶25, 26, 699, 707; 1/19/2018 Suffolk MTD Opp. at 56 (Dkt. # 287); MA AG FAC ¶¶906-907

Two Claims

Deceptive Marketing

Diversion Control Failures

Claimants Must Prove That Purdue And The Individuals Are Both The Cause In Fact And Proximate Cause Of The Claimed Injuries

Small v. Lorillard Tobacco Co.,
252 A.D.2d 1, 15 (N.Y. App. Div., 1st Dep't 1998) (G.B.L. §§349, 350; common-law fraud)

N.Y. SOC. SERV. LAW *§145-b(2)*

People ex rel. Spitzer v. Sturm, Ruger & Co.,
309 A.D.2d 91, 95-97 (1st Dept. 2003) (public nuisance)

Pasquaretto v. Long Island Univ.,
106 A.D.3d 794, 795 (2d Dept. 2013) (negligence)

Bilinski v. Keith Haring Found., Inc.,
96 F. Supp. 3d 35, 52 (S.D.N.Y. 2015) (unjust enrichment)

State v. Lead Indus., Ass'n, Inc., 951 A.2d 428, 451 (R.I. 2008) (lead paint public nuisance claims)

Claimants Face Insurmountable Causation Problems

Problem #1:	Claimants Cannot Show Purdue Marketing Statements Caused Doctors To Write Medically Unnecessary Prescriptions
Problem #2:	OxyContin Has Always Had A Small Market Share — And It Has Declined Since 2003
Problem #3:	For A Decade, The Opioid Crisis Has Been Driven By Heroin, Street Fentanyl, And Other Illegal Drugs, Not Prescription Opioids
Problem #4:	The Risk of Addiction From Medically Prescribed Opioid Use Is Demonstrably Low
Problem #5:	Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

Claimants Face Insurmountable Causation Problems

Problem #6:	Claimants Cannot Establish Their Injuries Were Caused By Purdue Opioids, As Opposed To Other Manufacturers'
Problem #7:	States, Municipalities And Other Claimants Continue To Approve And Reimburse Opioid Prescriptions
Problem #8:	The Individuals Did Not Make Or Participate In Making Any Purported Misstatement That Allegedly Caused Claimants' Losses
Problem #9:	No Evidence Alleged Purdue Diversion Control Failures Caused Claimants' Injuries
Problem #10:	Municipal Cost Recovery Rule Bars Lawsuits For Local Government Expenditures
Problem #11:	Derivative-Injury Rule Bars Claimants' Third Party Payer Claims

Problem #1:

Claimants Cannot Show Purdue Marketing Statements Caused Doctors To Write Medically Unnecessary Prescriptions

Cases in 2003–08 Found No Causation In Patient/Survivor Claims

Bodie v. Purdue Pharma Co., 236 Fed. App'x 511 (11th Cir. 2007)

No proof of causation because **patient's doctor testified he was aware of the risks of opioids, and prescribing decision unaffected by Purdue promotional literature**

Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693 (E.D. Ky. 2003)

No causation where **patients misused OxyContin contrary to label warnings** and warning to doctors was adequate

Labzda v. Purdue Pharma, L.P., 292 F. Supp. 2d 1346 (S.D. Fla. 2003)

Manufacturers not obligated to police prescribers; patient's intentional misuse broke causal chain

Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551 (N.D. Tex. 2006)

Plaintiff failed to show OxyContin marketing caused doctors to prescribe it to him

McCauley v. Purdue Pharma, L.P., 331 F. Supp. 2d 449 (W.D. Va. 2004)

Failure to establish causation against Purdue where **patients took multiple opioids concurrently**

Boysaw v. Purdue Pharma, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009)

No proof of causation against Purdue because patient was taking **multiple opioids** in addition to OxyContin

Timmons v. Purdue Pharma Co., 2006 U.S. Dist. LEXIS 3965, (M.D. Fla. Feb. 2, 2006)

Failure to show causation where **prescribers were aware of risks and were not influenced by Purdue marketing**

Cornelius v. Cain, 2004 WL 48102 (Fl. Cir. Ct. Jan. 5, 2004)

OxyContin **label warnings were adequate, doctors were aware of risks, and learned intermediary doctrine broke chain of causation**

Harris v. Purdue Pharma, L.P., 218 F.R.D. 590 (S.D. Ohio 2003)

Finding lack of commonality in class action based on learned intermediary doctrine; **plaintiffs would have to show that each plaintiff's doctor was deceived**

Cases Brought By States And Municipalities Face Additional Obstacles

They must:

- Establish additional causal steps between the patient and their damages
- Show that a vast number of prescribers were deceived by Purdue
- Show that Purdue's products caused their damages despite widespread use of other opioids
- Establish causal links to the Individuals, and
- Overcome statute of limitations problems in light of the 2007 settlements, allegations that damages were first suffered more than a decade ago, government investigations since 2007, and intense media coverage for years

States And Municipalities Cannot Prove Causation

City of New Haven v. Purdue Pharma, L.P., 2019 WL 423990, at *3 (Conn. Super. Ct. Jan. 8, 2019)

Dismissed public nuisance and other claims against opioid manufacturers because the steps between the manufacturers' conduct and the local government plaintiff's injuries were too great to support causation:

*"[C]ourts can't credibly consider cases derived from harms allegedly connected to defendants by **lengthy, multifaceted chains of causation** that must weigh their conduct while trying to separate that conduct from **the myriad of independent factors** that make up most broadly defined social crises like . . . opioid abuse."*

The Learned Intermediary Doctrine Breaks The Causal Chain

Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61 (4th Dep't 1979), *aff'd*, 52 N.Y.2d 768 (1980)

Prescribing physicians intervene as ***"the 'informed intermediary' between the manufacturer and the patient"*** to make decisions about medical treatment, ***"evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use."***

See also Martin v. Hacker, 83 N.Y.2d 1, 9 (1993); *Glucksman v. Halsey Drug Co.*, 160 A.D.2d 305, 307 (1st Dep't 1990)

Doctors have available many sources of information about the risks of opioids, including Purdue's:

- FDA-approved labeling disclosing the risks that Purdue supposedly concealed
- Medical journals and treatises
- Government agencies, including the FDA, CDC, DEA, and SAMHSA (the Substance Abuse & Mental Health Services Administration)
- FDA REMS (Risk Evaluation and Mitigation Strategies) communicating the risks of opioids
- Grand rounds, medical meetings, continuing medical education, discussions with colleagues

The Learned Intermediary Doctrine Breaks The Causal Chain

Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP,
585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008)

Dismissing RICO, consumer protection, fraud, negligent misrepresentation and unjust enrichment claims against drug manufacturer and medical marketing firm for lack of proximate cause: **it *"would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit."***

Sidney Hillman Health Center of Rochester v. Abbott Labs,
873 F.3d 574, 577 (7th Cir. 2017)

Affirming dismissal of insurers' RICO claims against drug manufacturers based on alleged off-label promotion, for failure to plead proximate causation, as **insurers were several steps removed in causal chain between alleged illegal marketing and paying for improper prescriptions, including numerous independent decisions by physicians and patients**

In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.,
2010 WL 3119499, at *7-9 (S.D. Ill. Aug 5, 2010)

Dismissing claims where court would "**have to delve into the specifics of each physician patient relationship to determine what damages were caused by [the] alleged fraudulent conduct, as opposed to what damages were caused by the physician's independent medical judgment**"

The Learned Intermediary Doctrine Breaks The Causal Chain

- Doctors make individual prescribing decisions
- The FDA-approved label provides prominent warnings about the risks of addiction, overdose, and death
- Purdue's marketing material was reviewed by the FDA and consistent with the FDA-approved label — as it was required by law to be

Learned Intermediary Doctrine Breaks The Causal Chain

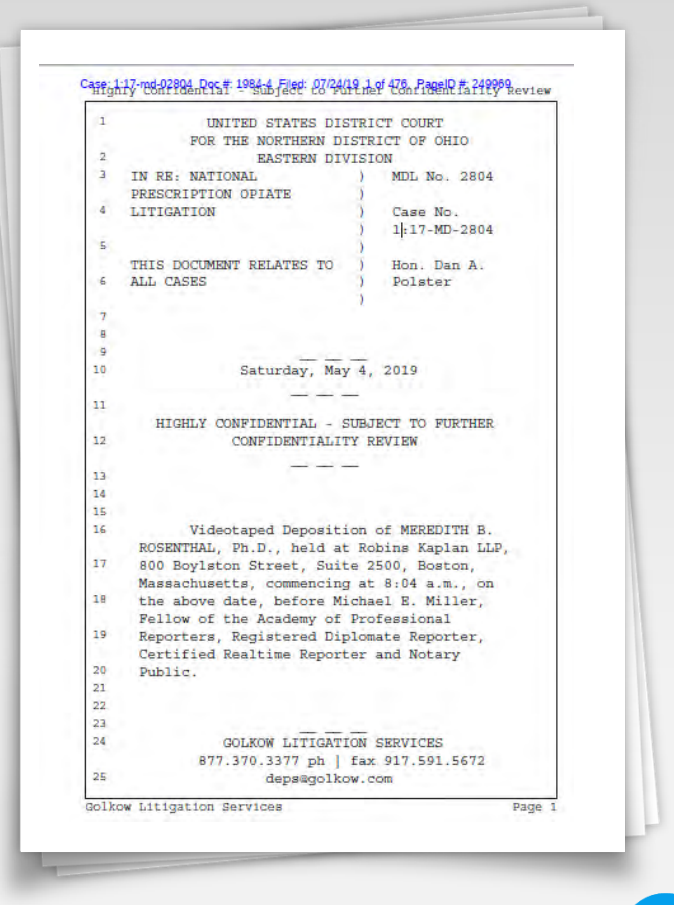
N.Y. PUB. HEALTH LAW §§ 3331(1)-(2), (5)-(7), 3343-a(2);
10 N.Y.C.R.R. 80.63(c)(1), 80.64

New York strictly limits opioid prescribing and requires doctors to closely monitor patients taking such medicines, referencing the State's opioid prescription monitoring database before each prescription is written.

Claimants Cannot Identify Prescriptions Written Because Of The Alleged Misconduct

Plaintiffs' economic expert in the MDL (Meredith Rosenthal) conceded she **could not identify which, if any, opioid prescriptions were medically improper and would not have been written but for the allegedly wrongful conduct** at issue in this case.

5/4/2019 Rosenthal Dep. Tr. 150:8-153:5 (MDL Dkt. #1984-4)



Case: 1:17-md-02804 Doc #: 1984-4 Filed: 07/24/19 1 of 478. PageID #: 249969

Highly Confidential - Subject to Further Confidentiality Review

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	Hon. Dan A. Polster

Saturday, May 4, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped Deposition of MEREDITH B. ROSENTHAL, Ph.D., held at Robins Kaplan LLP, 800 Boylston Street, Suite 2500, Boston, Massachusetts, commencing at 8:04 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

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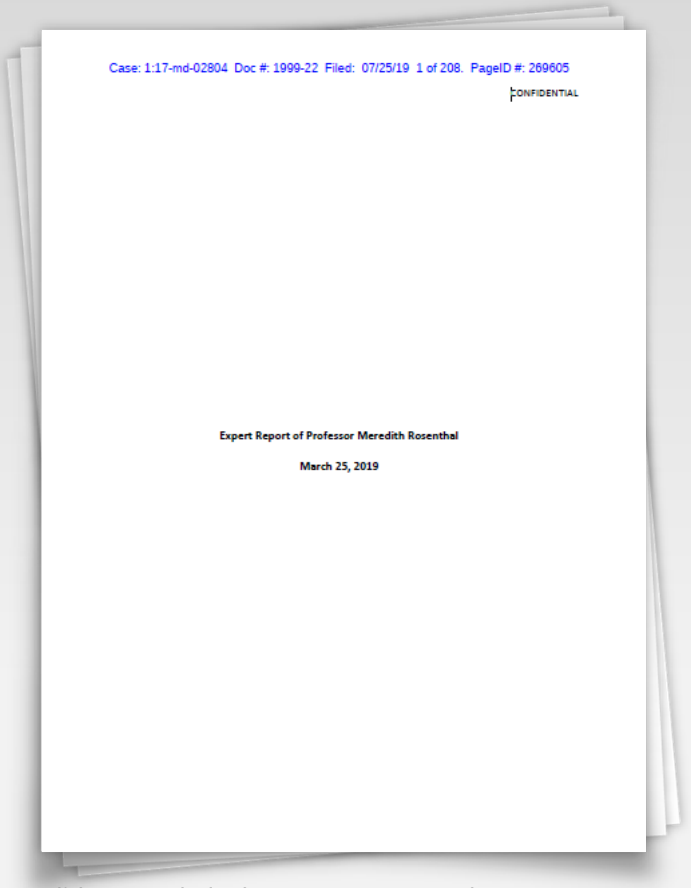
Claimants' Statistical Models Fail To Establish Causation

In the MDL, **Plaintiffs' experts have relied solely on statistical analyses**.

Plaintiffs' expert Meredith Rosenthal prepared a **regression model** to measure the **aggregate effect of all prescription opioid promotion on all prescription opioid sales nationwide**.

The model compared all "detailing" contacts by manufacturer sales representatives to the number of milligrams of morphine equivalent (MME) sales for all opioids at issue — in the aggregate, **without differentiating among manufacturers**



Expert Report of Meredith Rosenthal, PhD ¶¶58-60 (MDL Dkt. # 1999-22)

Claimants' Statistical Models Fail To Establish Causation

Correlation is not causation

- The proffered opinions do not account for the many other causes of increased opioid prescribing.
- They do not connect Purdue's marketing to prescriptions or decisions by particular doctors or to any resulting harm, as required

UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010)

"General [aggregate] proof of but-for causation is impossible" because *"at least some doctors were not misled by [Defendant's] alleged misrepresentations, and thus would not have written 'excess' prescriptions as identified by the plaintiffs."*

Claimants' Statistical Models Fail To Establish Causation

Ms. Rosenthal **assumed that all opioid detailing** from manufacturers' sales representatives to prescribers **was unlawful**.

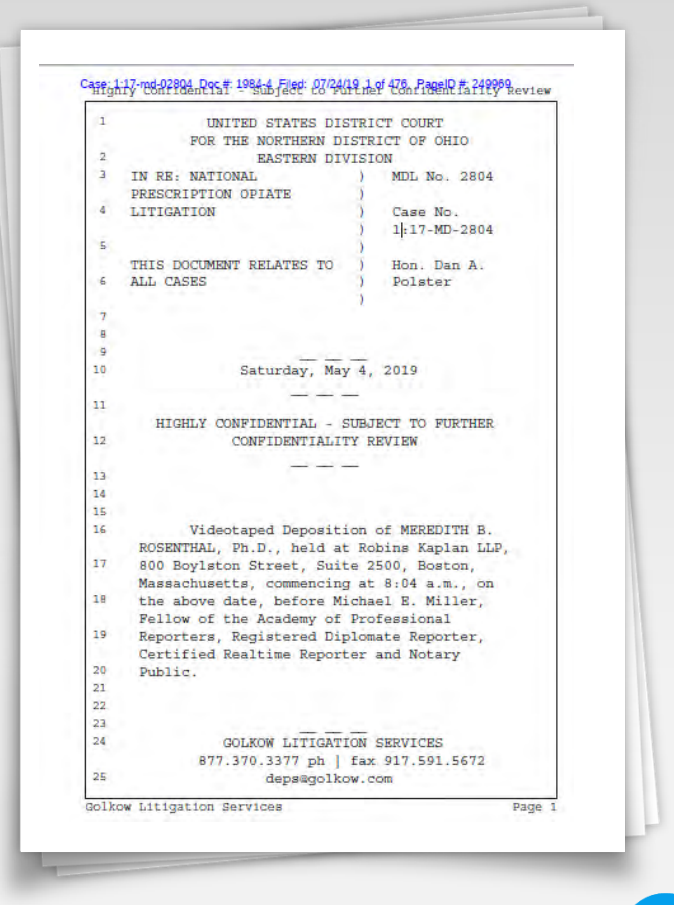
Rosenthal Report ¶ 75 (MDL Dkt. #1999-22); Rosenthal Dep. Tr. 149:24–150:7 (MDL Dkt. #1984-4)

Detailing and other promotions consistent with a medication's FDA-approved label **are lawful and appropriate**.

Detailing may help increase sales. **There is nothing wrong with increasing sales through lawful promotion**.

See, e.g., Sorrell v. IMS Health Inc., 564 U.S. 552, 557 (2011)

"Speech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment."



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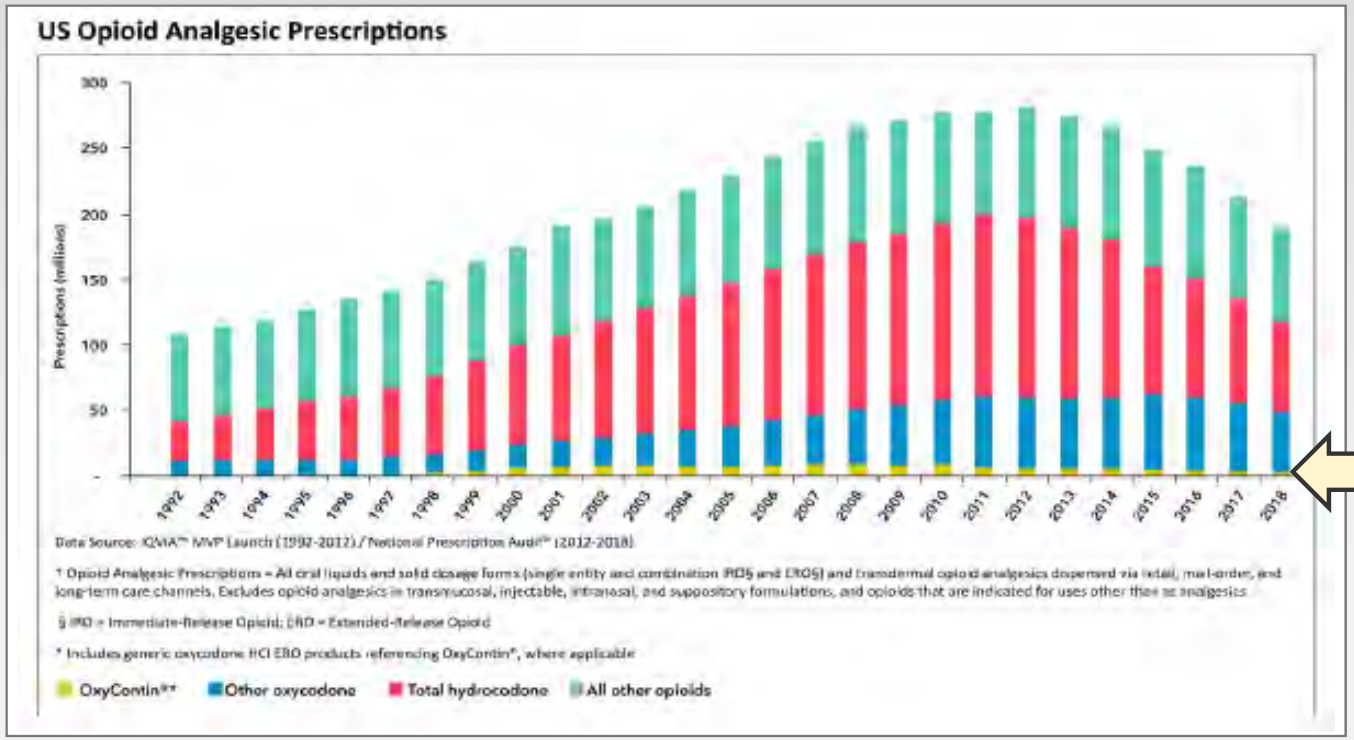
Problem #2:

OxyContin Has Always Had A Small Market Share, And It Has Declined Since 2003

Purdue/OxyContin's Small And Flat/Declining Market Share

OxyContin is less than 2% of the total prescription opioid market and has never been more than 4% of the market

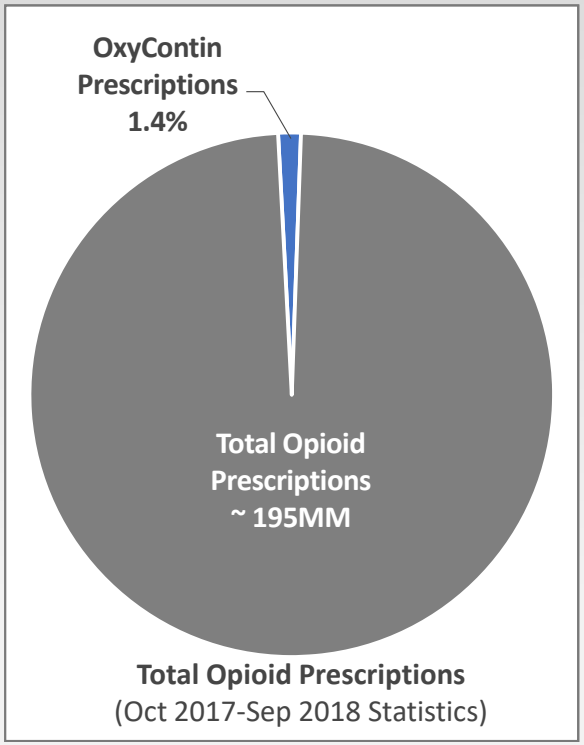


OxyContin is the yellow sliver at the very bottom of the bars

Debtors' Informational Brief (Dkt. #17), page 22

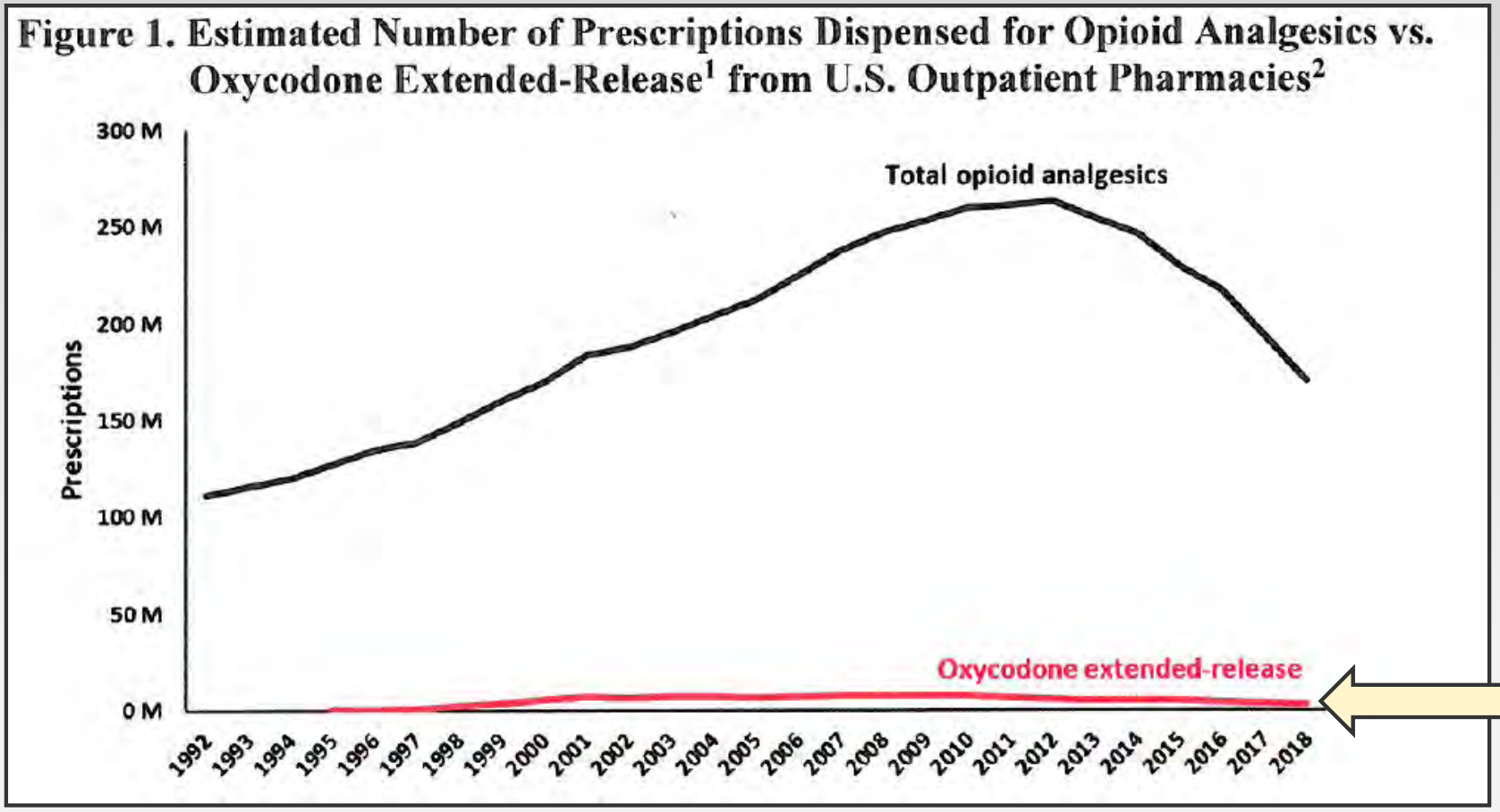
Purdue/OxyContin's Small And Flat/Declining Market Share

OxyContin was 1.4% of the prescription opioid market in the year ending Sept. 2018



Source: IQVIA NPA Data; http://web.archive.org/web/20190910153705/https://www.purduepharma.com/news-media/common-myths-about-oxycontin/

Extend-Release Opioids — Including OxyContin and Its Competitors — Form A Sliver of Total Opioids Sold

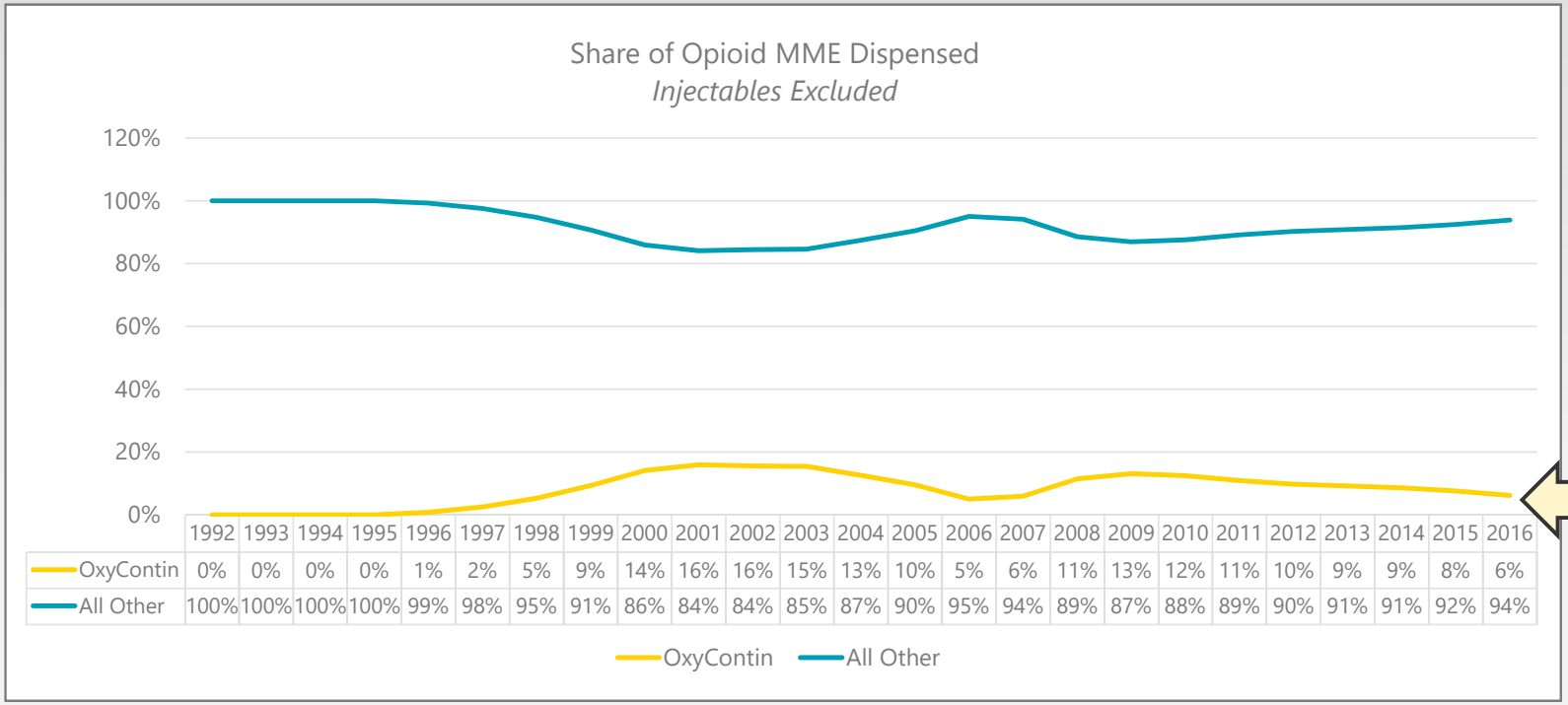


2020 FDA Letter to Senator Maggie Hassan: https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

OxyContin and all other EROs

OxyContin's Small And Flat/Declining Market Share

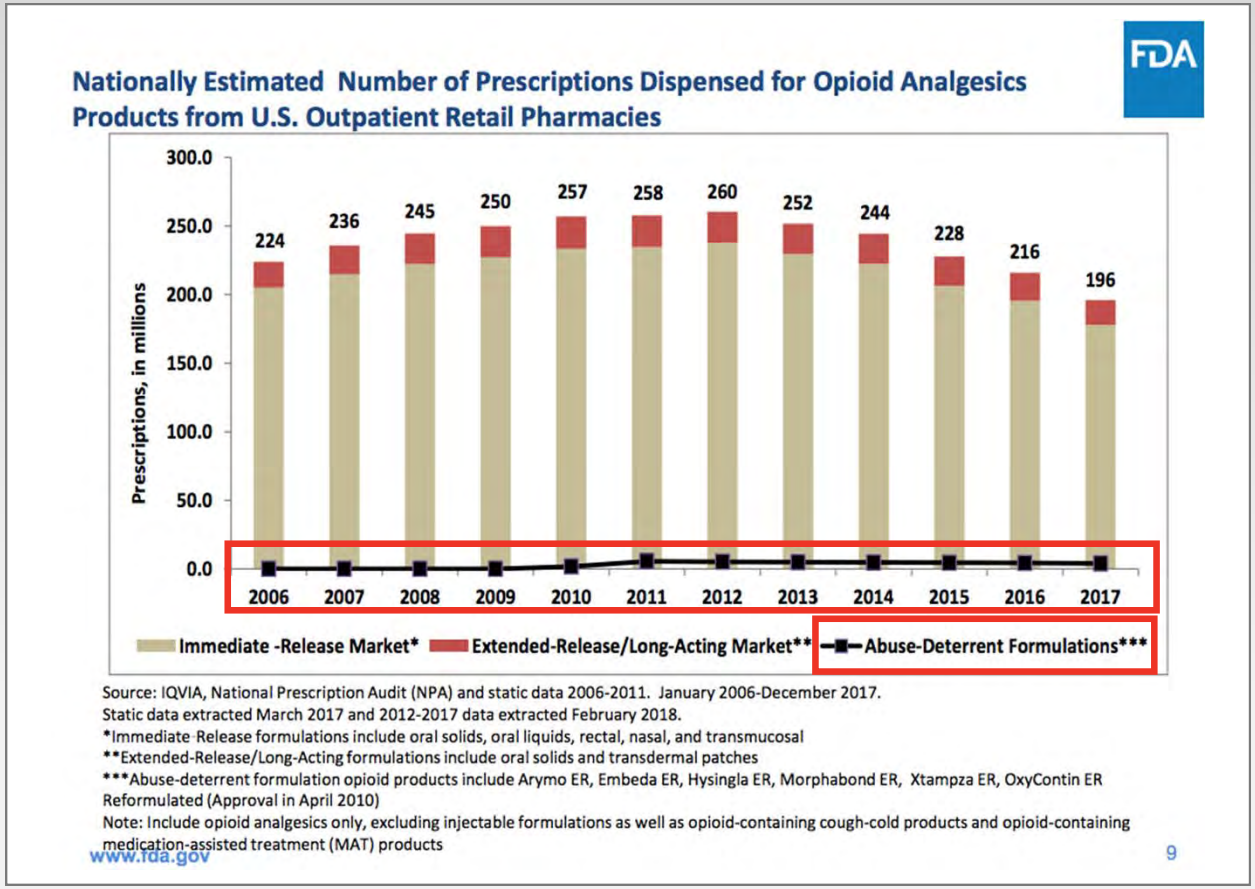
Measured by milligrams of morphine equivalent (MME), OxyContin declined from 13% of the total prescription opioid market in 2009 to 6% in 2016



	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
OxyContin	0%	0%	0%	0%	1%	2%	5%	9%	14%	16%	16%	15%	13%	10%	5%	6%	11%	13%	12%	11%	10%	9%	9%	8%	6%
All Other	100%	100%	100%	100%	99%	98%	95%	91%	86%	84%	84%	85%	87%	90%	95%	94%	89%	87%	88%	89%	90%	91%	91%	92%	94%

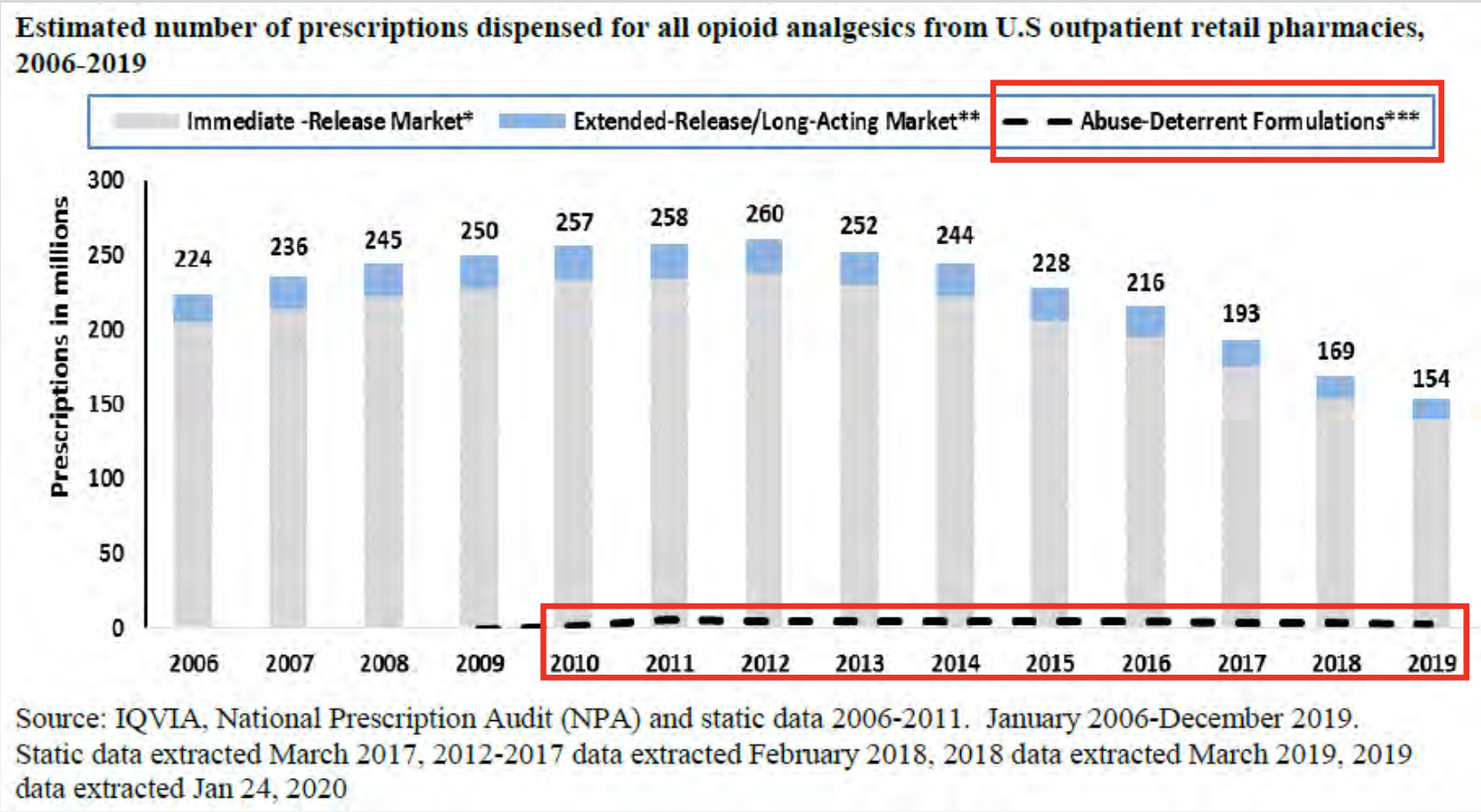
Source: IQVIA

Immediate-Release Prescription Opioids Have Always Dominated The Market



https://www.fda.gov/media/112084/download, Slide 9

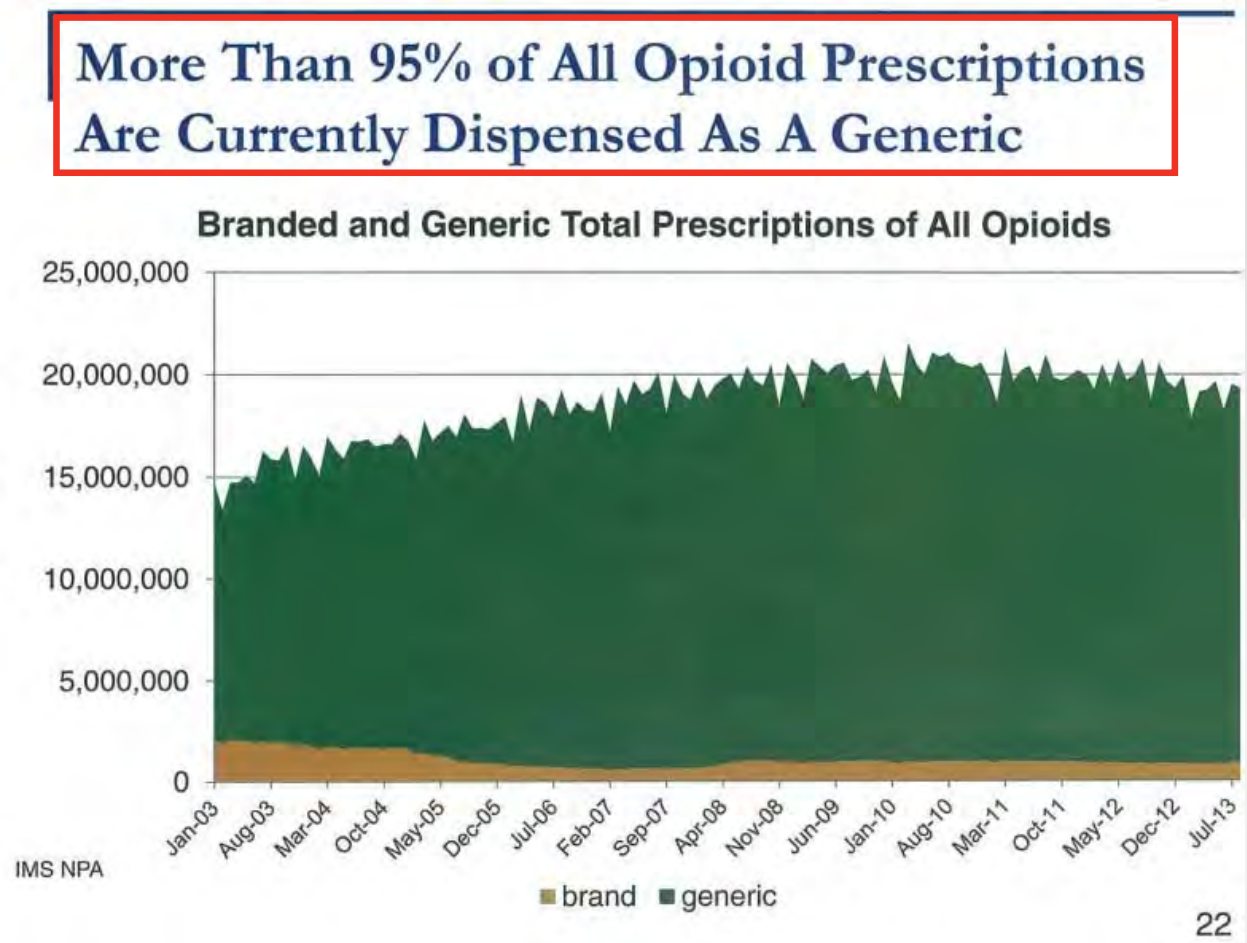
Immediate-Release Prescription Opioids Have Always Dominated The Market



Source: FDA Briefing Book for Sept. 10-11, 2020, Joint Meeting of DSaRM and AADPAC Advisory Committees, at p. 10, https://www.fda.gov/media/141914/download

Note: Abuse-deterrent formulations include Arymo ER, Embeda ER, Hysingla ER, Morphabond ER, Xtampza ER, OxyContin ER Reformulated (Approval in April 2010), RoxyBond IR. *Id.* at 10

Generic Prescription Opioids Have Always Dominated The Market



Source: Leventhal Supp. Ex. 51 at page 22, Nov. 2013 Year End Budget Book (PPLP004410008)

ERO Prescriptions Have Represented "A Very Small And Decreasing Fraction" of Opioid Prescriptions since 2010

2020 FDA Letter to Senator Maggie Hassan:

- "For at least 4 years after the [2001 OxyContin] labeling change — at a time when prescription opioid use was rising — the number of prescriptions dispensed for oxycodone ER was generally flat, **with the number of oxycodone ER prescriptions making up a very small and decreasing fraction of prescriptions since 2010**." (Page 5)

https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

There Is Widespread Confusion between Immediate-Release Oxycodone and OxyContin

Drug Overdose Deaths Hit 'Alarming' New Record in U.S., CDC Says
By Maggie Fox (December 18, 2015), NBC News:

> "The CDC . . . proposed new draft guidelines this month that include using every other possible approach to managing pain before giving someone **an opioid such as fentanyl or oxycontin** to control pain."

- **There is no reference to OxyContin in the linked CDC webpage (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)**
- **All references are to oxycodone**

https://www.nbcnews.com/health/health-news/drug-overdose-deaths-hit-new-record-u-s-cdc-says-n482746

There Is Widespread Confusion Between Immediate-Release Oxycodone and OxyContin

March 16, 2011 Testimony of DEA Administrator Michele Leonhart before House Appropriations Subcommittee on Commerce, Justice, Science & Related Agencies (Rep. Frank Wolf, Chair):

> Mr. Wolf. Now the company that manufacturers the pills, what company? I mean there was a successful case in the Western District of Virginia, is it the same company?
>
> Ms. Leonhart. It is a little bit different than the OxyContin problem, and a lot of people think that the drug that is the number one drug out of the pill mills in Florida is OxyContin, and that is not correct.
>
> Mr. Wolf. What is it?
>
> Ms. Leonhart. It is the generic form, it is Oxycodone.

https://www.govinfo.gov/content/pkg/CHRG-112hhrg67259/html/CHRG-112hhrg67259.htm

There Is Widespread Confusion Between Immediate-Release Oxycodone and OxyContin

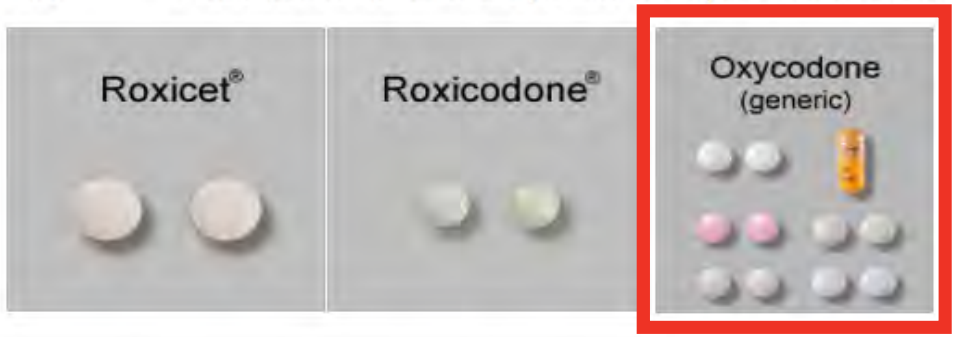
OxyContin

PR02 Please look at the names and pictures of the pain relievers shown below.

In the **past 12 months**, which, if any, of these pain relievers have you used?

Generic Oxycodone

PR03 Please look at the names and pictures of the pain relievers shown below.



In the **past 12 months**, which, if any, of these pain relievers have you used?

Substance Abuse and Mental Health Services Administration, 2015 National Survey on Drug Use and Health: Prescription Drug Images for the 2015 Questionnaire (Sept. 2016), at pages 8-9. https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2015.pdf.
See also https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2016.pdf at pages 8-9 (for 2016 survey);
https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2017.pdf at pages 8-9 (for 2017 survey).

The Introduction Of OxyContin Did Not Trigger The Opioid Crisis

2002 Congressional testimony of Dr. H. Westley Clark (Director, SAMHSA Center for Substance Abuse Treatment):

> *"This is merely the newest part of a prescription opioid diversion and abuse problem that has been rising since the mid-1980s. … [T]he incidence of new prescription opioid abuse and the number of new prescription opioid abusers has been rising steadily since well before the introduction of OxyContin."*

https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm

Opioid Prescriptions, Opioid Abuse And Opioid-Related Deaths Were Rising Before The Launch Of OxyContin In 1996

Opioid Prescriptions (1991-2013)

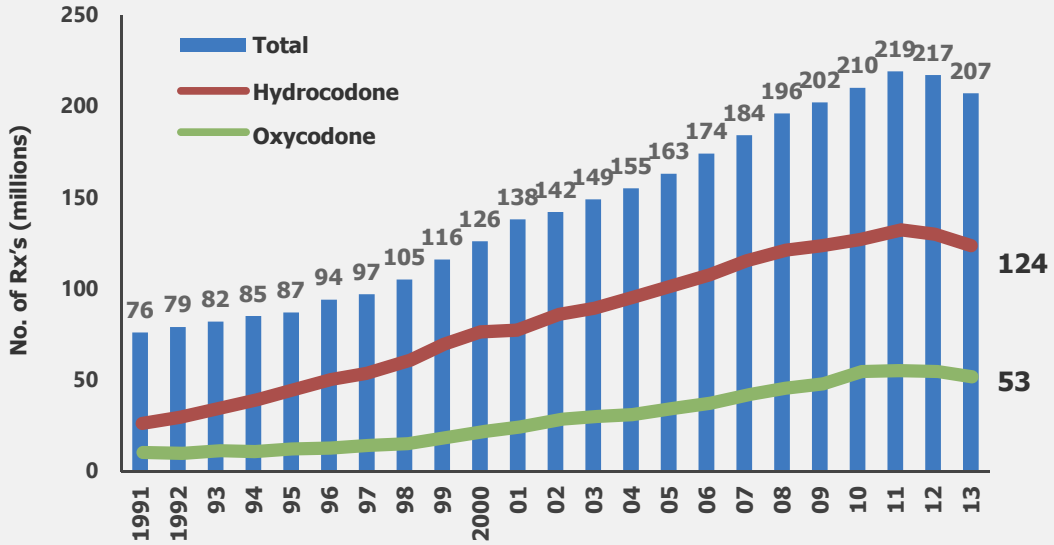
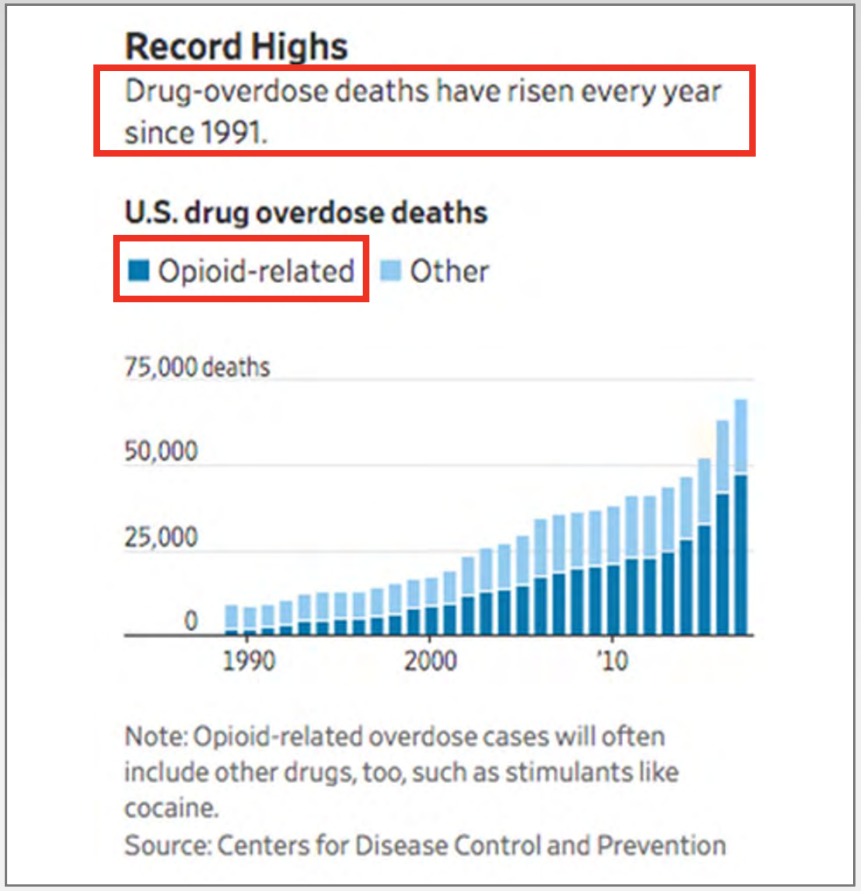


Figure 1 - Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse

Opioid Prescriptions, Opioid Abuse And Opioid-Related Deaths Were Rising Before The Launch Of OxyContin In 1996

Opioid-Related Overdose Deaths (1990-2017)

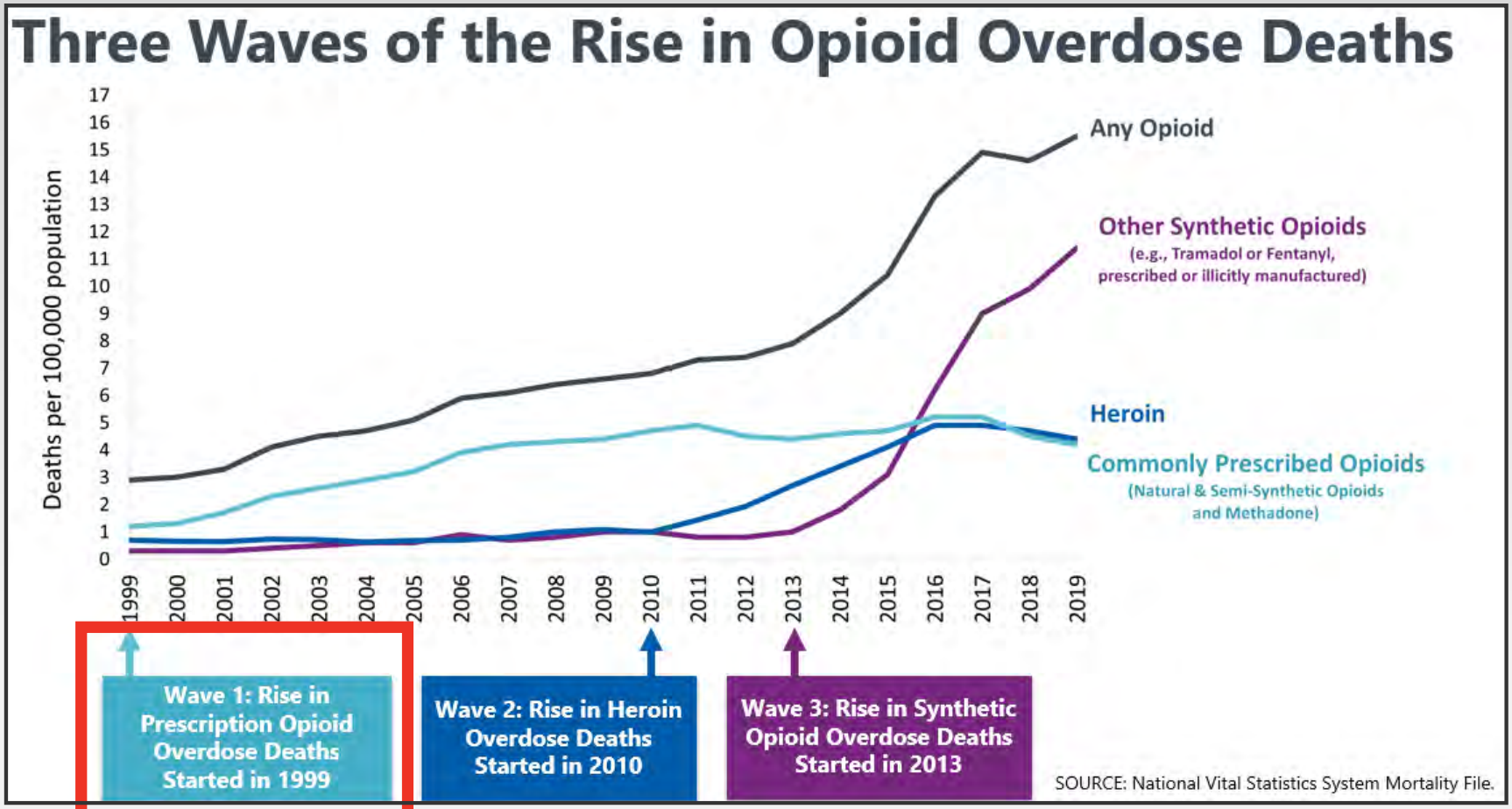


https://www.wsj.com/articles/overdose-deaths-likely-to-fall-for-first-time-since-1990-11561541406

Problem #3:

For Several Years, The Opioid Crisis Has Been Driven By Heroin, Street Fentanyl And Other Illegal Drugs, Not Prescription Opioids

Three Waves Of The Rise Of Opioid Overdose Deaths



- Deaths from **Synthetic Opioids** increased by more than 1000% from 2011-2019
- **Prescription Opioids** were involved in fewer than 25% of opioid deaths in 2019

https://www.cdc.gov/drugoverdose/images/3-waves-2019.PNG

Illicit Fentanyl And Heroin Are Driving Today's Opioid Crisis

- Since 2013, the opioid crisis has rapidly worsened because of street drugs, like fentanyl and heroin smuggled from China and Mexico
- Between 2013 and 2016, fentanyl-related deaths approximately doubled each year
- Of the 47,600 opioid-related overdose deaths in 2017, 28,466 involved synthetic opioids, an increase of 45% between 2016 and 2017 and a ten-fold increase in the prior five years

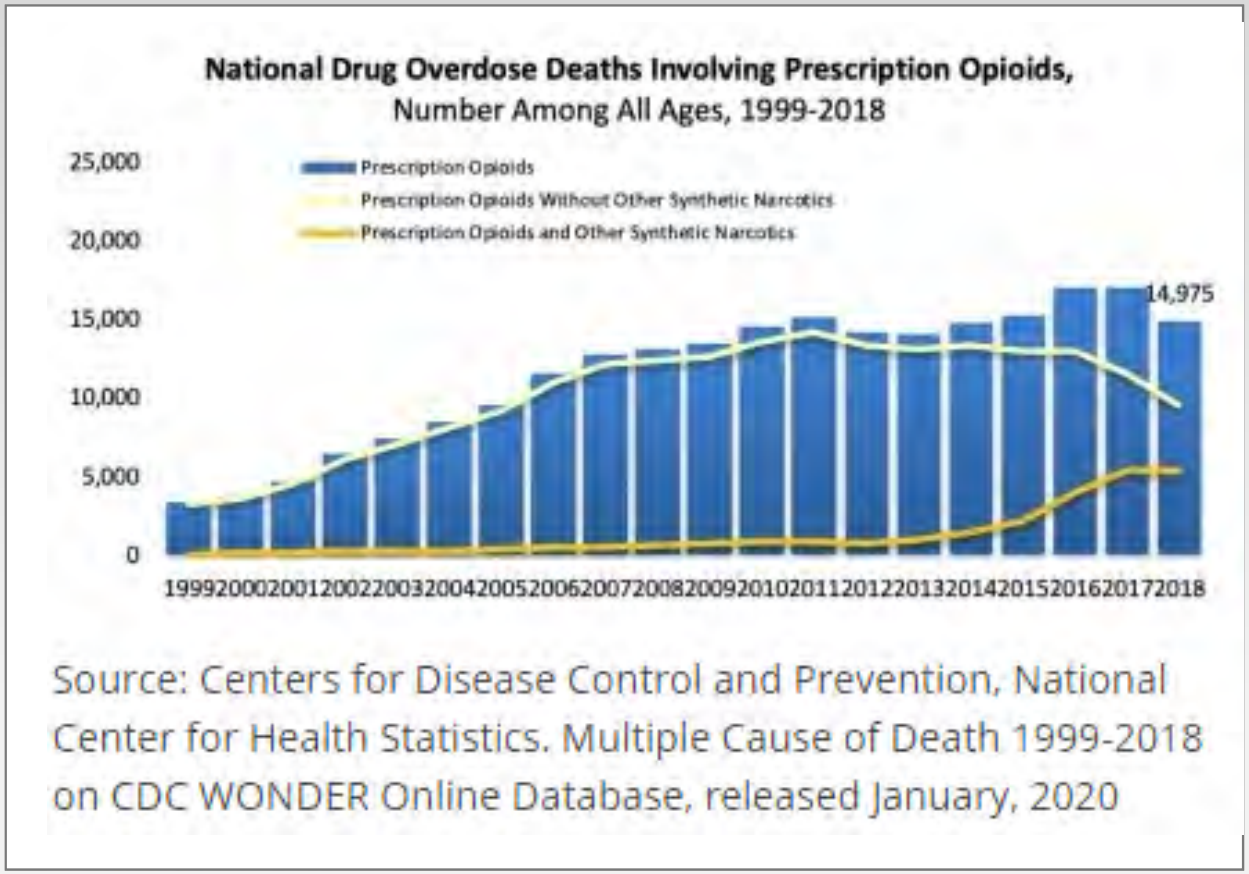
https://www.cdc.gov/drugoverdose/epidemic/index.html
https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_03-508.pdf
https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w

Massachusetts Department of Public Health (2019): No Single Substance Or Practice Caused the Opioid Crisis

"It should be noted that opioid-related deaths began increasing sharply in 2012, no similar increase in opioid prescriptions was recorded. This suggests that no single substance or health care practice is solely responsible for the current opioid crisis. Rather, it's a complex issue with a number of contributing factors."

Massachusetts Chapter 55 Report (3/1/2019), https://chapter55.digital.mass.gov/#top

Overdose Deaths Involving Prescription Opioids Alone Peaked In 2011



National Institutes of Health, National Institute on Drug Abuse, https://web.archive.org/web/20210127234432/https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates

A 2021 Study Found No Direct Association Between Legally-Obtained Prescription Opioids And Injury-Related Mortality between 2006-2017

- "We hypothesized that prescription opioid use would be positively associated with injury-related deaths in the U.S.
- "For each state, we analyzed mortality data from the US CDC and prescription opioid data from the US Department of Justice from 2006–2017.
- "There was no relationship between amounts of opioids and injury-related mortality, including unintentional deaths, suicides, and homicides."

***

"Our inability to detect a relationship between legal prescription opioid use and injury mortality points to the fact that many factors influence trauma mortality."

E.I. Truong, S.K. Kishawi, V.P. Ho et al., *Opioids and Injury Deaths: A Population-Based Analysis of the United States from 2006 to 2017, Injury*

https://www.injuryjournal.com/article/S0020-1383(21)00233-3/fulltext

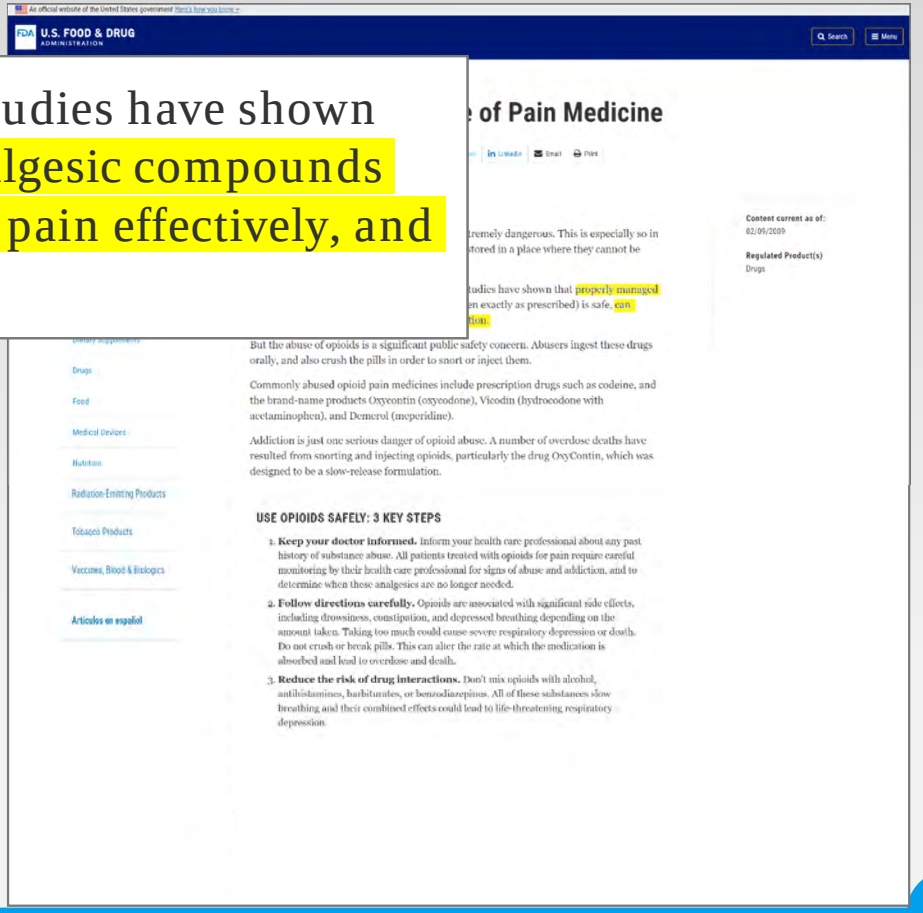
Problem #4:

The Risk of Addiction From Medically Prescribed Opioid Use Is Demonstrably Low

FDA: Medically-Managed Use of Opioids "Rarely Causes Addiction"

According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction.

https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine
(last visited March 30, 2021)



U.S. FOOD & DRUG ADMINISTRATION

Search Menu

of Pain Medicine

Content current as of: 02/09/2009

Regulated Product(s) Drugs

Drugs
Food
Medical Devices
Nutrition
Radiation-Emitting Products
Tobacco Products
Vaccines, Blood & Biologics
Articulos en español

But the abuse of opioids is a significant public safety concern. Abusers ingest these drugs orally, and also crush the pills in order to snort or inject them.

Commonly abused opioid pain medicines include prescription drugs such as codeine, and the brand-name products Oxycontin (oxycodone), Vicodin (hydrocodone with acetaminophen), and Demerol (meperidine).

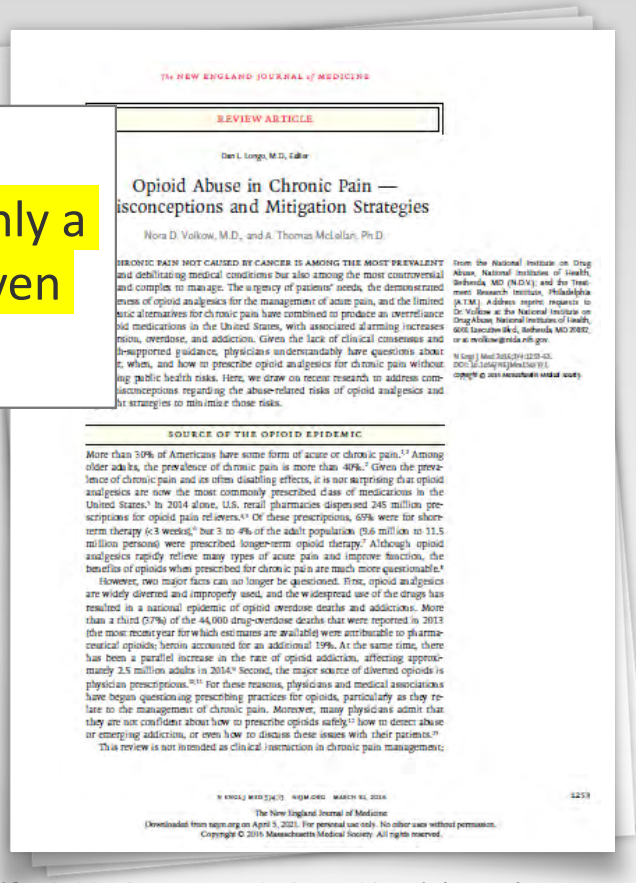
Addiction is just one serious danger of opioid abuse. A number of overdose deaths have resulted from snorting and injecting opioids, particularly the drug OxyContin, which was designed to be a slow-release formulation.

USE OPIOIDS SAFELY: 3 KEY STEPS

1. **Keep your doctor informed.** Inform your health care professional about any past history of substance abuse. All patients treated with opioids for pain require careful monitoring by their health care professional for signs of abuse and addiction, and to determine when these analgesics are no longer needed.
2. **Follow directions carefully.** Opioids are associated with significant side effects, including drowsiness, constipation, and depressed breathing depending on the amount taken. Taking too much could cause severe respiratory depression or death. Do not crush or break pills. This can alter the rate at which the medication is absorbed and lead to overdose and death.
3. **Reduce the risk of drug interactions.** Don't mix opioids with alcohol, antihistamines, barbiturates, or benzodiazepines. All of these substances slow breathing and their combined effects could lead to life-threatening respiratory depression.

A 2016 Study Confirmed The Low Risk of Addiction from Medically Prescribed Opioid Use

Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids — even among those with preexisting vulnerabilities.



THE NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Dan L. Longo, M.D., Editor

Opioid Abuse in Chronic Pain — isconceptions and Mitigation Strategies

Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D.

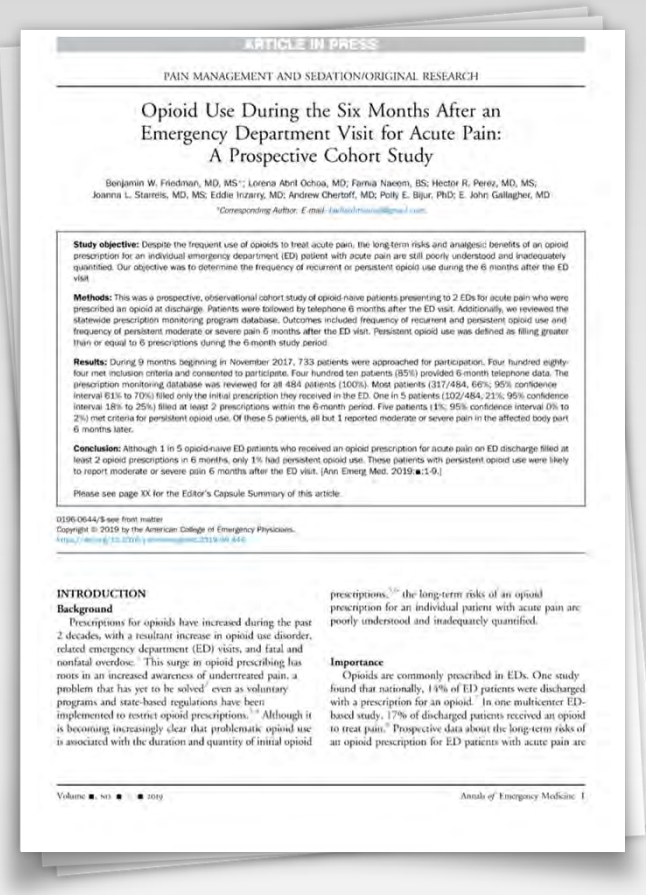
SOURCE OF THE OPIOID EPIDEMIC

Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain--Misconceptions and Mitigation Strategies*, 384 New Eng. J. Med.1253, 1256 (2016)

https://www.nejm.org/doi/pdf/10.1056/NEJMra1507771?articleTools=true

A 2019 Study Showed Only 1% Of ER Patients with No Opioid Use in Past 6 Months Who Were Prescribed Opioids Developed Persistent Opioid Use

- A study published in the *Annals of Emergency Medicine* in late 2019 followed 484 opioid-naïve patients who visited the emergency room between November 2017 and August 2018 and were prescribed opioids on discharge
- Six months later, only 5 of those patients — or 1% — had developed persistent opioid use



ARTICLE IN PRESS

PAIN MANAGEMENT AND SEDATION/ORIGINAL RESEARCH

Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study

Benjamin W. Friedman, MD, MS*; Lorena Abril Ochoa, MD; Famia Naeem, BS; Hector R. Perez, MD, MS; Joanna L. Starrels, MD, MS; Eddie Irizarry, MD; Andrew Chertoff, MD; Polly E. Bijur, PhD; E. John Gallagher, MD

*Corresponding Author. E-mail:

Study objective: Despite the frequent use of opioids to treat acute pain, the long-term risks and analgesic benefits of an opioid prescription for an individual emergency department (ED) patient with acute pain are still poorly understood and inadequately quantified. Our objective was to determine the frequency of recurrent or persistent opioid use during the 6 months after the ED visit.

Methods: This was a prospective, observational cohort study of opioid-naive patients presenting to 2 EDs for acute pain who were prescribed an opioid at discharge. Patients were followed by telephone 6 months after the ED visit. Additionally, we reviewed the statewide prescription monitoring program database. Outcomes included frequency of recurrent and persistent opioid use and frequency of persistent moderate or severe pain 6 months after the ED visit. Persistent opioid use was defined as filling greater than or equal to 6 prescriptions during the 6-month study period.

Results: During 9 months beginning in November 2017, 733 patients were approached for participation. Four hundred eighty-four met inclusion criteria and consented to participate. Four hundred ten patients (85%) provided 6-month telephone data. The prescription monitoring database was reviewed for all 484 patients (100%). Most patients (317/484, 66%; 95% confidence interval 61% to 70%) filled only the initial prescription they received in the ED. One in 5 patients (102/484, 21%; 95% confidence interval 18% to 25%) filled at least 2 prescriptions within the 6-month period. Five patients (1%; 95% confidence interval 0% to 2%) met criteria for persistent opioid use. Of these 5 patients, all but 1 reported moderate or severe pain in the affected body part 6 months later.

Conclusion: Although 1 in 5 opioid-naive ED patients who received an opioid prescription for acute pain on ED discharge filled at least 2 opioid prescriptions in 6 months, only 1% had persistent opioid use. These patients with persistent opioid use were likely to report moderate or severe pain 6 months after the ED visit. [Ann Emerg Med. 2019;■:1-9.]

Please see page XX for the Editor's Capsule Summary of this article.

0196-0644/$-see front matter
Copyright © 2019 by the American College of Emergency Physicians.

INTRODUCTION

Background

Prescriptions for opioids have increased during the past 2 decades, with a resultant increase in opioid use disorder, related emergency department (ED) visits, and fatal and nonfatal overdose.[1] This surge in opioid prescribing has roots in an increased awareness of undertreated pain, a problem that has yet to be solved[2] even as voluntary programs and state-based regulations have been implemented to restrict opioid prescriptions.[3,4] Although it is becoming increasingly clear that problematic opioid use is associated with the duration and quantity of initial opioid prescriptions,[5,6] the long-term risks of an opioid prescription for an individual patient with acute pain are poorly understood and inadequately quantified.

Importance

Opioids are commonly prescribed in EDs. One study found that nationally, 14% of ED patients were discharged with a prescription for an opioid.[7] In one multicenter ED-based study, 17% of discharged patients received an opioid to treat pain.[8] Prospective data about the long-term risks of an opioid prescription for ED patients with acute pain are

Volume ■, no ■ : ■ 2019 Annals of Emergency Medicine 1

Benjamin W. Friedman, MD, MS, et al., *Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study*, Annals of Emergency Medicine (2019) https://www.annemergmed.com/article/S0196-0644(19)31134-5/pdf

2007 Study: Only a Small Percentage of Patients Entering Addiction Treatment Used OxyContin — And Most of Those Were Illicit Users

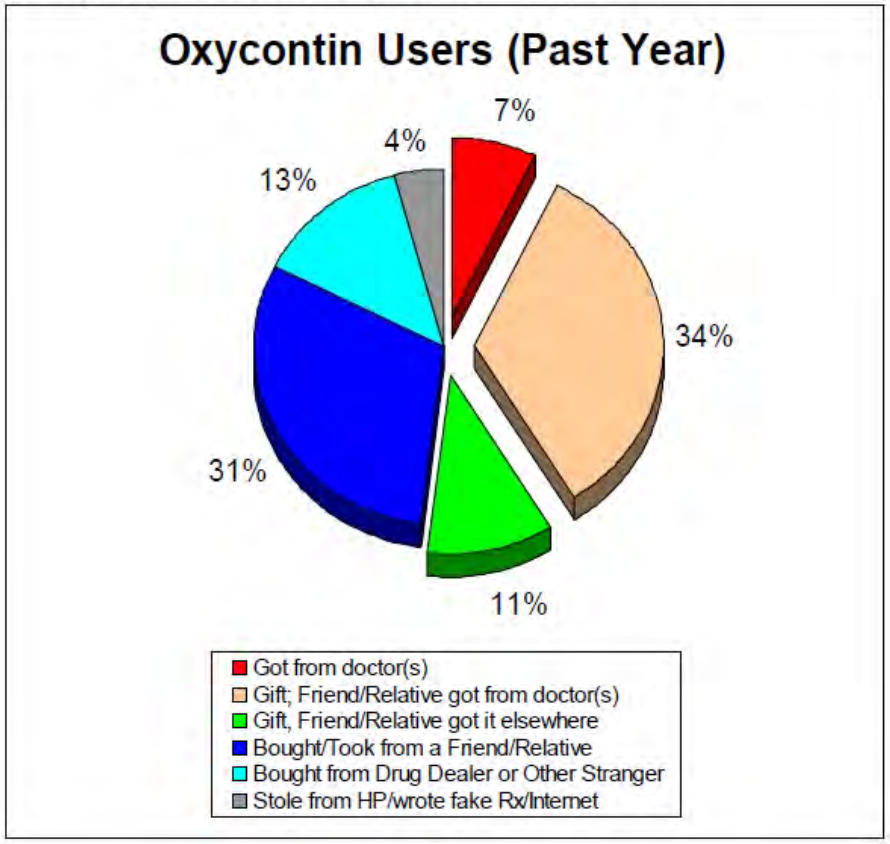
- A 2007 study found that 5% of 27,816 subjects admitted to 157 addiction treatment programs reported prior use of OxyContin.
- 78% of them also reported that OxyContin had not been prescribed to them for any medical reason.

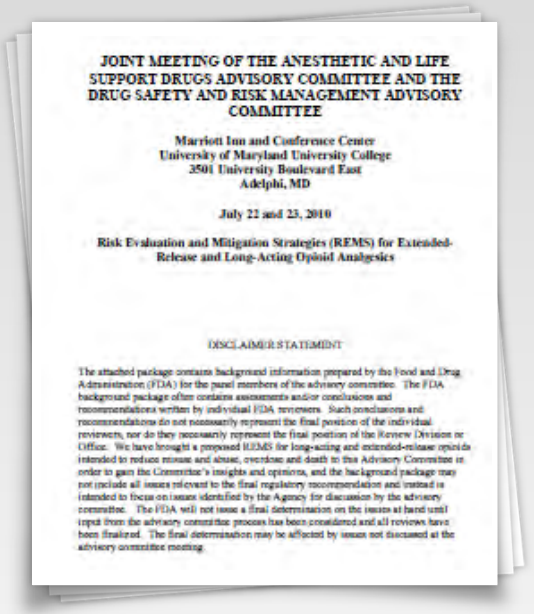
Source: Deni Carise, Ph.D., et al., *Prescription OxyContin Abuse Among Patients Entering Addiction Treatment*, American Journal of Psychiatry, Nov. 2007; 164(11):1750-1756

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2785002/

2008 SAMHSA Survey: Only 7% of OxyContin Abusers Obtained Their Drugs from A Doctor

Figure 1: Sources of OxyContin for recent non-medical use among OxyContin users, NSDUH Survey 2008





JOINT MEETING OF THE ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

Marriott Inn and Conference Center
University of Maryland University College
3501 University Boulevard East
Adelphi, MD

July 22 and 23, 2010

Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics

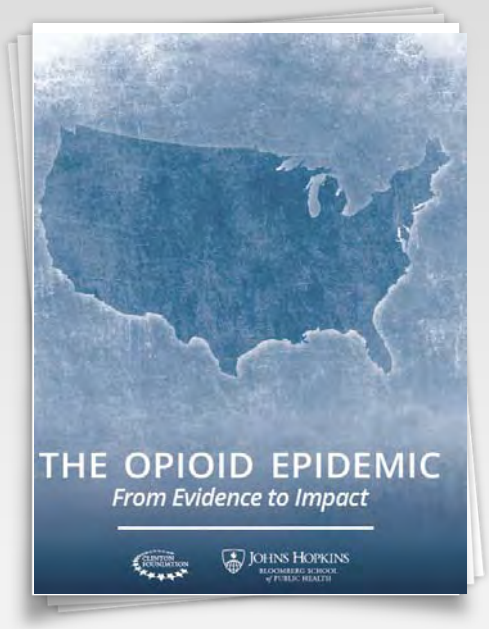
DISCLAIMER STATEMENT

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often contains assessments and/or conclusions and recommendations written by individual FDA reviewers. Such conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office. We have brought a proposed REMS for long-acting and extended-release opioids intended to reduce misuse and abuse, overdose and death to this Advisory Committee in order to gain the Committee's insights and opinions, and the background package may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the advisory committee. The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the advisory committee meeting.

July 22-23, 2010 Joint Meeting of the FDA Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Mgmt. Advisory Committee , *Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics* (PPLP003366082, at -089)

2016 Johns Hopkins/Clinton Foundation Report: 70% of Abusers Illegally Obtain Opioids From Friends And Family

Most patients fail to store opioid products in locked locations, including patients with children and adolescents who are particularly vulnerable to risks of opioid misuse and overdose. Many patients also retain unused opioids instead of disposing with them.... Collectively, these practices create household reservoirs of opioids that facilitate misuse and diversion all across America. In some cases, prescription opioids are diverted intentionally, while in other cases, they are used without the knowledge of the person for whom they were prescribed. Approximately 70 percent of people who report non-medical use of prescription opioids state their most recently used drug came from a friend or family member.



https://www.jhsph.edu/events/2017/americas-opioid-epidemic/report/2017-JohnsHopkins-Opioid-digital.pdf

Problem #5:

Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

2020 FDA Letter to Senator Maggie Hassan:

"Multiple patient factors that have an association with opioid overdose (e.g., mental health diagnoses, family history of substance use disorder) may have as strong or stronger association that the magnitude of association for a higher-dose vs. lower-dose opioid analgesic prescription." (Page 13)

https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf

Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

Among many other factors Claimants ignore:

- Family members and other unauthorized users unlawfully accessing lawfully-prescribed pills
- Individual patients' responses to opioids
- Patients not taking the drugs as prescribed
- Rogue doctors overprescribing for personal financial gain
- Illegal diversion and sale on the black market
- Socioeconomic factors

Claimants Ignore Numerous Other Factors Causing Their Claimed Injuries

Socioeconomic factors:

1. Diminishing job opportunities for the least educated
2. The dissolution of stable family structures
3. Lack of access to proper physical and mental healthcare
4. The growing isolation of many individuals from the broader community

See, e.g., NAT'L INST. ON MINORITY HEALTH AND HEALTH DISPARITIES, *The Drug Overdose Epidemic Affects All Communities*, NIH.GOV (Oct. 25, 2019), https://nimhd.nih.gov/news-events/features/community-health/overdose-epidemic.html ("**the opioid crisis may be part of a larger, longer-term process. Economic, sociological, and psychological factors, such as despair, loss of purpose, and dissolution of communities, may be at work to accelerate the crisis**."); Jalal, *et al.*, *Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016*, 361 SCIENCE 1218 (Sep. 21, 2018) ("**Sociological and psychological 'pull' forces may be operative to accelerate demand, such as despair, loss of purpose, and dissolution of communities**.").

Problem #6:

Claimants Cannot Establish Their Injuries Were Caused By Purdue Opioids, As Opposed To Other Manufacturers'

Claimants Impermissibly Lump Together All Opioid Manufacturers

Claimants' experts in the MDL did not attempt to analyze the impact of any individual opioid manufacturer's alleged unlawful conduct:

Rosenthal

"My model … is not designed to assign liability to individual manufacturers …."

Rosenthal Dep. Tr. 164:4-9 (MDL Dkt. #1984-4)

Cutler

"[My model] is attributing the harm to the defendants as a whole. It is not attributing it to any specific defendant."

Cutler Dep. Tr. 68:14–69:3 (MDL Dkt. # 1976-9)

"I made no attempt to calculate the proportion of fault due to any individual defendant."

Id. at 57:12-16

Claimants Impermissibly Lump Together All Opioid Manufacturers

Claimants must show that the specific conduct of each opioid manufacturer proximately caused each of their injuries.

RESTATEMENT (SECOND) TORTS §432(2)

Where there is concurrent conduct by more than one actor, to show the conduct of each was independently sufficient to cause *"the harm,"* there needs to be sufficient evidence that each actor's conduct would have ***by itself*** constituted a ***substantial factor*** in bringing about *"the harm"*

Cresser v. Am. Tobacco Co., 174 Misc.2d 1, 4 (Sup. Ct. Kings Cty. 1997)

Dismissing complaints naming multiple cigarette manufacturers as defendants in products liability actions that did not specify the brand or brands of cigarettes that were smoked

Pang v. Minch, 559 N.E.2d 1313, 1324 (Ohio 1990)

"The burden of proof is upon the plaintiff to demonstrate that the conduct of ***each defendant*** was a substantial factor in producing the harm"

Claimants Impermissibly Lump Together All Opioid Manufacturers

1. Claimants have no evidence that would allow a fact-finder to determine that alleged wrongful conduct by Purdue — let alone the Individuals — was a substantial factor in bringing about their alleged harm
2. The Manufacturer Defendants' products are not interchangeable
   - They vary widely in their approved indications, formulation, and potency
   - They are distinctly labeled and easily traceable
   - OxyContin's extended-release abuse-deterrent formulation distinguishes it from most opioids on the market
3. The Manufacturer Defendants are competitors who employed differing marketing strategies over different periods for their different opioid products

Claimants Impermissibly Lump Together All Opioid Manufacturers

Claimants never analyzed the effect of each manufacturer's allegedly wrongful conduct.

- Rosenthal's model *"is intended to, and does, capture the* ***average effect of all detailing****"* — across Defendants and non-defendants, and without regard to whether any fraud occurred in a particular interaction.

See Rosenthal Daubert Opp'n at 11 (MDL Dkt. # 2176)

At most the model is capable of measuring the total effect of all the detailing by all manufacturers, whether or not Plaintiffs sued them — not the contribution of Purdue's detailing.

- Plaintiffs' expert Cutler also admitted that he had *"****not done anything with respect to any specific defendant.****"*

4/26/2019 Cutler Dep. Tr. 68:12-13 (MDL Dkt. # 1961-9/1976-9)

Market Share Theory Of Causation Fails On The Facts

This *"extraordinary"* doctrine requires fungibility and equal degrees of risk

See Hamilton v. Beretta U.S.A. Corp., 96 N.Y.2d 222, 240 (2001)

*"**[C]ourts in New York and other jurisdictions have refused to extend the market share theory where [1] products were not fungible and [2] differing degrees of risk were created**."*

Hamilton refused to apply the market share theory because [1] guns are not *"fungible,"* since *"it is often possible to identify the caliber and manufacturer of the handgun that caused injury to a particular plaintiff,"* and [2] *"[e]ach manufacturer engaged in different marketing activities that allegedly contributed to the illegal handgun market in different ways and to different extents."*

Id. at 242; 240-41

Market Share Theory Of Causation Fails On The Facts

1. The Manufacturer Defendants' products are not interchangeable
    - They vary widely in their approved indications, formulation, and potency
    - They are distinctly labeled and easily traceable to a manufacturer
    - OxyContin's extended-release abuse-deterrent formulation distinguishes it from most opioids on the market
2. The Manufacturer Defendants are competitors and employed different marketing strategies over different periods to promote different opioids

Problem #7:

States, Municipalities And Other Claimants Continue To Approve And Reimburse Opioid Prescriptions

This Precludes Any Claim That Purdue's Alleged Misrepresentations Were Material To Claimants' Reimbursement Decisions

Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP, 136 A3d 688, 696 (Del. 2016) (analyzing New York law)

"[Third-party payors] who continue to pay or reimburse for [a medication], while claiming they were harmed by allegedly false advertising, are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it. They were injured by their own conduct."

See also Clearmont Prop., LLC v. Eisner, 58 A.D.3d 1052, 1056 (3rd Dept. 2009); *Barrett v. Huff*, 6 A.D.3d 1164, 1167 (4th Dep't 2004)

Problem #8:

Individuals Did Not Make Or Participate In Making Any Of The Purported Misstatements Allegedly Causing Claimants' Losses

Directors Are Not Liable For A Tort Committed By Their Company Unless They Personally Participated In It

Lloyd v. Moore, 115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dept 2014)	Defendant "cannot be held individually liable to plaintiff" if he "did not personally participate in malfeasance or misfeasance constituting an affirmative tortious act."
Bernstein v. Starrett City, Inc., 303 A.D.2d 530, 532 (N.Y. App. Div., 2d Dept 2003)	"[A] corporate officer may not be held liable for the negligence of the corporation merely because of his or her official relationship to it."
MLM LLC v. Karamouzis, 2 A.D.3d 161, 161-62 (N.Y. App. Div., 1st Dept 2003)	Challenged "conduct amounts, at most, to nonfeasance, for which defendant is not liable."
Wesolek v. Jumping Cow Enters., Inc., 51 A.D.3d 1376, 1379 (N.Y. App. Div., 4th Dept 2008)	Sole shareholder and director not liable for company's alleged negligence "as a matter of law."
3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS §1137 (2019)	Corporate director "is not personally liable for torts of the corporation . . . merely by virtue of holding corporate office, but can only incur personal liability by participating in the wrongful activity."

The Individuals Did Not Make Or Participate In Any Of The Purported Misstatements That Allegedly Caused Claimants' Losses

The Individuals did not participate in any allegedly misleading marketing during the relevant post-2007 period

- They did not personally participate in drafting or approving the content of any marketing or advertising material
- They did not approve any allegedly deceptive marketing statements made to prescribers
- They reasonably relied on management reports, advice of outside compliance counsel, internal corporate reviews and audits, compliance monitoring, and assurances from a federal monitor in coming to the understanding that Purdue's marketing was in compliance with law
- This is demonstrated in detail in **Defense Presentation Part 2: Marketing Claims**

Problem #9:
Diversion Control Claims

Claimants Claim Defendants Flooded The Market With Opioids

Defendants Flooded Plaintiff Counties with Suspiciously Large Amounts of Opioids

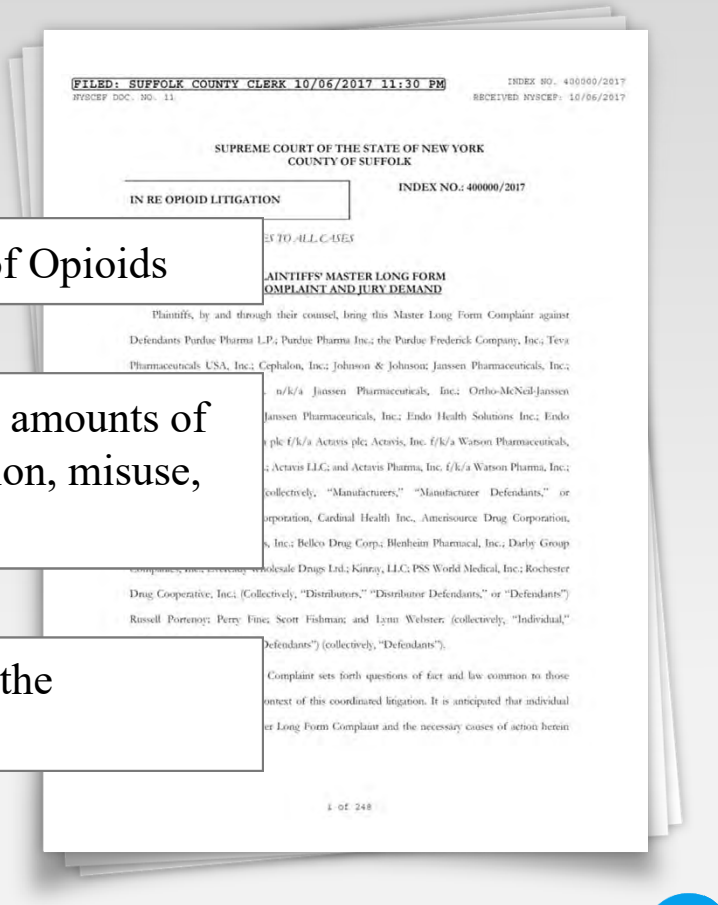
MLFC pp. 219-220, Facts Sub-heading

The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs Plaintiffs' counties that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

MLFC ¶744

The Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

MLFC ¶745


FILED: SUFFOLK COUNTY CLERK 10/06/2017 11:30 PM INDEX NO. 400000/2017
NYSCEF DOC. NO. 11 RECEIVED NYSCEF: 10/06/2017

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

IN RE OPIOID LITIGATION

INDEX NO.: 400000/2017

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; the Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo ple f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, ; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; collectively, "Manufacturers," "Manufacturer Defendants," or orporation, Cardinal Health Inc., Amerisource Drug Corporation, , Inc.; Bellco Drug Corp.; Blenheim Pharmacal, Inc.; Darby Group wholesale Drugs Ltd.; Kinray, LLC; PSS World Medical, Inc.; Rochester Drug Cooperative, Inc.; (Collectively, "Distributors," "Distributor Defendants," or "Defendants") Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster; (collectively, "Individual," Defendants") (collectively, "Defendants").

Complaint sets forth questions of fact and law common to those ontext of this coordinated litigation. It is anticipated that individual er Long Form Complaint and the necessary causes of action herein

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Purdue's 2020 Guilty Plea And Civil Settlement Do Not Establish Diversion-Control Failures As Against The Individuals

- Purdue's plea and settlement have no collateral estoppel effect against former directors who had no control over Purdue when it agreed to enter into them

  Stichting Ter Behartiging Van de Belangen Van Oudaandeelhouders In Het Kapitaal Van Saybolt Int'l B.V. v. Schreiber, 327 F.3d 173, 184, 186 (2d Cir. 2003)

- None of the facts Purdue pled to was litigated, and Purdue denied all other facts alleged in its civil settlement. Those are inadmissible under Fed. R. Evid. 408
- In approving Purdue's entry into the plea agreement and civil settlement, the Bankruptcy Court did not find that any of the allegations admitted or denied by Purdue was true — the merits of DOJ's claims were not litigated
- Neither the plea nor the settlement is even final — both are conditioned on the Plan's providing that Purdue will emerge as a public benefit company
- Claimants must prove their claims of diversion-control failure against the family

Claimants' Diversion Control Claims Causation Burden

To establish proximate cause for their diversion-control claims, Claimants must prove:

1	2	3	4
Purdue's diversion-control failures – as opposed to other manufacturers' or distributors'	Caused excess shipments of Purdue's opioids into the relevant jurisdiction	The *"excess"* shipments were diverted for non-medical use	The non-medical use of the diverted medications caused them direct harm

- **Claimants must then prove the Individuals personally participated in the diversion control failures**

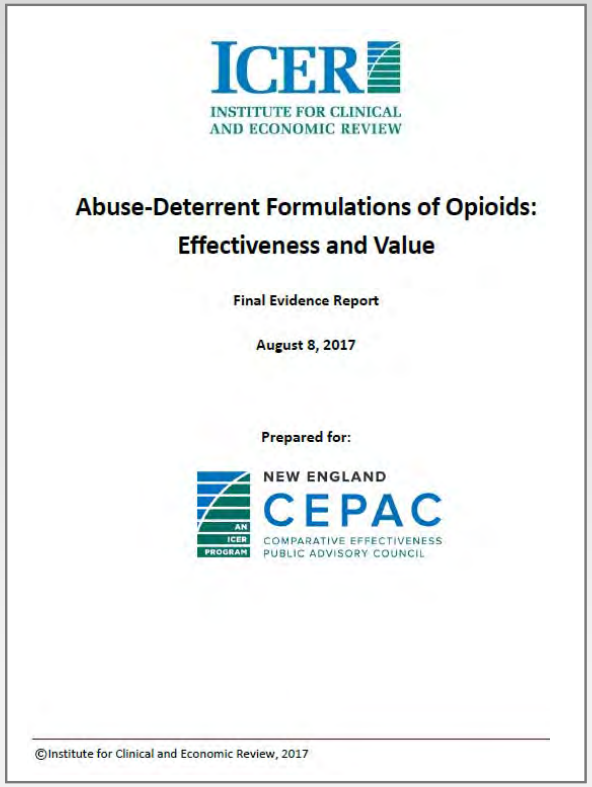
Diversion Control Claims Fail For Lack Of Causation

- Claimants cannot prove:
  - That any failure by Purdue to control the distribution of prescription opioids caused excess shipments of Purdue opioids into the relevant jurisdiction
  - That these excess shipments were used diverted for non-medical use
  - That these diverted medications caused them harm and
  - That this harm occurred during the relevant limitations period

Claimants Cannot Prove They Were Harmed By Any Allegedly "Excess" Shipments Diverted For Non-Medical Use

The volume of prescription opioids diverted annually for non-medical use is extremely difficult to estimate.

Institute for Clinical and Economic Review, *Abuse-Deterrent Formulations of Opioids: Effectiveness and Value: Final Evidence Report* (Aug. 8, 2017), available at www.https//necepac_adf_final_report_08_08_17.pdf


ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Abuse-Deterrent Formulations of Opioids: Effectiveness and Value

Final Evidence Report

August 8, 2017

Prepared for:

NEW ENGLAND CEPAC
COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL

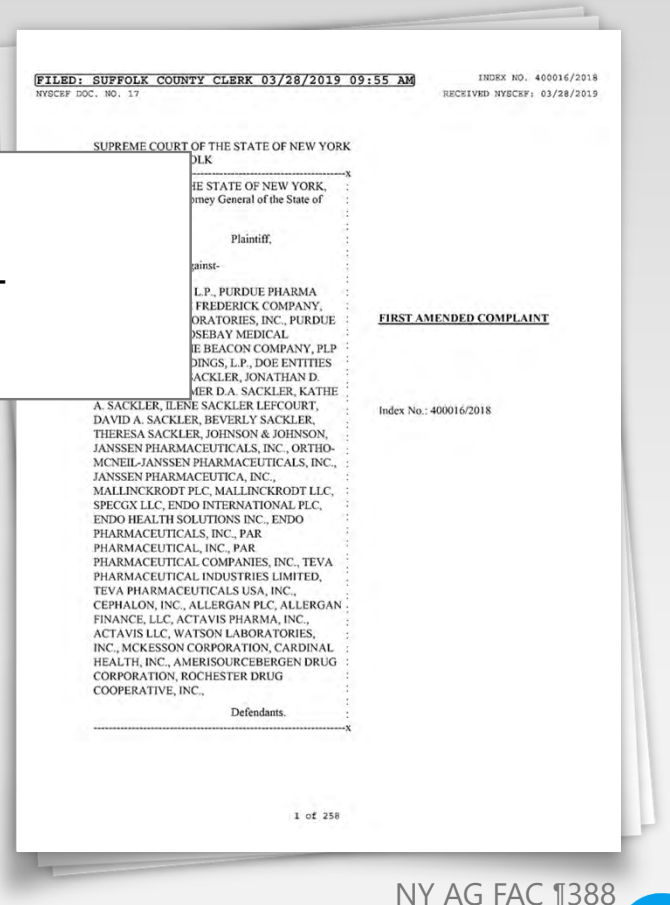
©Institute for Clinical and Economic Review, 2017

Diversion Control Claims Against The Individuals Fail For Lack Of Personal Participation

New York AG FAC ¶388:

388. For example, the Sacklers oversaw: . . .

- Purdue's improper response to signs of 'abuse and diversion' by high-prescribing doctors.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NYSCEF DOC. NO. 17 RECEIVED NYSCEF: 03/28/2019

SUPREME COURT OF THE STATE OF NEW YORK
OLK

HE STATE OF NEW YORK,
orney General of the State of

Plaintiff,

gainst-

L.P., PURDUE PHARMA
FREDERICK COMPANY,
ORATORIES, INC., PURDUE
SEBAY MEDICAL
E BEACON COMPANY, PLP
DINGS, L.P., DOE ENTITIES
ACKLER, JONATHAN D.
MER D.A. SACKLER, KATHE
A. SACKLER, ILENE SACKLER LEFCOURT,
DAVID A. SACKLER, BEVERLY SACKLER,
THERESA SACKLER, JOHNSON & JOHNSON,
JANSSEN PHARMACEUTICALS, INC., ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC.,
JANSSEN PHARMACEUTICA, INC.,
MALLINCKRODT PLC, MALLINCKRODT LLC,
SPECGX LLC, ENDO INTERNATIONAL PLC,
ENDO HEALTH SOLUTIONS INC., ENDO
PHARMACEUTICALS, INC., PAR
PHARMACEUTICAL, INC., PAR
PHARMACEUTICAL COMPANIES, INC., TEVA
PHARMACEUTICAL INDUSTRIES LIMITED,
TEVA PHARMACEUTICALS USA, INC.,
CEPHALON, INC., ALLERGAN PLC, ALLERGAN
FINANCE, LLC, ACTAVIS PHARMA, INC.,
ACTAVIS LLC, WATSON LABORATORIES,
INC., MCKESSON CORPORATION, CARDINAL
HEALTH, INC., AMERISOURCEBERGEN DRUG
CORPORATION, ROCHESTER DRUG
COOPERATIVE, INC.,

Defendants.

FIRST AMENDED COMPLAINT

Index No.: 400016/2018

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NY AG FAC ¶388

Diversion Control Claims Against The Individuals Fail For Lack Of Personal Participation

- Claimants have no evidence tying any Individual to any alleged diversion-control failure
- The Individuals did not personally participate in Purdue's anti-diversion activities
- They responsibly monitored the anti-diversion activities, relying on extensive information provided by management and corporate systems in place at Purdue to prevent diversion
- This is demonstrated in detail in **Defense Presentation Part 3: Negligent Diversion Claims**

Problem #10:

Municipal Cost Recovery Rule Bars Lawsuits For Local Government Expenditures In Many Jurisdictions

The Municipal Cost Recovery (Free Public Services) Rule

Many jurisdictions recognize the municipal cost recovery rule, which bars local government entities from bringing lawsuits to recover for their expenditure on government services

New York:

County of Erie v. Colgan Air, Inc., 711 F.3d 147, 150–51 (2d Cir. 2013)

Municipal cost recovery *"doctrine plainly bars the County's claims to recover public expenditures."*

Matter of James AA, 188 A.D.2d 60, 63–64 (3d Dep't 1993)

Rule is *"longstanding and still applicable."*

Koch v. Consol. Edison Co. of N.Y., 62 N.Y.2d 548, 560 (1984)

Rule prevented New York City from recovering *"expenditures made in the performance of governmental functions"* during the blackout of 1977.

The Municipal Cost Recovery Rule

Massachusetts:

Town of Freetown v. New Bedford Wholesale Tire, 384 Mass. 60, 61 (1981)

Free public services rule barred town's attempt to recover costs of its expenses arising from defendants' *"negligently dump[ing]"* used tires on town land *"creating a nuisance"*

The Municipal Cost Recovery Rule

County of Erie v. Colgan Air, Inc., 711 F.3d 147 (2d Cir. 2013)

County of Erie held there ***"could not, strictly speaking, be a general public nuisance exception"*** **to the municipal cost recovery rule** ***"because it would be the exception that swallows the rule****, since many expenditures for public services could be re-characterized by skillful litigants as expenses incurred in abating a public nuisance."*

Id. at 153

County of Erie recognized that municipalities have a statutory right to recover the costs for abating certain public nuisances under N.Y. PUB. HEALTH LAW §1306, when they are recovering the costs of performing a third-party's (normally the property owner's) costs. *Id.* at 153

But N.Y. PUB. HEALTH LAW §1306 does not apply because the New York municipalities are trying to recover **the costs of performing government services.**

Problem #11:

Derivative-Injury Rule Bars Claimants' Third Party Payer Claims

Derivative-Injury Rule Bars Claimants' Third-Party Payer Claims

Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc., 3 N.Y.3d 200, 206 (2004)

"[A]n insurer or other third-party payer of medical expenditures may not recover derivatively for injuries suffered by its insured." Its "sole remedy is in equitable subrogation…."

- Claimants have made no subrogation claims.
- This bars, at a minimum, the claims for recoupment of medical and drug costs incurred by the Claimants' employees and Medicaid beneficiaries.

Statutory Consumer Fraud Claims

Statutory Marketing Claims: 7 Principal Problems

1. Extraterritoriality
2. Statutes of Limitations Barring Recovery for Pre-2007 Conduct
3. No Personal Participation in Post-2007 Conduct
4. Purdue's Post-2007 Marketing Was Not Deceptive
5. Preemption
6. No Scienter
7. First Amendment

Problem #1: Extraterritoriality

States Cannot Enforce Their Laws Extraterritorially

Watson v. Emp'rs Liab. Assurance Corp.,
348 U.S. 66, 70 (1954)

"[A] state is without power to exercise 'extraterritorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries."

BMW of North America, Inc. v. Gore,
517 U.S. 559, 585 (1996)

A single State may not "impos[e] its regulatory policies on the entire Nation."

Shaffer v. Heitner,
433 U.S. 186, 197 (1977)

"Any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would offend sister States and exceed the inherent limits of the State's power."

Bristol-Myers Squibb Co. v. Superior Court of Cal.,
137 S. Ct. 1773, 1780 (2017)

The due-process limits on "the coercive power of a State" over non-resident litigants are "a consequence of territorial limitations on the power of the respective States."

Each State Must Establish Personal Jurisdiction Over Each Defendant

Bristol-Myers Squibb Co. v. Superior Court of Cal., 137 S. Ct. 1773, 1781–82 (2017)	No personal jurisdiction over manufacturer that operated laboratories and had hundreds of employees in state where plaintiffs' claims did not arise out of or relate to manufacturer's contacts with state
BNSF Ry. Co. v. Tyrrell, 137 S. Ct. 1549, 1554 (2017)	No personal jurisdiction over railroad with over 2,000 miles of track in state because claims were unrelated to any activity occurring within the state
Walden v. Fiore, 571 U.S. 277, 291 (2014)	No personal jurisdiction over defendant whose conduct was not in or directed at the forum state, even though the foreseeable effects of defendant's conduct were felt in the forum state
Daimler AG v. Bauman, 571 U.S. 117, 136-39 (2014)	No personal jurisdiction over parent auto manufacturer with wholly-owned subsidiary that was the largest supplier of luxury vehicles in state because claims did not arise from parent's contacts with state
Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915, 930 (2011)	No personal jurisdiction over company that regularly sold products in state because claims did not arise from those sales
J. McIntyre Mach., Ltd. v. Nicastro, 564 U.S. 873, 886-87 (2011)	No personal jurisdiction over manufacturer of a product sold by a different company to a customer in the state, where manufacturer targeted the United States market as a whole but not the specific state

Personal Jurisdiction Requires Purposeful Availment

Each State must show both that:

1. **Each individual defendant "purposefully reached out beyond [his or her] State and into another," and** (*Walden v. Fiore*, 571 U.S. at 285)

2. **The claim against the individual "arise[s] out of or relate[s] to the defendant's contacts with the forum"** (*Bristol-Myers Squibb*, 137 S. Ct. at 1780; *Ford Motor Co. v. Mont. 8th Judicial Dist. Court*, 141 S.Ct. 1017, 1025 (2021))

Five Threshold Personal Jurisdiction Problems

1. **No personal jurisdiction over a director or shareholder based on conduct of the corporation**

Keeton v. Hustler Magazine, Inc., 465 U.S. 770, 781 n.13 (1984)

> ***"[J]urisdiction over an employee does not automatically follow from jurisdiction over the corporation which employs him ...."***

5 Threshold Personal Jurisdiction Problems

2. No personal jurisdiction over a director in any particular state based on corporation's nationwide marketing

Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 780 (3d Cir. 2018)	"**What is necessary is a deliberate targeting of the forum**, so efforts to exploit a national market that necessarily included [the state] are insufficient" to establish jurisdiction in the state
Mouzon v. Radiancy, Inc., 85 F. Supp. 3d 361, 372 (D.D.C. 2015)	**No personal jurisdiction over a CEO "[e]ven if [he] played a central and dominant part" in the campaign and "directly profited" from it because plaintiffs "ha[d] not alleged that [he] himself targeted" the marketing campaign to the forum (D.C.)**
Fasugbe v. Willms, 2011 WL 3667440, at *3-4 (E.D. Cal. Aug. 22, 2011)	**Allegations that CEO was the "guiding spirit" behind corporation's alleged false advertising insufficient to establish personal jurisdiction**
Delman v. J. Crew Grp., Inc., 2017 WL 3048657, at *2 (C.D. Cal. May 15, 2017)	**No personal jurisdiction over CEO whom plaintiffs alleged was "hands-on micro-manager of the [corporation]", "acutely aware of pricing and marketing policy" and "only one of two [executives] having any operational responsibility"**
Federated Rural Elec. Ins. Corp. v. Kootenai Elec. Coop., 17 F.3d 1302, 1305 (10th Cir. 1994)	Advertising "in nationally distributed papers or journals does not rise to the level of purposeful contact with a forum required by the Constitution in order to exercise personal jurisdiction over the advertiser"

5 Threshold Personal Jurisdiction Problems

3. Corporate officers and employees are agents of the Company, not agents of the directors or owners

3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS §1066 (2019)

"[O]fficers and agents are not agents of the directors but are agents of the corporation."

Karabu Corp v. Gitner,
16 F. Supp. 2d 319, 324–25 (S.D.N.Y. 1998) (Sotomayor, D.J.)

Under an agency analysis, allegations that corporate officers "directed" corporate conduct were insufficient to establish personal jurisdiction

Gerstle v. Nat'l Credit Adjusters,
76 F. Supp. 3d 503, 510 (S.D.N.Y. 2015)

Under an agency analysis, "generalizations that [corporate officers] 'oversaw' or 'authorized' 'illegal policies' not described in any factual detail" insufficient

5 Threshold Personal Jurisdiction Problems

4. The corporation is not the agent of the directors — the directors are agents of the corporation

In re Banco Santander Sec.-Optimal Litig., 732 F. Supp. 2d 1305, 1326 (S.D. Fla. 2010), *aff'd*, 439 F. App'x 840 (11th Cir. 2011)	No personal jurisdiction over corporate directors on an agency theory where plaintiffs "do not specify any actions that the directors took that would alter the standard legal presumption that directors and officers are agents of the corporation, not the other way around"
Twin-Lick Oil Co. v. Marbury, 91 U.S. 587, 589 (1875)	"The directors are the officers or agents of the corporation"
Crowell v. Randell, 35 U.S. 368, 382 (1836)	Directors "are but agents of the corporation"
Topik v. Catalyst Research Corp., 339 F. Supp. 1102, 1106 (D. Md. 1972), *aff'd*, 473 F.2d 907 (4th Cir. 1973)	"[C]orporate employees who acted in [the state] were agents of the corporation and not agents of the individual directors"
Wilby v. Savoie, 86 A.3d 362, 375-76 (R.I. 2014)	Individuals, "as officers and directors [of a corporation] … were agents of [the corporation]"
Pritchard v. Myers, 174 Md. 66, 76 (1938)	"[T]he relation between a corporation and its directors is generally that of principal and agent."
Newman v. Forward Lands, Inc., 418 F. Supp. 134, 136 (E.D. Pa. 1976)	Directors "were merely agents of the corporation."

5 Threshold Personal Jurisdiction Problems

5. Receipt of a board report Is not conduct aimed at a particular State

Stewart v. Am Ass'n of Physician Specialists, Inc.,
2014 WL 2011799, at *4-5 (C.D. Cal. May 15, 2014)

"Mere knowledge" of wrongdoing by others in forum does not support jurisdiction.

Ontel Prod., Inc. v. Project Strategies Corp.,
899 F. Supp. 1144, 1149 (S.D.N.Y. 1995)

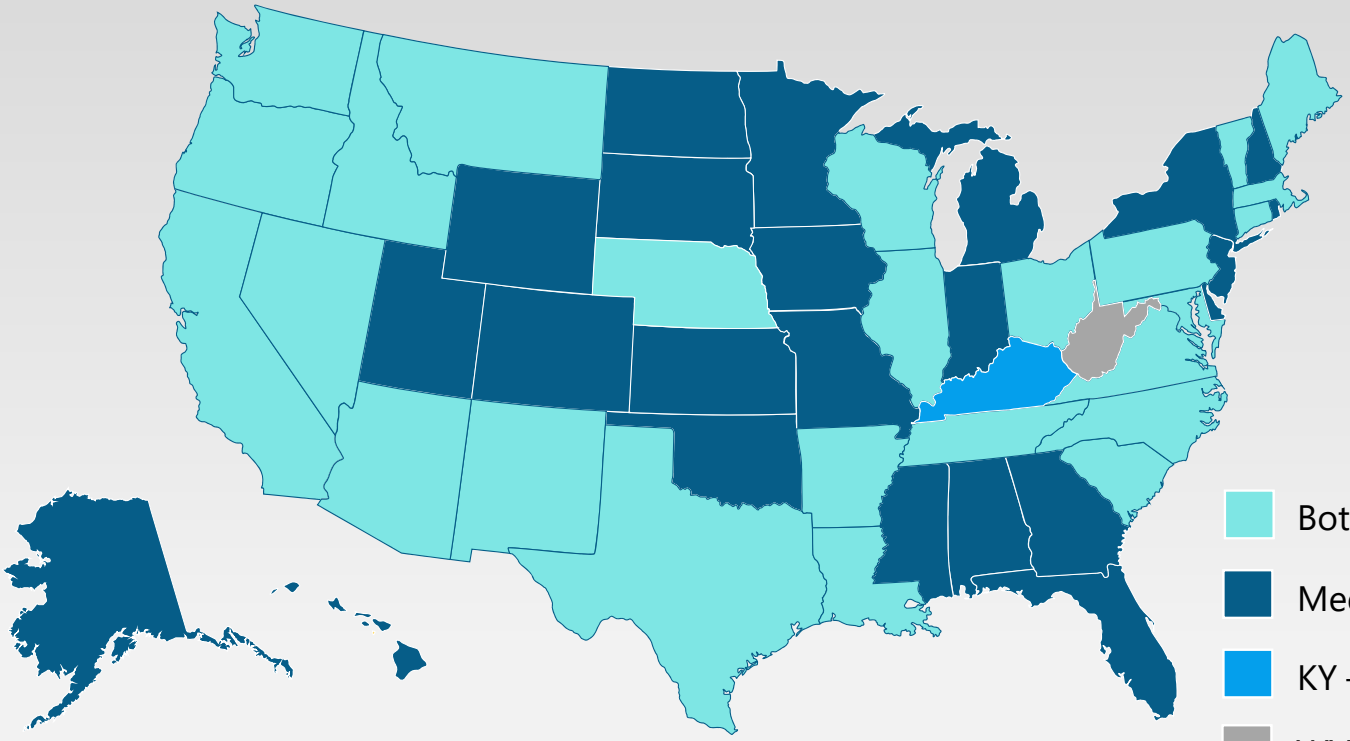
"It is not enough that [the defendant] likely possessed authority to direct all the activities that gave rise to this suit. If that were the case, the President of every company would be subject to jurisdiction in New York based on activities with which he or she had no personal involvement and over which he or she exercised no decision making authority."

Lavastone Capital LLC v. Coventry First LLC,
2015 WL 4940471, at *8 (S.D.N.Y. July 30, 2015)

"The fact that [the officer] had authority to approve … transactions is not sufficient without evidence that she actually exercised that authority with respect to transactions that are relevant to the claims at issue here."

Problem #2:
Statutes Of Limitations

2007 Settling Jurisdictions — Claims Before 2007 Have Been Released



Both Medicaid and Consent Judgment

Medicaid Claims Settlements

KY – Consent Judgment and 2015 Settlement

WV – 2004 Settlement

State Statutes Of Limitations Limit Claimants' Ability To Recover

- *E.g.*, The New York's GBL §§349 and 350 claims have 3-year statute of limitations
- *E.g.*, Massachusetts' claims have 3- and 4-year statutes of limitations
- No tolling doctrines apply
  - All States and the District of Columbia were aware by 2007 of issues relating to Purdue's opioid issues — they had settled claims for alleged Purdue misconduct
  - All States and the District of Columbia had contractual rights to demand additional information from Purdue at any time
  - Intense media coverage of Purdue's marketing and diversion issues dates to the turn of the century and has escalated exponentially over the years
  - There was nothing concealed about Purdue's marketing — it was sent to third parties

Problem #3:
No Personal Participation Post-2007

Directors Are Not Liable For Torts Committed By Their Company Unless They Personally Participated In It

3A FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS §1137 (2019)	**Corporate director "is not personally liable for torts of the corporation . . . merely by virtue of holding corporate office, but can only incur personal liability by participating in the wrongful activity."**
Lloyd v. Moore, 115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dept 2014)	**Corporate officer "cannot be held individually liable to plaintiff" if he "did not personally participate in malfeasance or misfeasance constituting an affirmative tortious act."**
Bernstein v. Starrett City, Inc., 303 A.D.2d 530, 532 (N.Y. App. Div., 2d Dept 2003)	"[A] corporate officer may not be held liable for the negligence of the corporation merely because of his or her official relationship to it."
MLM LLC v. Karamouzis, 2 A.D.3d 161, 161-62 (N.Y. App. Div., 1st Dept 2003)	Challenged "conduct amounts, at most, to nonfeasance, for which defendant is not liable."
Wesolek v. Jumping Cow Enters., Inc., 51 A.D.3d 1376, 1379 (N.Y. App. Div., 4th Dept 2008)	Sole shareholder and director not liable for company's alleged negligence "as a matter of law."

Awareness Of Misconduct Does Not Create Individual Liability

Reynolds v. Lifewatch, Inc.,
136 F. Supp. 3d 503, 526 (S.D.N.Y. 2015)

*"**In cases where courts have found individual defendants to have participated in the misrepresentations at issue, the complaints specifically alleged personal participation, rather than mere awareness or control.**"*

Lloyd v. Moore,
115 A.D.3d 1309, 1310 (N.Y. App. Div., 4th Dep't 2014)

"Plaintiff . . . submitted no evidence that defendant affirmatively created the dangerous . . . condition at the property or did anything to make it worse; at most, defendant merely failed to remedy the condition."

No Personal Participation In Any Alleged Post-2007 Mismarketing

- No participation in or approval of the content of marketing materials
- No participation in or approval of content of sales reps' presentations
- Directors reasonably relied on review of all marketing material reviewed by Legal, Medical Services and Regulatory Affairs
- Directors reasonably relied on audits of compliance program by outside counsel and by management
- Directors reasonably relied on reports from management that marketing was in compliance with all applicable state and federal law — and for 5 years, on a federal monitor's confirmation of Purdue's compliance with its Corporate Integrity Agreement

Problem #4:
Purdue's Post-2007 Marketing Was Not Deceptive

See **Defense Presentation Part 2**

Problem #5: Preemption

***See* Defense Presentation Part 5**

Problem #6:
No Scienter (No Intent to Deceive, Manipulate Or Defraud)

See Defense Presentation Parts 1, 2 and 3

Problem #6 – Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

Many statutes require the State to prove scienter or provide a good faith defense

- Mass. Gen. Laws Ann. ch. 93A, §4 permits civil penalties only "If the court finds that a person has employed any method, act or practice which he knew or should have known to be in violation of said section two."
- Utah's Consumer Sales Protection Act §13-11-4(2) requires a showing of an intent to deceive.
  - "[A] supplier commits a deceptive act or practice if the supplier knowingly or intentionally . . ."

Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

- The evidence proving the good faith of the Individuals is set forth in detail in Defense Presentation Parts 1 (Generally), 2 (Marketing) and 3 (Diversion)
- Purdue's marketing:
  - Is literally true
  - Is consistent with the FDA-approved label
  - Was reviewed by Medical, Legal and Regulatory Affairs and
  - Was submitted to the FDA for review before use

United States ex rel. Berg v. Honeywell Int'l,
740 F. App'x 535, 539 (9th Cir. 2018)

The fact that defendant showed the challenged calculations to the relevant government regulator "*negates scienter*."

Claimants Cannot Show That The Individuals Acted With An Intent To Deceive

- Purdue had an extensive compliance program
- The Board relied on Purdue's management to determine what marketing materials would say and to ensure that the marketing messages were:
  1. Consistent with FDA and other legal requirements, and
  2. Accurate and supported by appropriate science
- The Board was consistently informed, in quarterly compliance reports, that Purdue was in compliance with all state and federal laws
- For 5 years, the Board was informed that a federal monitor found Purdue in compliance with its Corporate Integrity Agreement, which was designed to ensure compliance with federal healthcare law

See Defense Presentation Part 1

Problem #7: First Amendment

First Amendment

Sorrell v. IMS Health, Inc.,
564 U.S. 552 (2011)

"***Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment***. . . . *[The] creation and dissemination of information are speech within the meaning of the [Constitution].*"

Miller v. California,
413 U.S. 15, 34 (1973)

Including speech with "*serious . . . scientific value*."

First Amendment

Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York,
447 U.S. 557, 564 (1980)

First Amendment protection applies to commercial speech, as long as it is "*neither misleading nor related to unlawful activity.*"

United States v. Caronia,
703 F.3d 149, 164 (2d Cir. 2012)

Government prohibition on accurate speech regarding "*off-label*" drug uses violated the First Amendment.

Public Nuisance

Public Nuisance: 7 Principal Problems

Problem #1:	Novel and Legally Flawed Theory
Problem #2:	Articulation of What the Nuisance Is
Problem #3:	Preemption
Problem #4:	Purdue's Marketing Was Not Deceptive
Problem #5:	Causation
Problem #6:	Claimants Cannot Establish that Purdue—Let Alone the Individuals—Played a Substantial Role in Creating a Nuisance
Problem #7:	Claims Against Purdue Do Not Create Claims Against Former Directors

Problem #1:
Novel And Legally Flawed Theory

Public Nuisance Claims Must Be Based On Interference With A Public Right

Restatement (Second) of Torts §821B (1979)

*"A public nuisance is an unreasonable interference with **a right common to the general public.**"*

Restatement (Second) of Torts §821B (1979)

*"**A public right is one common to all members of the general public. It is collective in nature** and not like the individual right that everyone has not to be assaulted or defamed or defrauded or negligently injured."*

Id., cmt. g

Public Nuisance Claims Are Not Traditionally Based On Impact Of Lawful Products On Individual Users

Claimants' theory of the opioid crisis is that individuals became addicted to or abused opioids that:

- They should not have been prescribed because of improper marketing or
- They should not have received as a result of illegal diversion

That is harm to individuals, not harm to "a right common to the general public"

These Public Nuisance Claims Are Novel And Legally Flawed

Tioga Pub. Sch. Dist. No 15 v. U.S. Gypsum Co., 984 F.2d 915, 920 (8th Cir. 1993)

Extending public nuisance laws to make a company that sells a lawful product liable **for what others do with the product** would expand public nuisance far law beyond its traditional limits:

> "*Nuisance thus would become a monster that would devour in one gulp the entire law of tort* ..." (reversing public nuisance claim arising from asbestos containing materials).

Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

City of Chicago v. Beretta U.S.A. Corp., 213 Ill.2d 351, 381–82, 432 (2004)

Lawful sale of **firearms** does not constitute a public nuisance (Illinois law).

The court would not recognize novel public nuisance claims: ***"Any change of this magnitude in the law affecting a highly regulated industry must be the work of the legislature, brought about by the political process, not the work of the courts."***

Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp., 273 F.3d 536, 540 (3d Cir. 2001)

Lawful sale of **firearms** does not constitute a public nuisance (New Jersey law).

Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

State v. Lead Indus. Ass'n, 951 A.2d 428, 456–57 (R.I. 2008)

Lead paint does not constitute a public nuisance.

Indep. Cty. v. Pfizer, Inc., 534 F. Supp. 2d 882, 890 (E.D. Ark. 2008), *aff'd* 552 F.3d 659 (8th Cir. 2009)

Dismissing public nuisance claims based on use of **FDA-approved over-the-counter cold medicine**: *"Because Defendants are not landowners, Plaintiffs cannot succeed on their public nuisance claim."*

Public Nuisance Law Does Not Reach What An Individual Does With A Lawful Product

People ex rel. Spitzer v. Sturm, Ruger & Co., 309 A.D.2d 91, 96–97, 105 (1st Dep't 2003)

Lawful sale of firearms does not constitute a public nuisance (New York law).

Warning that allowing public nuisance to create an end-run on product liability law would *"open the courthouse doors"* to a *"flood"* of challenges to *"countless … types of commercial enterprises"* marketing lawful, nondefective products.

City of Philadelphia v. Beretta U.S.A. Corp., 277 F.3d 415, 421 (3d Cir. 2002)

Lawful sale of **firearms** does not constitute a public nuisance (Pennsylvania law).

City of St. Louis v. Cernicek, 2003 WL 22533578, at *2 (Mo. Cir. Ct. Oct. 15, 2003)

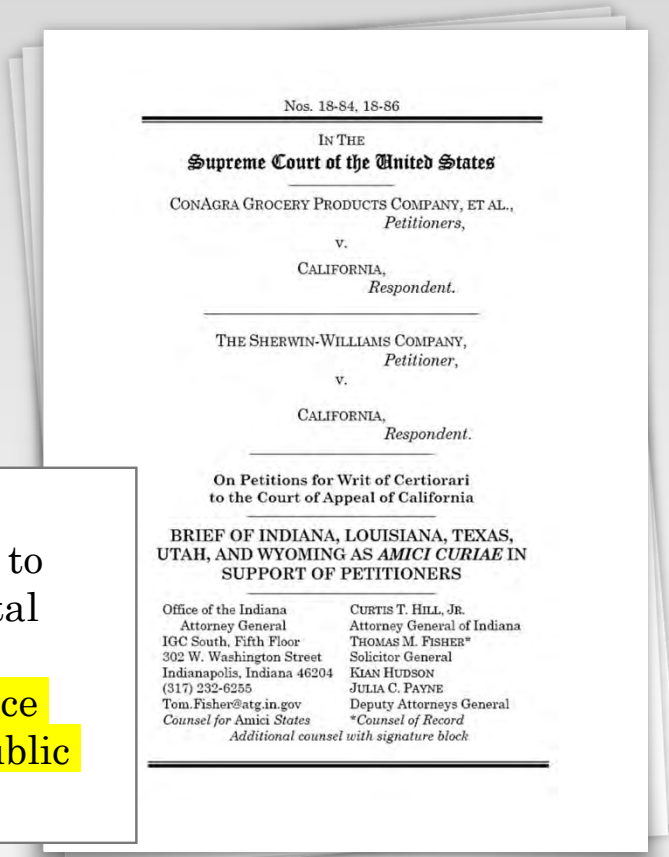
Lawful sale of **firearms** does not constitute a public nuisance (Missouri law).

Five States Recently Argued In The Supreme Court That Nuisance Law Does Not Apply To Products Claims

In 2018, five states argued in the Supreme Court that public nuisance laws cannot be stretched to convert products liability suits—based on the collective effect of harms to individuals—into public nuisance liability

Amicus brief of **Indiana**, **Louisiana**, **Texas**, **Utah** and **Wyoming**, in *ConAgra Grocery Products Company v. California*, No. 18-84 (U.S. Aug. 16, 2018):

> Public nuisance law is derived from hundreds of years of common law tradition. But in recent years, state and local governments have sought to use public nuisance lawsuits for a new purpose: to regulate broad societal problems through litigation or failing that, to enable mass transfers of wealth from industry to preferred groups. These new regulatory nuisance lawsuits drift far afield of the original common law understanding of public nuisance doctrine.



Nos. 18-84, 18-86

IN THE
Supreme Court of the United States

CONAGRA GROCERY PRODUCTS COMPANY, ET AL.,
Petitioners,
v.
CALIFORNIA,
Respondent.

THE SHERWIN-WILLIAMS COMPANY,
Petitioner,
v.
CALIFORNIA,
Respondent.

On Petitions for Writ of Certiorari
to the Court of Appeal of California

BRIEF OF INDIANA, LOUISIANA, TEXAS, UTAH, AND WYOMING AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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Deputy Attorneys General
**Counsel of Record*
Additional counsel with signature block

Amicus Brief of Indiana, Louisiana, Texas, Utah and Wyoming, in *ConAgra Grocery Products Company v. California*, No. 18-84 (U.S. Aug. 16, 2018) *Available at* https://tinyurl.com/nuisanceamicus.

Courts Have Rejected Public Nuisance Claims Against Purdue

State ex rel. Jennings v. Purdue Pharma L.P.,
2019 WL 446382, at *12 (Del. Super. Ct. Feb. 4, 2019)

Dismissing nuisance claim brought by Delaware Attorney General—noting *"a clear national trend to limit public nuisance to land use."*

State ex rel. Stenehjem v. Purdue Pharma L.P.,
2019 WL 2245743, *13 (D.N.D. May 10, 2019)

Dismissing public nuisance claim brought by North Dakota Attorney General—declining to *"extend[] the public nuisance statutes to cases involving the sale of goods,"* *and holding that "[t]he State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the 'overprescribing and sale' of opioids manufactured by Purdue."*

Courts Have Rejected Public Nuisance Claims Against Purdue

City of New Haven v. Purdue Pharma, L.P., 2019 WL 423990, at *4-6 (Conn. Super. Ct. Jan. 8, 2019)

Dismissing claims, including public nuisance claims, brought by local government under Connecticut law because the links between the alleged misconduct and the plaintiffs' expenditures are too attenuated.

Grewal v. Purdue Pharma L.P., 2018 WL 4829660, at *17-18 (N.J. Super. Oct. 2, 2018)

Dismissing New Jersey's public nuisance claim *"with prejudice for failure to state a claim"* as barred by the New Jersey Products Liability Act.

City of Everett v. Purdue Pharma L.P., 2017 WL 4236062, at *9 (W.D. Wash. Sept. 25, 2017)

Dismissing public nuisance claims brought by local government under Washington law: *"[T]he Court agrees with Purdue and will dismiss Everett's public nuisance claim for failure to allege a connection to property."*

Problem #2:

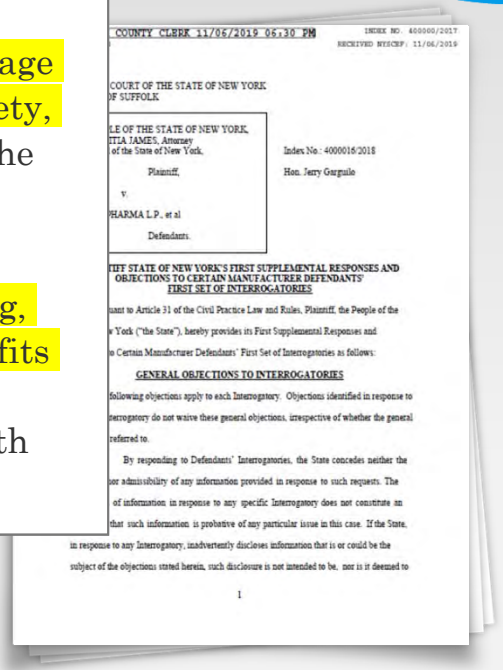
Because Claimants Do Not Allege A Conventional Public Nuisance, They Cannot Articulate What The Nuisance Is

What Is The Public Nuisance?

New York AG:

As used in these paragraphs, 'public nuisance' refers to this recognized cause of action and Defendants' conduct and omissions that have offended, interfered with, and/or caused damage to the public in the exercise of common rights, including, but not limited to, the health, safety, and comfort of a considerable number of people. In particular, through these paragraphs, the State has alleged that Defendants' conduct has caused and/or contributed to the current epidemic of opioid addiction in the State of New York.

This epidemic is marked by, inter alia, the following harms: the oversupply, overprescribing, and diversion of prescription opioids, inaccurate perceptions concerning the risks and benefits of opioids by both the public and the medical community, widespread prescription opioid misuse and opioid use disorder, neonatal-abstinence-syndrome births, opioid overdoses (both fatal and non-fatal), and increased rates of crime and incarceration.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COURT OF THE STATE OF NEW YORK
OF SUFFOLK

Index No.: 4000016/2018
Hon. Jerry Garguilo

PLAINTIFF STATE OF NEW YORK'S FIRST SUPPLEMENTAL RESPONSES AND OBJECTIONS TO CERTAIN MANUFACTURER DEFENDANTS' FIRST SET OF INTERROGATORIES

GENERAL OBJECTIONS TO INTERROGATORIES

People v. Purdue Pharma, L.P., Plaintiff State of New York's First Supplemental Response to Certain Manufacturer Defendants' First Set of Interrogatories at 7 (Oct. 29, 2019) (NYSCEF Doc. No. 1843)

What Is The Public Nuisance?

Identified harms:

- "the oversupply, overprescribing, and diversion of prescription opioids"
- "inaccurate perceptions concerning the risks and benefits of opioids by both the public and the medical community"
- "widespread prescription opioid misuse"
- "opioid overdoses"
- "increased rates of crime and incarceration"

"The Oversupply, Overprescribing, And Diversion Of Prescription Opioids"

Oversupply

- The supply of prescription opioids is set by the Drug Enforcement Agency
- The DEA can increase the annual production quota only if it determines that there is a legitimate medical need for that amount of the drug (21 C.F.R. §1303.11)
- Claimants cannot rely on Purdue's plea to prove fraud on the DEA or oversupply
- The plea and settlement have no collateral estoppel effect against former directors who had no control over Purdue when it agreed to enter into them (Defense Presentation Part 1)
- DOJ never alleged, and Purdue never admitted, that Purdue's fraud on the DEA had any effect on any quota the DEA set (Defense Presentation Part 5)
- DEA was at all times well aware that OxyContin was abused and diverted and took that into account in setting Purdue's opioid quota (Defense Presentation Part 5)

"The Oversupply, Overprescribing, And Diversion Of Prescription Opioids"

Overprescribing

Each prescription of opioids is given by a licensed doctor based on a determination that prescription opioids are appropriate for an individual patient.

- **The former Purdue Directors were not involved in this decision**
- **The prescribing doctors are all aware that prescription opioids have a high potential for addiction**
- **Under the learned intermediary doctrine, that severs the chain of causation.**

Bodie v. Purdue Pharma Co., 236 F. App'x 511, 521 (11th Cir. 2007)

"Because the evidence suggests that the learned intermediary, Dr. Mangieri, prescribed OxyContin ***based on his independent knowledge of the drug and its high potential for addiction,*** *we cannot conclude that the allegedly inadequate warning (that is, the claimed defect) proximately caused Bodie's injury of addiction."*

Bodie v. Purdue Pharma Co., 236 F. App'x 511, 521 (11th Cir. 2007)

"The Oversupply, Overprescribing, And Diversion Of Prescription Opioids"

Diversion

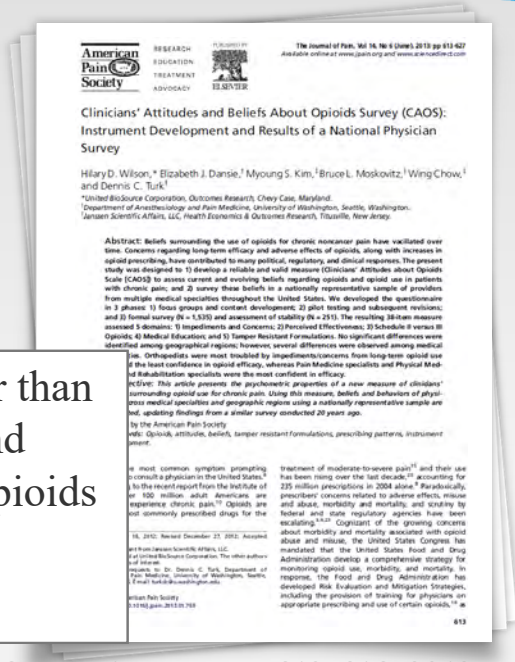
- Diversion of prescription opioids is a crime — the result of third-party criminal activity
- To avert diversion, Purdue implemented a Suspicious Order Monitoring (SOM) system in addition to its ADD Program and other anti-diversion programs
- The Board understood that Purdue vigorously implemented the SOM system, the ADD Program and all of its anti-diversion programs

March 2017 Ethics And Compliance Report at 49, 50, 53 (PPLP004413913); *see generally* Defense Presentation Part 3

"Inaccurate Perceptions" About Opioids

"Inaccurate Perceptions Concerning the Risks and Benefits of Opioids by Both the Public and the Medical Community"

- The New York AG's position is that ideas it disagrees *with* are a public nuisance
- No case holds that ideas can constitute a public nuisance
- The CDC 2016 Guidelines – which the New York AG relies on – cites studies showing that the medical community is aware of the risk of addiction and abuse associated with opioids


American Pain Society

Clinicians' Attitudes and Beliefs About Opioids Survey (CAOS): Instrument Development and Results of a National Physician Survey

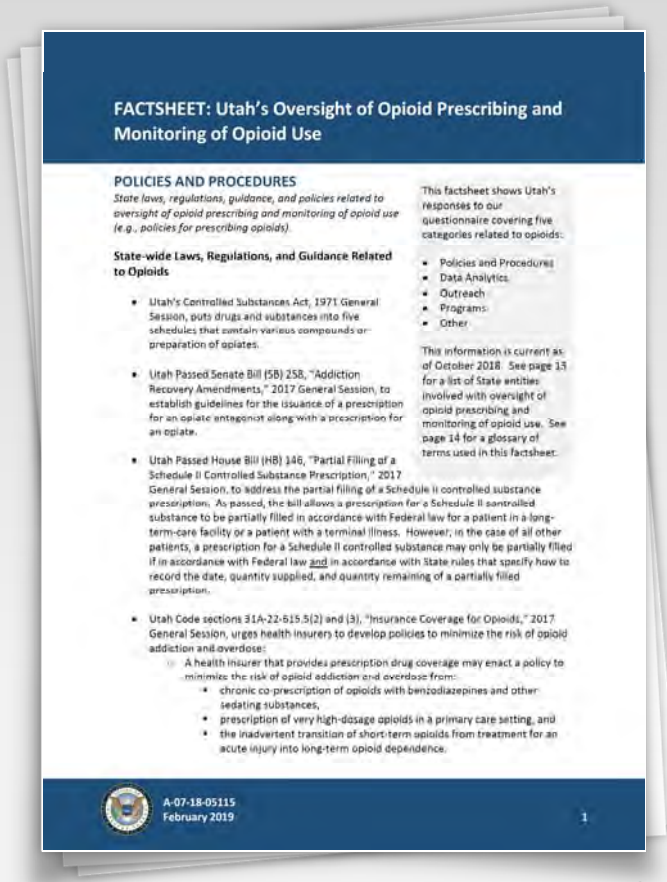
Hilary D. Wilson,* Elizabeth J. Dansie,† Myoung S. Kim,† Bruce L. Moskovitz,† Wing Chow,‡ and Dennis C. Turk†

Physicians strongly agreed that patients "sometimes take opioids for reasons other than pain" (mean = 7.42, SD = 2.24) and that "addiction" (mean = 7.43, SD = 2.16) and "physical dependence" (mean = 7.35, SD = 2.06) were "impediments to taking opioids for long periods of time." Moreover, physicians also strongly disagreed with the statement "Patients rarely misuse/abuse opioids" (mean = 3.37, SD = 2.36).

Hilary D. Wilson et al., *Clinicians' Attitudes and Beliefs about Opioids Survey*, 14 J. OF PAIN 613, 616 (2013).

No Need for Nuisance Remedy

- Governments can educate prescribers about opioids
  - *E.g.*, 2016 CDC Guidelines.
- States have mandatory education for prescribers
- The media has widely reported on abuse of and addiction
- Purdue does not control what highly educated and regulated prescribers know about prescription opioids
- The Individuals have no control over this
- The FDA-approved label provides all warnings deemed appropriate by the federal regulator charged with making that determination



FACTSHEET: Utah's Oversight of Opioid Prescribing and Monitoring of Opioid Use

POLICIES AND PROCEDURES

State laws, regulations, guidance, and policies related to oversight of opioid prescribing and monitoring of opioid use (e.g., policies for prescribing opioids).

State-wide Laws, Regulations, and Guidance Related to Opioids

- Utah's Controlled Substances Act, 1971 General Session, puts drugs and substances into five schedules that contain various compounds or preparation of opiates.
- Utah Passed Senate Bill (SB) 258, "Addiction Recovery Amendments," 2017 General Session, to establish guidelines for the issuance of a prescription for an opiate antagonist along with a prescription for an opiate.
- Utah Passed House Bill (HB) 146, "Partial Filling of a Schedule II Controlled Substance Prescription," 2017 General Session, to address the partial filling of a Schedule II controlled substance prescription. As passed, the bill allows a prescription for a Schedule II controlled substance to be partially filled in accordance with Federal law for a patient in a long-term-care facility or a patient with a terminal illness. However, in the case of all other patients, a prescription for a Schedule II controlled substance may only be partially filled if in accordance with Federal law and in accordance with State rules that specify how to record the date, quantity supplied, and quantity remaining of a partially filled prescription.
- Utah Code sections 31A-22-615.5(2) and (3), "Insurance Coverage for Opioids," 2017 General Session, urges health insurers to develop policies to minimize the risk of opioid addiction and overdose:
  - A health insurer that provides prescription drug coverage may enact a policy to minimize the risk of opioid addiction and overdose from:
    - chronic co-prescription of opioids with benzodiazepines and other sedating substances,
    - prescription of very high-dosage opioids in a primary care setting, and
    - the inadvertent transition of short-term opioids from treatment for an acute injury into long-term opioid dependence.

This factsheet shows Utah's responses to our questionnaire covering five categories related to opioids:

- Policies and Procedures
- Data Analytics
- Outreach
- Programs
- Other

This information is current as of October 2018. See page 13 for a list of State entities involved with oversight of opioid prescribing and monitoring of opioid use. See page 14 for a glossary of terms used in this factsheet.

A-07-18-05115
February 2019

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https://oig.hhs.gov/oas/reports/region7/71805115_Factsheet.pdf

"Widespread Prescription Opioid Misuse"

- **Misuse of prescription opioids is a crime and severs causation**

People ex rel. Spitzer v. Sturm, Ruger & Co., 309 A.D.2d 91, 99 (1st Dep't 2003)

Dismissing public nuisance claims against gun manufacturers because the *"indisputable intervention of unlawful … acts of criminals"* severs the chain of proximate causation.

In re Opioid Litigation, 2018 WL 3115102, at *21–22 (Sup. Ct. Suffolk Cnty. June 18, 2018)

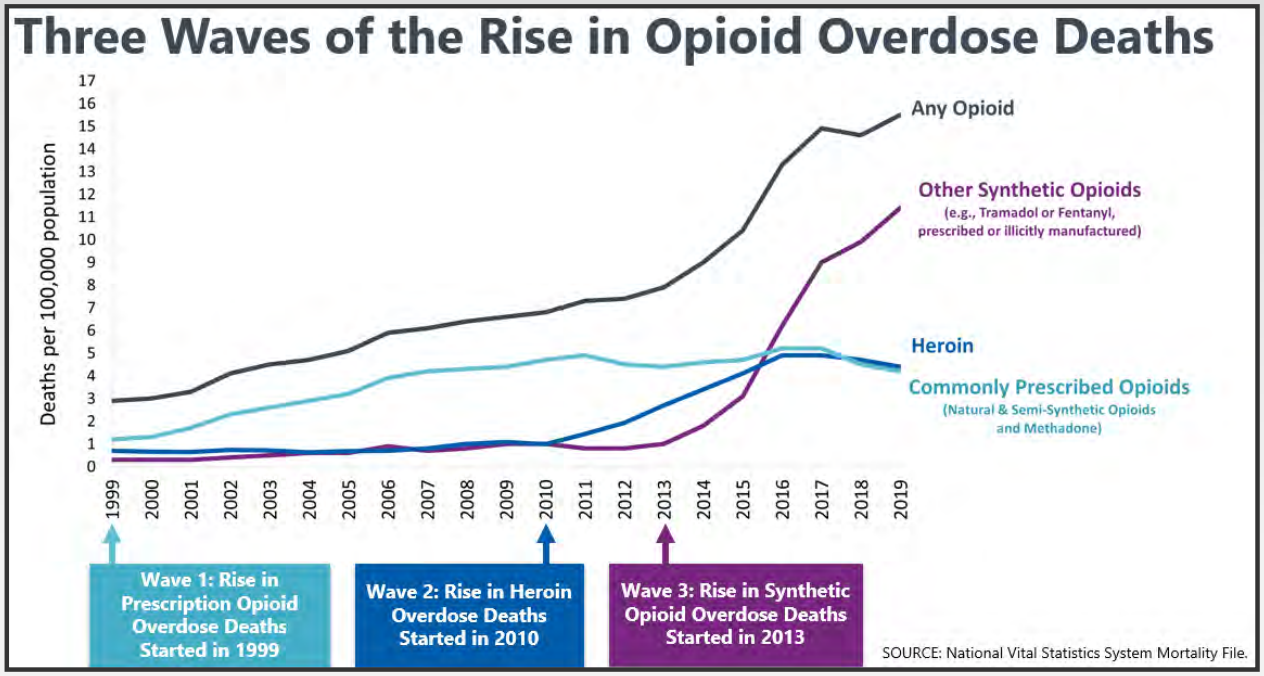
In the New York Counties lawsuit, Justice Garguilo indicated the plaintiff counties must show injury from the ***"legal use"*** of opioids.

“Increased Rates of Crime and Incarceration”

- Neither Purdue nor the Individuals are responsible for crimes committed by third parties
- High rates of incarceration are the result of years of government policy

"Opioid Overdoses"

There have been three waves of the opioid crisis



https://www.cdc.gov/drugoverdose/epidemic/index.html

The data show the rise in overdose deaths for several years has largely been a crisis of ***illegal opioids*** (heroin and illicit fentanyl)

Problem #3: Preemption

The Claim That An FDA-Approved Drug Is A Nuisance Is Preempted

- The essence of the Claimants' claim is that FDA-approved drugs are a public nuisance
- That second-guesses the FDA's judgment that these drugs should be available
- State laws cannot make the sale of FDA-approved medicine unlawful or automatically tortious

See Defense Presentation Part 5

The Claim An FDA-Approved Drug Is A Nuisance Is Preempted

Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 489 (2013)

If a state law makes it inherently tortious for the manufacturer of an FDA-approved medicine to sell FDA-approved medicine, then the state law is preempted.

Zogenix, Inc. v. Patrick, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014)

"The FDA has the authority to approve for sale to the public a range of safe and effective prescription drugs—here, opioid analgesics. If the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health."

Zogenix, Inc. v. Patrick, 2014 WL 3339610, at *4 (D. Mass. July 8, 2014)

Enjoining amended regulations adopted by Massachusetts aimed at making an FDA-approved opioid less available because it interfered with the federal scheme.

The Claim An FDA-Approved Drug Is A Nuisance Is Preempted

Claimants argue their claims are not about the distribution of FDA-approved drugs

- They claim the public nuisance does not arise from the distribution of the FDA-approved drugs, but from the impact of misleading marketing.

Claimants are forced to disclaim any argument that FDA-approved labels were deceptive

- They claim that the marketing was deceptive because it differed from the label.

There is no evidence to support this supposed distinction

Wos v. E.M.A. ex rel. Johnson, 568 U.S. 627, 636-37 (2013)

> *"Pre-emption is not a matter of semantics.... In a preemption case,* ***a proper analysis requires consideration of what the state law in fact does, not how the litigant might choose to describe it****."*

Problem #4:
Purdue's Post-2007 Marketing Was Not Deceptive

See Defense Presentation Part 2

Purdue's Post-2007 Marketing Was Not Deceptive

- The risk of addiction and abuse was always prominently disclosed
- The risk of addiction and abuse was well-understood by prescribers
- All marketing material was reviewed by the FDA and consistent with the FDA-approved label
- Purdue had a rigorous compliance program to avoid misleading marketing:
  - To ensure everything said was true and consistent with FDA-approved labels
  - To retrain and remediate employee errors or misconduct in marketing, including by termination of employment

Problem #5: Causation

Proximate Causation Is Required to Recover Damages on a Public Nuisance Claim

People ex rel. Spitzer v. Sturm, Ruger & Co., 309 A.D.2d 91, 105 (1st Dep't 2003)

Plaintiff in a public nuisance suit must establish both that defendants caused or contributed to the nuisance and that their conduct was a *"proximate cause"* of plaintiff's injury (dismissing claim based on remoteness of causation).

City of Chicago v. Beretta U.S.A. Corp., 2013 Ill.2d 351, 412 (2004)

Affirming dismissal of public nuisance claims against firearms distributors for lack of proximate cause because their illegal use was *"several times removed from the initial sale of individual weapons by these defendants."*

- ***See* Slides 3-71, above (no causation in fact)**

Problem #6:

Claimants Cannot Establish That Purdue — Or The Individuals — Played A Substantial Role In Creating A Nuisance

Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

City of Bloomington v. Westinghouse Elec. Corp., 891 F.2d 611, 614 (7th Cir. 1989)

Manufacturer of PCBs not liable for public nuisance caused by another company's use of PCBs; ***the manufacturer did not have "control of the product" after the other company purchased it and therefore did not "participate[] in carrying on the nuisance."***

State v. Lead Indus., Ass'n, 951 A.2d 428, 449 (R.I. 2008)

Plaintiff must show that the defendant "***ha[d] control over the instrumentality causing the alleged nuisance at the time the damage occurs."***

Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

Henry v. St. Croix Alumina, LLC, 2007 WL 6030275, at *16 (D.V.I. Aug. 10, 2007)

"[C]ourts that have interpreted nuisance law require that an entity can be liable based on a nuisance claim if that entity has ***the ability or opportunity to abate the nuisance****."*

Granting summary judgment for supplier because it did not have control over premises after a certain date and therefore *"had no opportunity, or authority to abate the storage or containment of the bauxite"* (collecting cases).

Neither Purdue Nor The Individuals Had Any Control Over The Nuisance Or Instrumentalities Creating It

Widespread abuse of and addiction to opioids are far beyond Purdue's and any Individual's control

- Purdue and the Individuals **cannot control illegal opioids**
- Purdue and the Individuals cannot control **how doctors prescribe opioids**
- Purdue and the Individuals cannot control **what patients do with prescribed or illegal opioids**
- Purdue and the Individuals cannot control **doctors' understanding of the risks of opioids**

State ex rel. Stenehjem v. Purdue Pharma L.P., 2019 WL 2245743, *13 (D.N.D. May 10, 2019)

Dismissed public nuisance claims on this ground: "*The reality is that **Purdue has no control over its product after it is sold to distributors, then to pharmacies, and then prescribed to consumers,** i.e. after it enters the market. Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give.*"

Purdue Did Not Substantially Participate In Creating The Opioid Crisis

Restatement (Second) of Torts §834 (1979)

To prevail on a public nuisance claim, a plaintiff must also show that the defendant's participation was ***"substantial participation"*** in creating the nuisance.

Restatement (Second) of Torts §834 (1979)

*"When a person is **only one of several persons** participating in carrying on an activity, **his participation must be substantial** before he can be held liable for the harm resulting from it. This is true because to be a legal cause of harm a person's conduct must be a substantial factor in bringing it about."*

Id., cmt. d

Purdue Did Not Substantially Participate In Creating The Opioid Crisis

Purdue was one small player in the distribution of opioids in the United States. Others include:

- Other opioid manufacturers, who occupied 96% or more of the prescription opioid market
- Drug distributors and pharmacies, which had control of any product that was diverted
- Government regulators including:
  - The CDC, which advises about public health issues
  - The DEA, which decides how many opioids there will be
  - The FDA, which approves the drugs and their labelling
  - State licensing authorities
- Criminals, who divert lawful opioids and distribute illegal ones like heroin and illicit fentanyl

Problem #7:

Claims Against Purdue Do Not Create Claims Against Former Directors

Directors Are Not Liable For A Public Nuisance Created By Their Company Unless They Personally Participated In It

Sahu v. Union Carbide Corp., 2012 WL 2422757, at *11 (S.D.N.Y. June 26, 2012), *aff'd* 528 F. App'x 96 (2d Cir. 2013)

Personal participation in public nuisance required—approval of budget *"does not rise to the level of participation in the commission of a tort."*

None Of The Individuals Personally Participated In Creating The Alleged Nuisance

- None reviewed or approved the content of marketing material
- None made or approved allegedly deceptive marketing statements to HCPs
- None decided what Purdue's sales representatives would say to HCPs
- None personally participated in executing Purdue's anti-diversion programs

See Defense Presentations Nos. 2 and 3

None Of The Individuals Personally Participated In Creating The Alleged Nuisance

Courts dismiss nuisance claims for violations of environmental statutes against senior corporate officers absent personal participation

Estate of Goldberg v. Goss-Jewett Co., 2019 WL 4221398, at *3 (C.D. Cal. June 4, 2019)

Corporate president not personally liable under CERCLA. "*[T]he normal relationship that the president of a corporation has with the corporation*" does not support liability. It would be impermissible ***"to hold [President] liable as an operator simply because, as president of Goss-Jewett, he was ultimately in charge of all aspects of the corporation."***

Directors Are Not Liable For The Torts Of Their Companies Unless They Personally Participated In Them

T.V. Spano Bldg. Corp. v. Dep't of Nat. Res. & Envtl. Control, 628 A.2d 53, 62 (Del. 1993)

"[C]orporate officer who had broad, general authority for the Raintree project and direct knowledge of the disposal trenches" ***not liable, for violations of public nuisance law****, where "****he did not direct, control, approve, consent to, or ratify the decision*** *to dispose of the construction waste."*

People ex rel. Madigan v. Tang, 346 Ill. App. 3d 277, 288 (2004)

Corporate CEO not liable for **environmental violations** under Illinois statute. **Plaintiff failed to show the defendant's *"personal involvement or active participation in the acts resulting in liability."*** General allegations that defendant had the power to control the company or general responsibility for supervising its conduct were not enough to support liability.

Claims By Opioid Users And Their Families

Types of Claims Brought

- Strict products liability
- Failure to warn
- Breach of implied warranty
- Breach of express warranty
- Fraud
- Negligent marketing

Claims Have Historically Been Unsuccessful

Opioid users and family members have been unable show causation because of:

- Prescribing physicians' awareness of the risks of opioids
- The absence of evidence that a physician's decision to write a prescription was caused by deceptive marketing
- Patients' misuse of OxyContin contrary to label warnings
- Patients' concurrent use of multiple opioids
- Warnings on the OxyContin label
- The learned intermediary doctrine

Claims Have Historically Been Unsuccessful

- Doctors testified they were aware of the risks of opioids
- No evidence the prescriber would have acted differently with different warning
- Intentional misuse of medication, breaking the chain of causation
- Patient taking multiple opioids

United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 575 (W.D. Va. 2007)

"As to any individuals injured by the use of OxyContin, the difficulties of establishing causation are demonstrated by numerous civil suits that have been filed by such persons against Purdue.... **Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding [from 1995 to 2001] proximately caused their injuries**."

Cases in 2003–08 Found No Causation in Patient/Survivor Claims

Bodie v. Purdue Pharma Co., 236 Fed. App'x 511 (11th Cir. 2007)

No proof of causation because **patient's doctor testified he was aware of the risks of opioids, and prescribing decision unaffected by Purdue promotional literature**

Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693 (E.D. Ky. 2003)

No causation where **patients misused OxyContin contrary to label warnings** and warning to doctors was adequate

Labzda v. Purdue Pharma, L.P., 292 F. Supp. 2d 1346 (S.D. Fla. 2003)

Manufacturers not obligated to police prescribers; patient's intentional misuse broke causal chain

Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551 (N.D. Tex. 2006)

Plaintiff failed to show OxyContin marketing caused doctors to prescribe it to him

McCauley v. Purdue Pharma, L.P., 331 F. Supp. 2d 449 (W.D. Va. 2004)

Failure to establish causation against Purdue where **patients took multiple opioids concurrently**

Boysaw v. Purdue Pharma, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009)

No proof of causation against Purdue because patient was taking **multiple opioids** in addition to OxyContin

Timmons v. Purdue Pharma Co., 2006 U.S. Dist. LEXIS 3965, (M.D. Fla. Feb. 2, 2006)

Failure to show causation where **prescribers were aware of risks and were not influenced by Purdue marketing**

Cornelius v. Cain, 2004 WL 48102 (Fl. Cir. Ct. Jan. 5, 2004)

OxyContin **label warnings were adequate, doctors were aware of risks, and learned intermediary doctrine broke chain of causation**

Harris v. Purdue Pharma, L.P., 218 F.R.D. 590 (S.D. Ohio 2003)

Finding lack of commonality in class action based on learned intermediary doctrine; **plaintiffs would have to show that each plaintiff's doctor was deceived**

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 6: Causation, Statutory Consumer Fraud, Public Nuisance, Claims By Opioid Users And Their Families

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