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

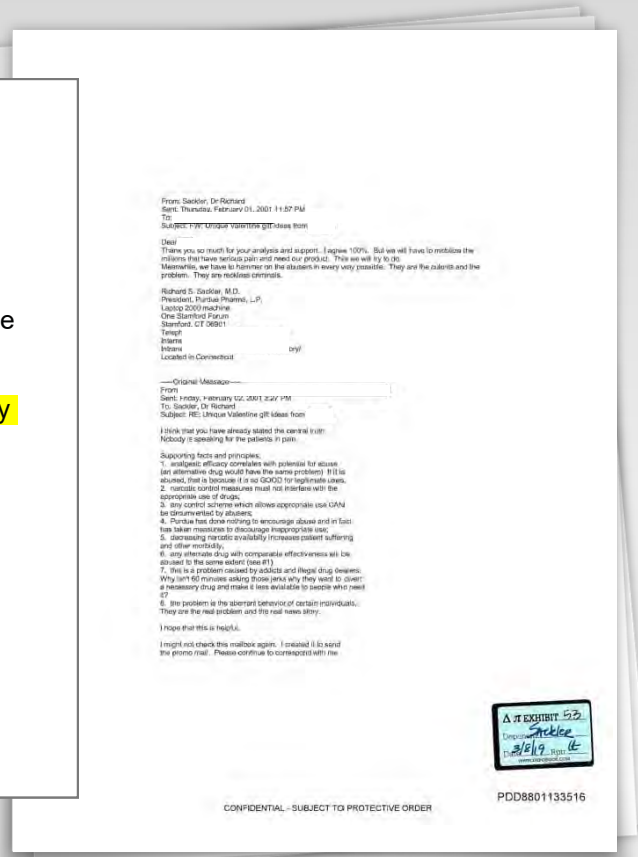
Sent: Thursday, February 01, 2001 11 :57 PM
To:
Subject: FW: Unique Valentine gift ideas from

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.

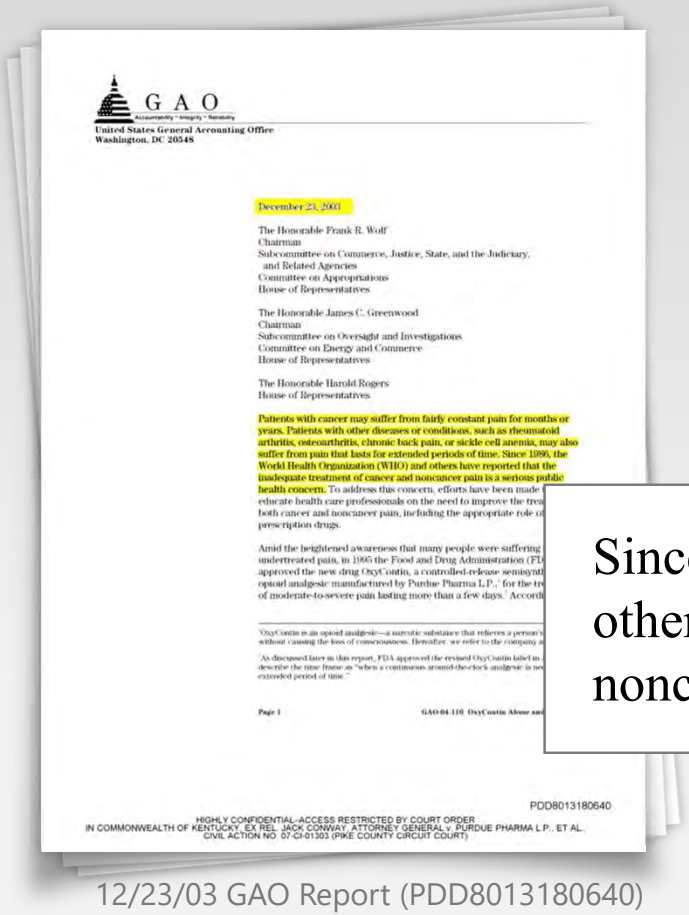
Meanwhile, we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.

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)

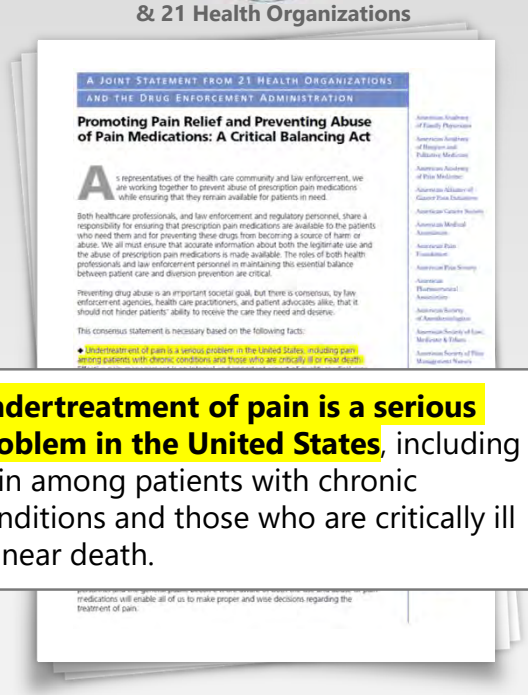
GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

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

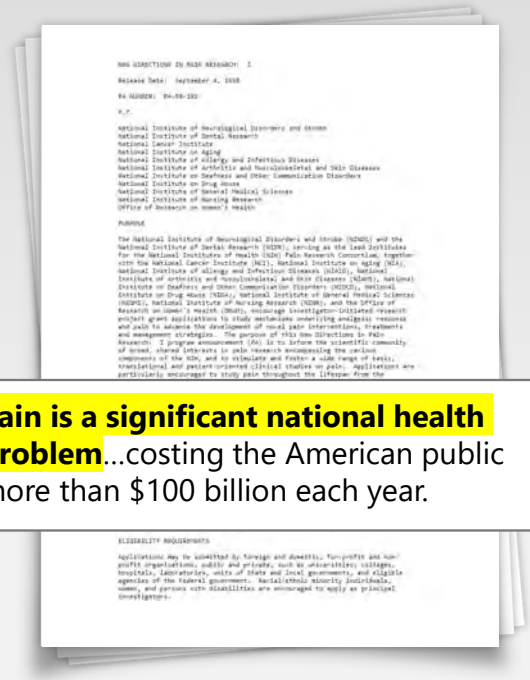

A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION

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.

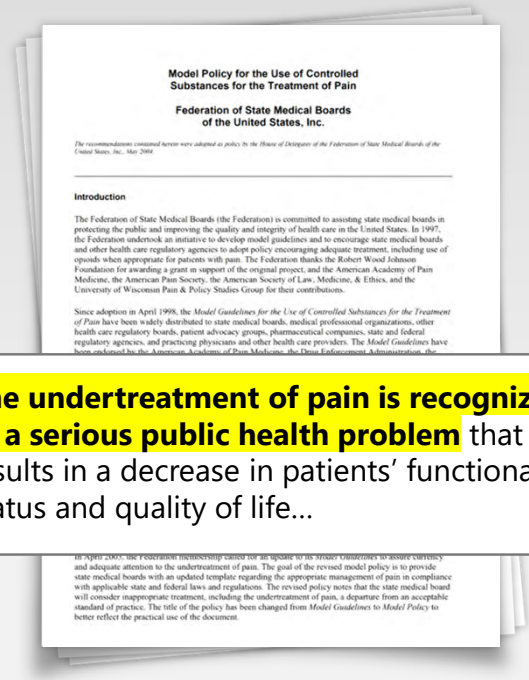
A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, *Promoting Pain Relief and Preventing Abuse of Pain Medication: A Critical Balancing Act* (2001)

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

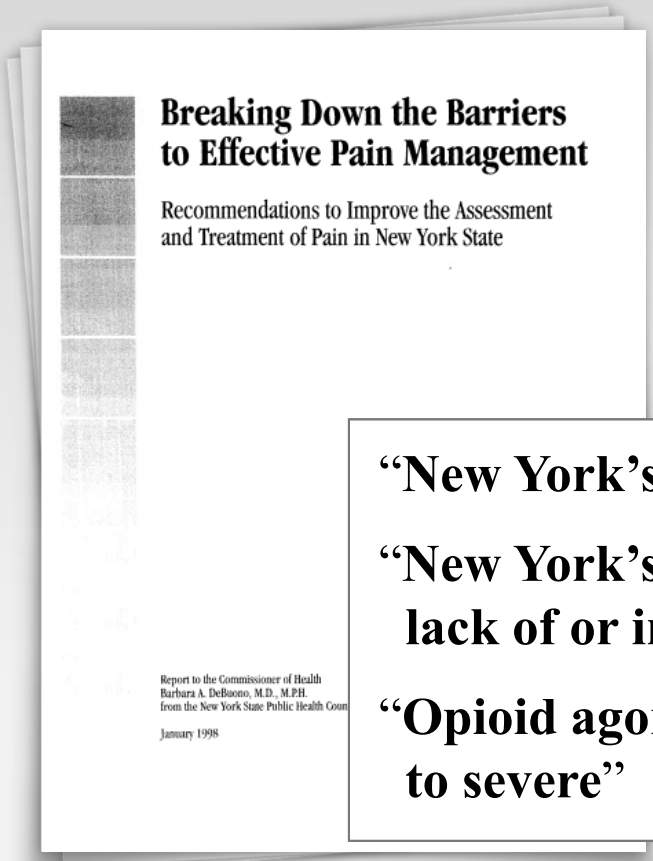
Federation of State Medical Boards of the United States, Inc.

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

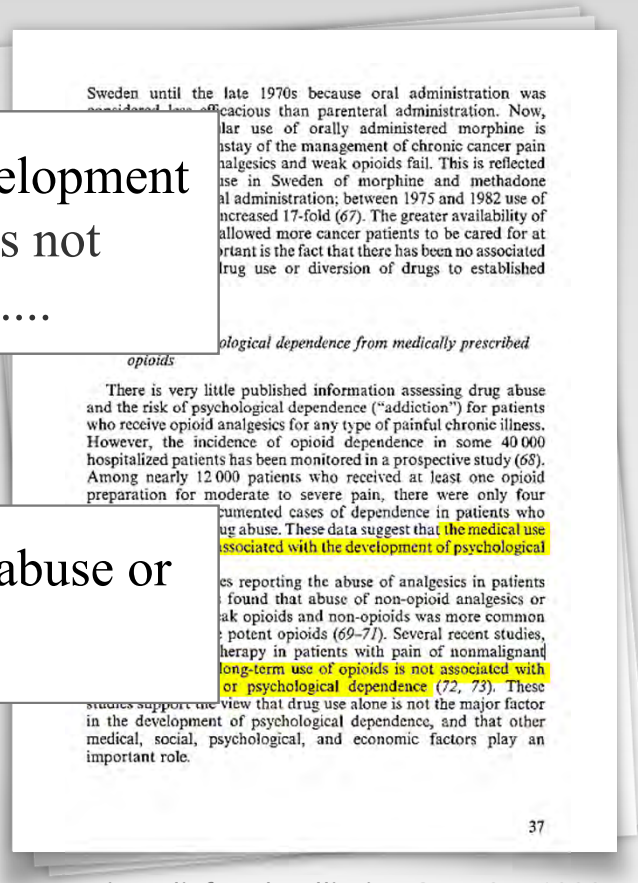
Prevailing Scientific Consensus: Medical Use of Opioids Is Rarely Associated with Addiction

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.

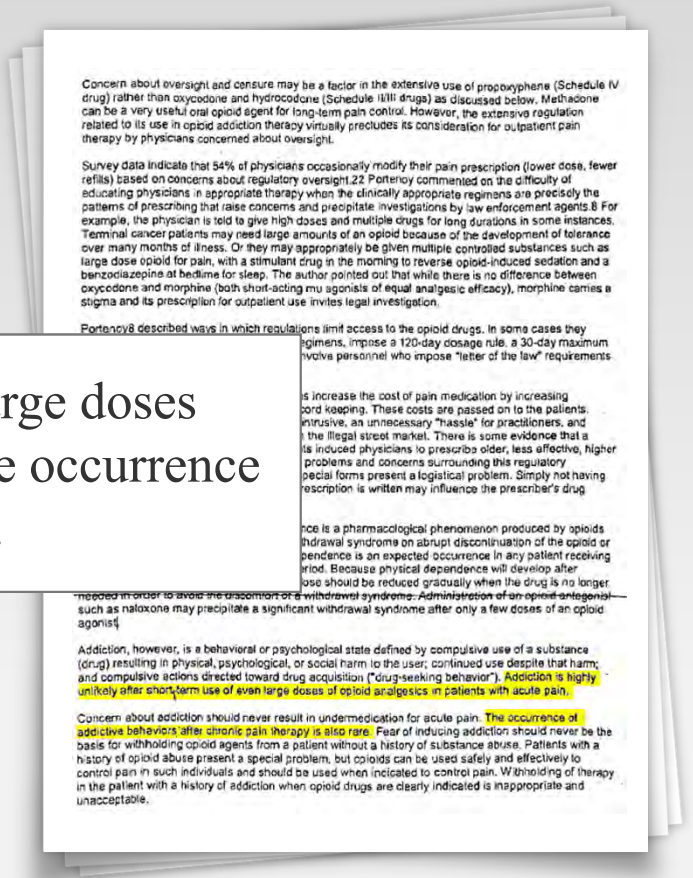
37

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

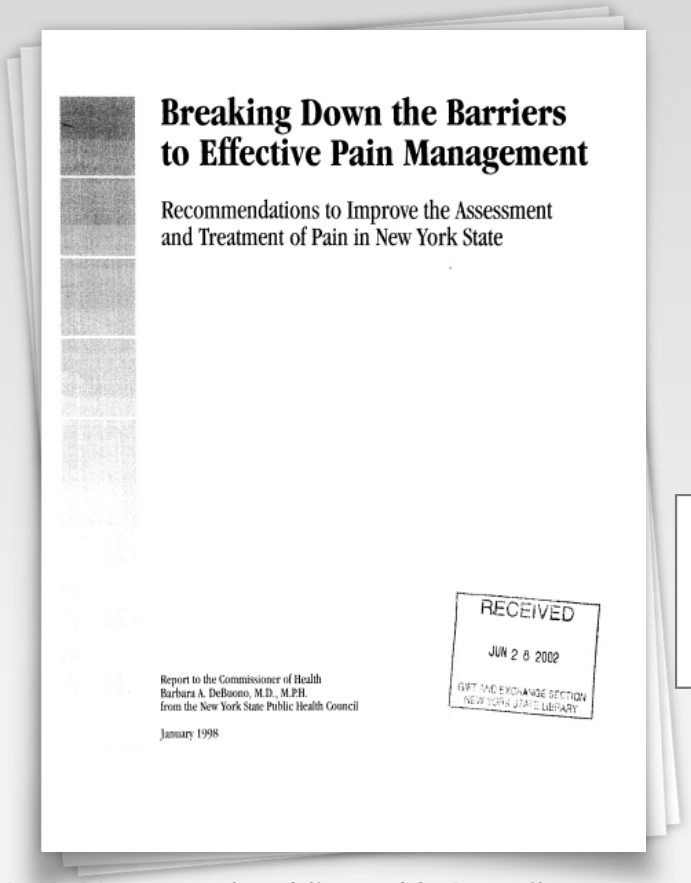
nce is a pharmacological phenomenon produced by opioids
thdrawal syndrome on abrupt discontinuation of the opioid or
pendence is an expected occurrence in any patient receiving
riod. Because physical dependence will develop after
ose should be reduced gradually when the drug is no longer
~~needed in 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.

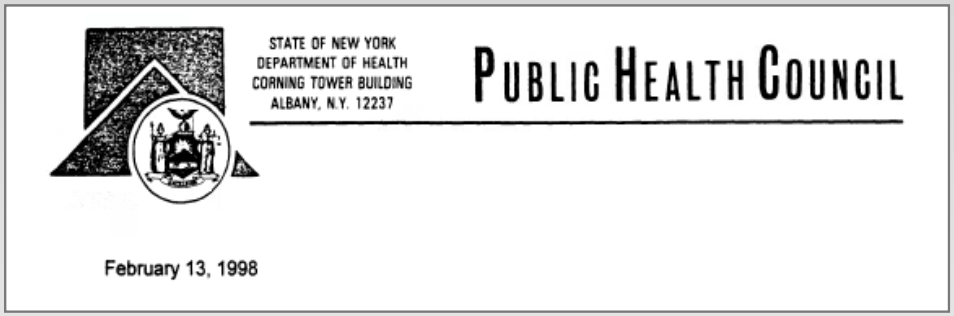
Concern about addiction should never result in undermedication for acute pain. The occurrence of addictive behaviors after chronic pain therapy is also rare. Fear of inducing addiction should never be the basis for withholding opioid agents from a patient without a history of substance abuse. Patients 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

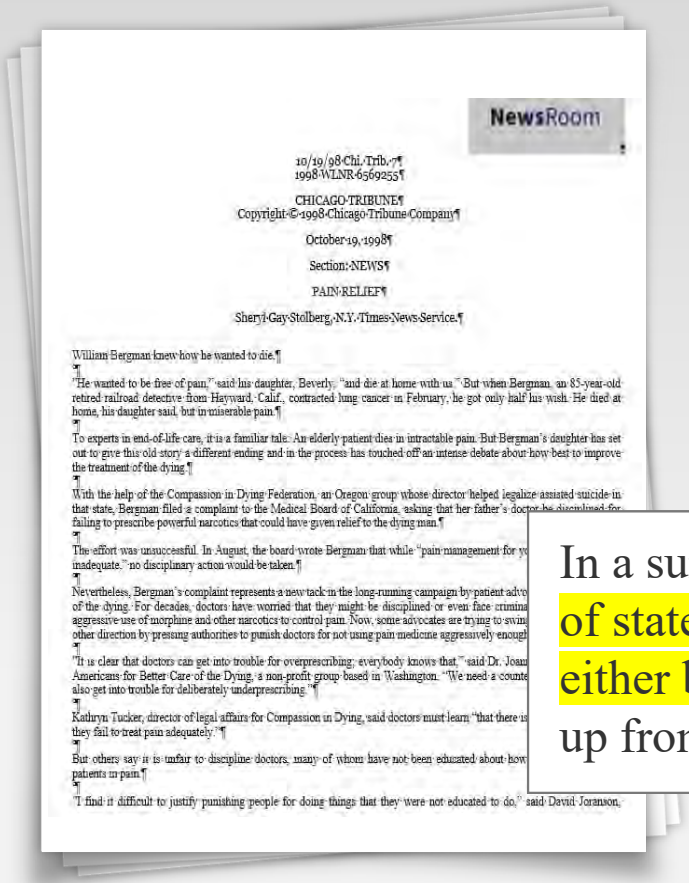
Oregon Board Disciplines Doctor for Not Treating Patients' Pain

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

CHICAGO TRIBUNE
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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

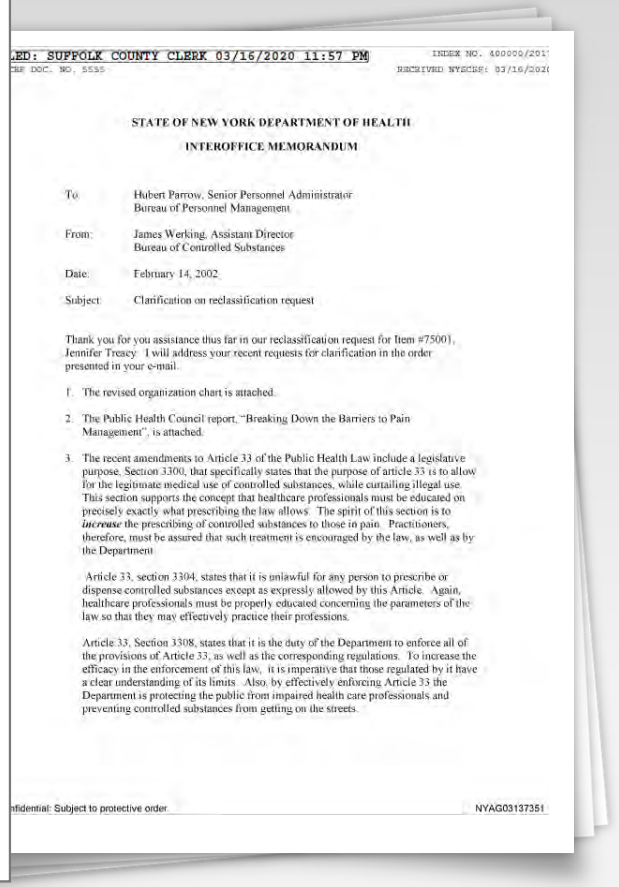
INTEROFFICE MEMORANDUM

***

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

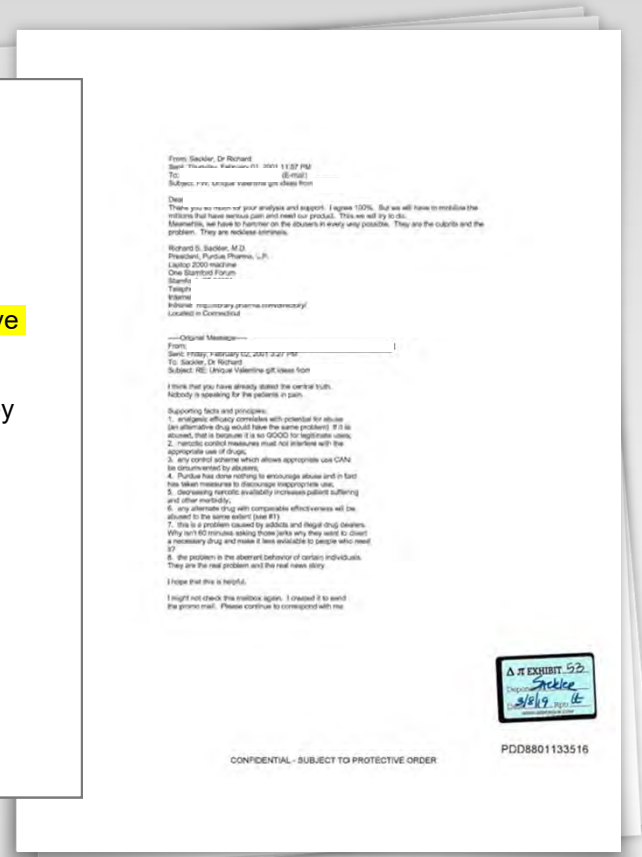
Sent: Thursday, February 01, 2001 11 :57 PM
To:
Subject: FW: Unique Valentine gift ideas from

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



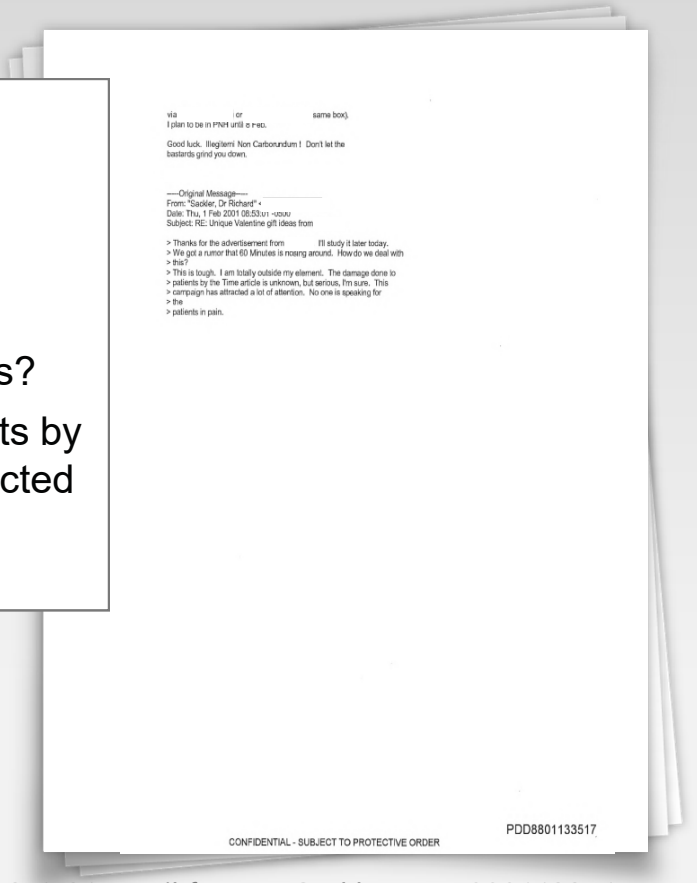
2/1/01 Email from R. Sackler (PDD8801133516)

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)

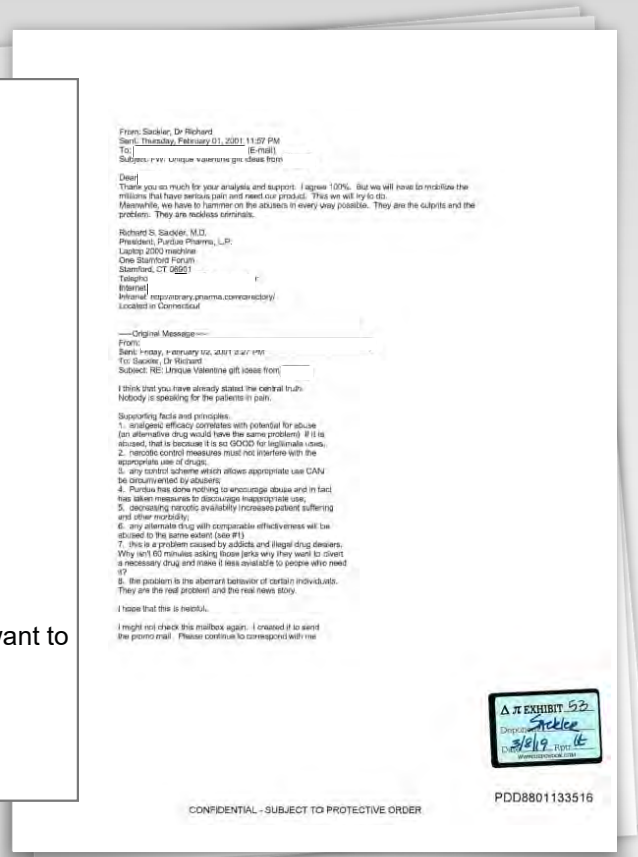
February 1, 2001 Email

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. …

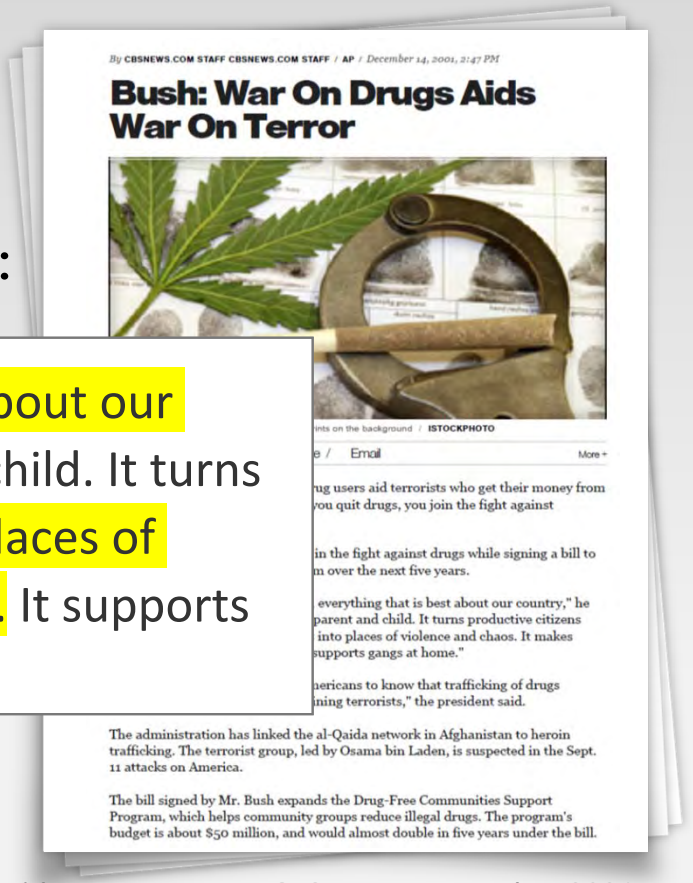


2/1/01 Email to R. Sackler (PDD8801133516)

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.

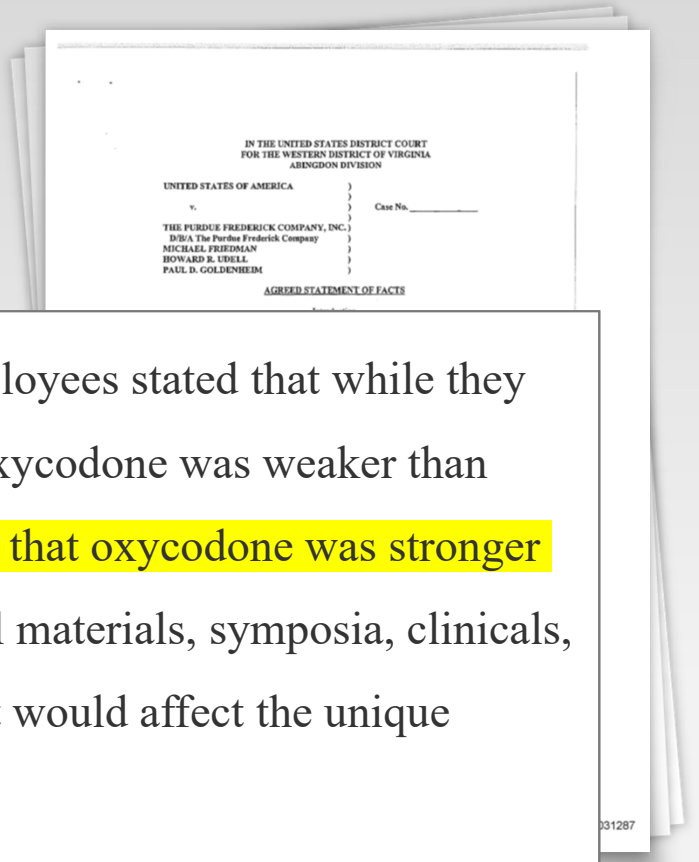
> OxyContin had fewer 'peak and trough' blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

> 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

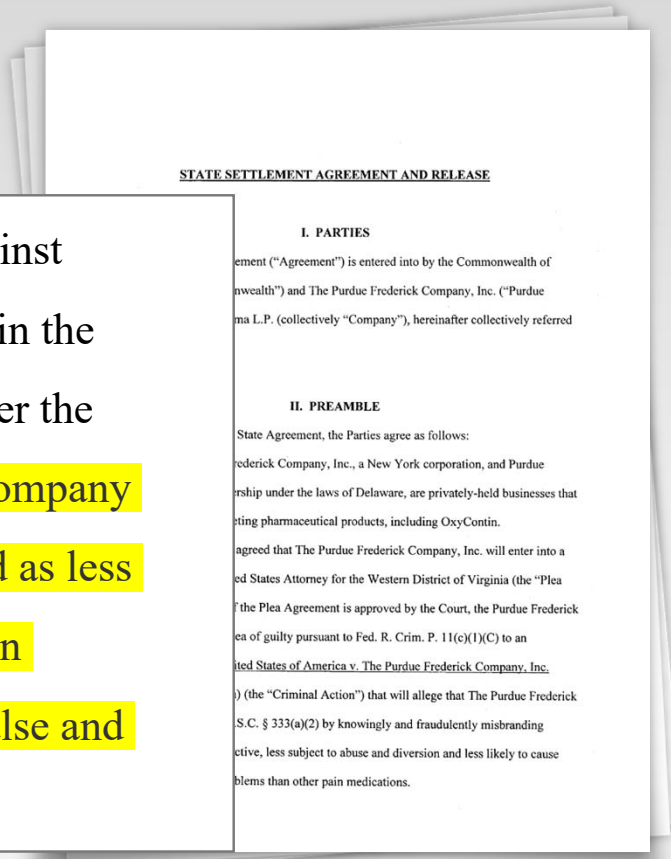
1. Alabama
2. Alaska
3. **Arizona**
4. **Arkansas**
5. **California**
6. Colorado
7. **Connecticut**
8. Delaware
9. **District of Columbia**
10. Florida
11. Georgia
12. Hawaii
13. **Idaho**
14. **Illinois**
15. Indiana
16. Iowa
17. Kansas
18. **Louisiana**
19. **Maine**
20. **Maryland**
21. **Massachusetts**
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.

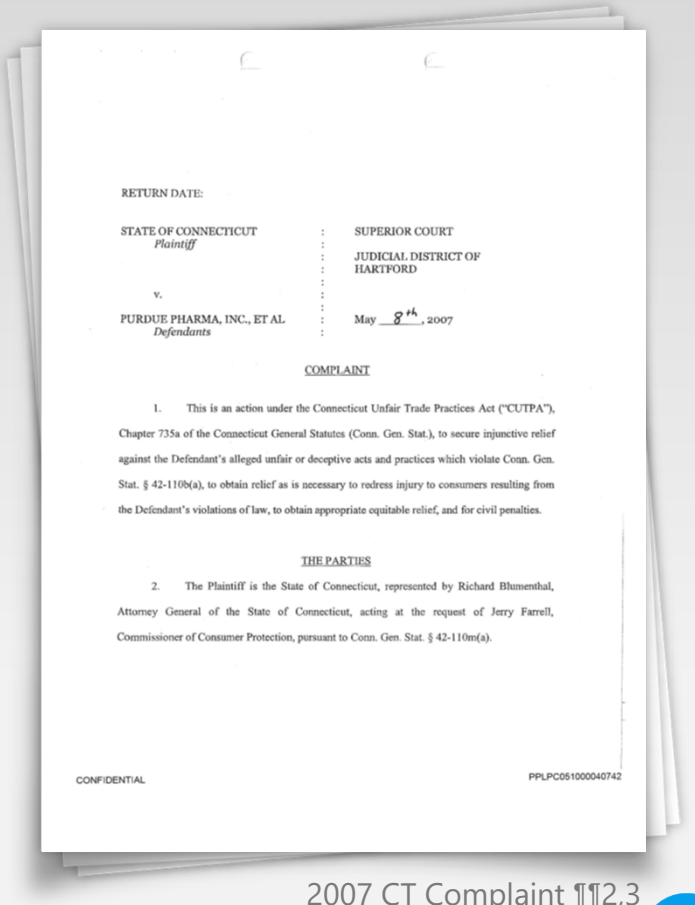
The States alleged that Purdue:

…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

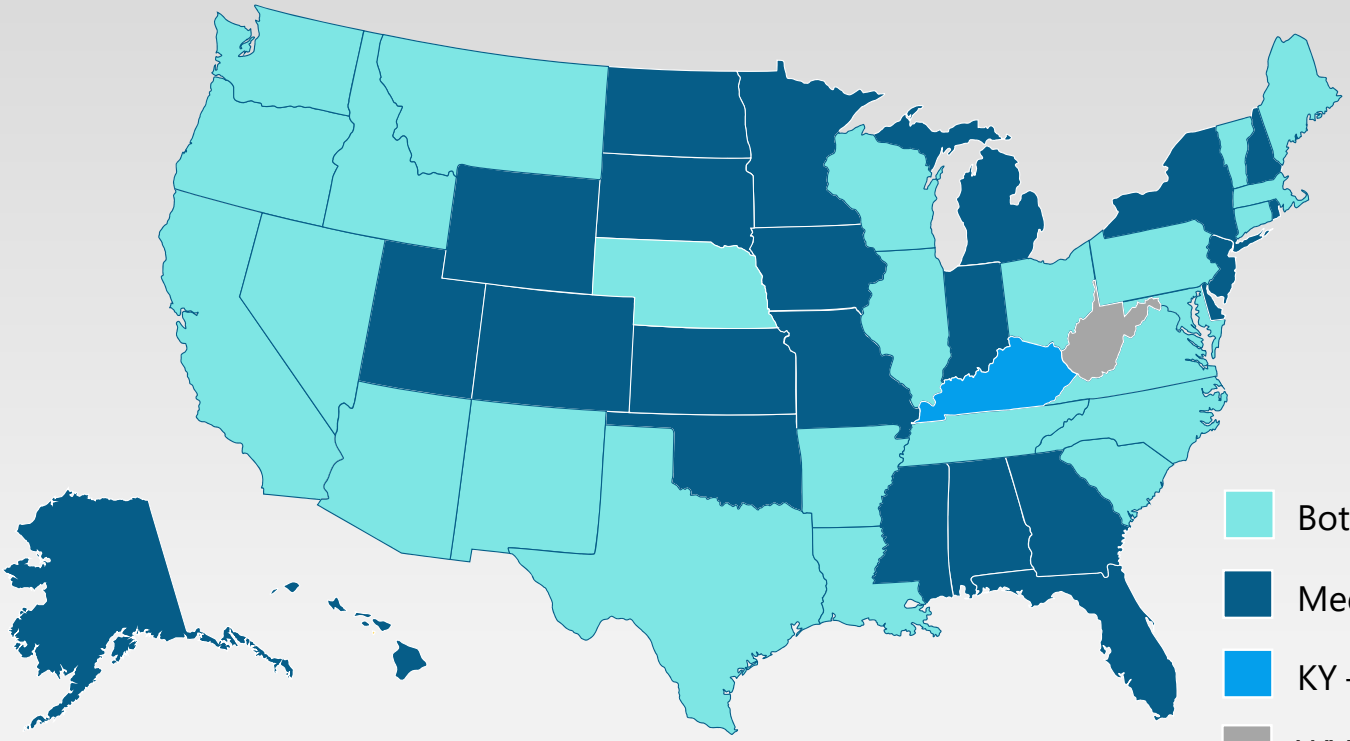
…the State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, co-promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and 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



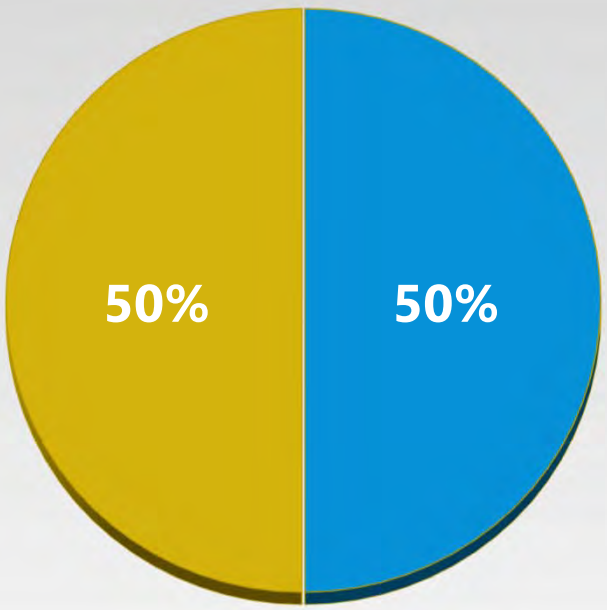
Both Medicaid and Consent Judgment

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

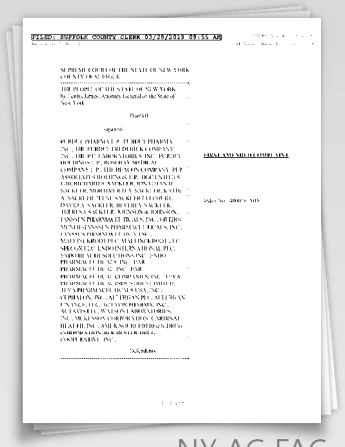
THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

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.

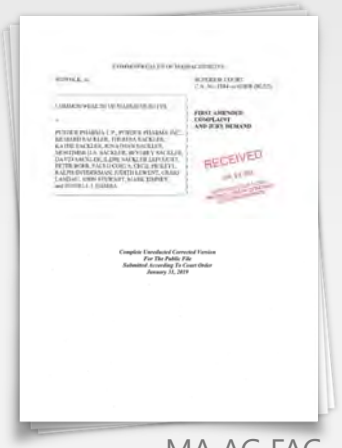


NY AG FAC

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



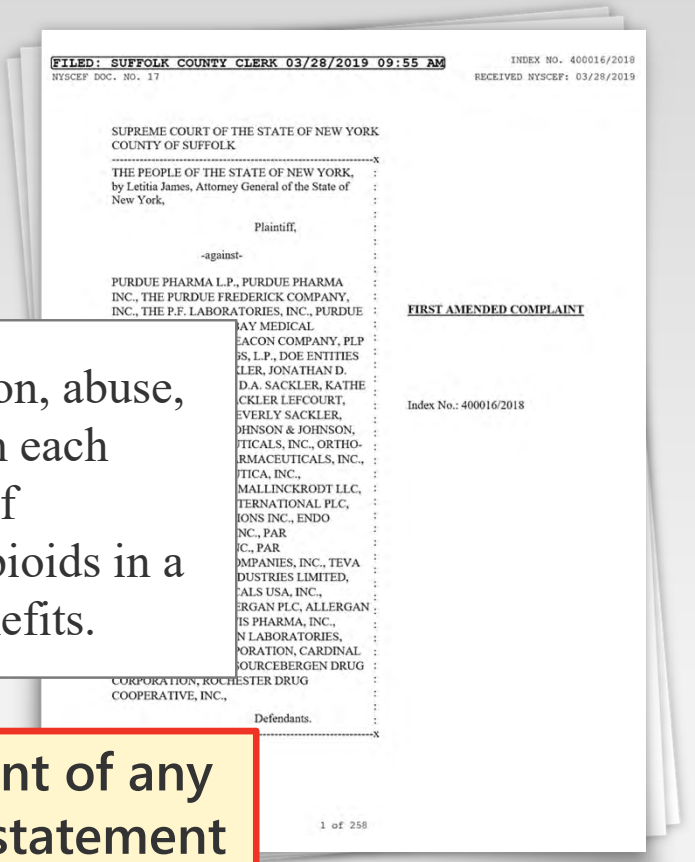
MA AG FAC

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

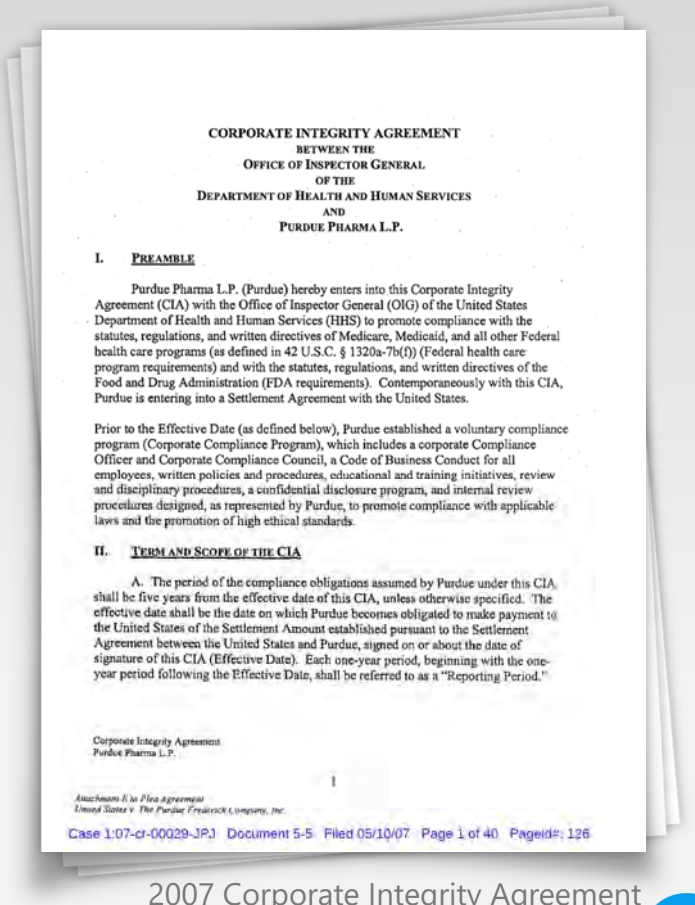
OFFICE OF INSPECTOR GENERAL

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

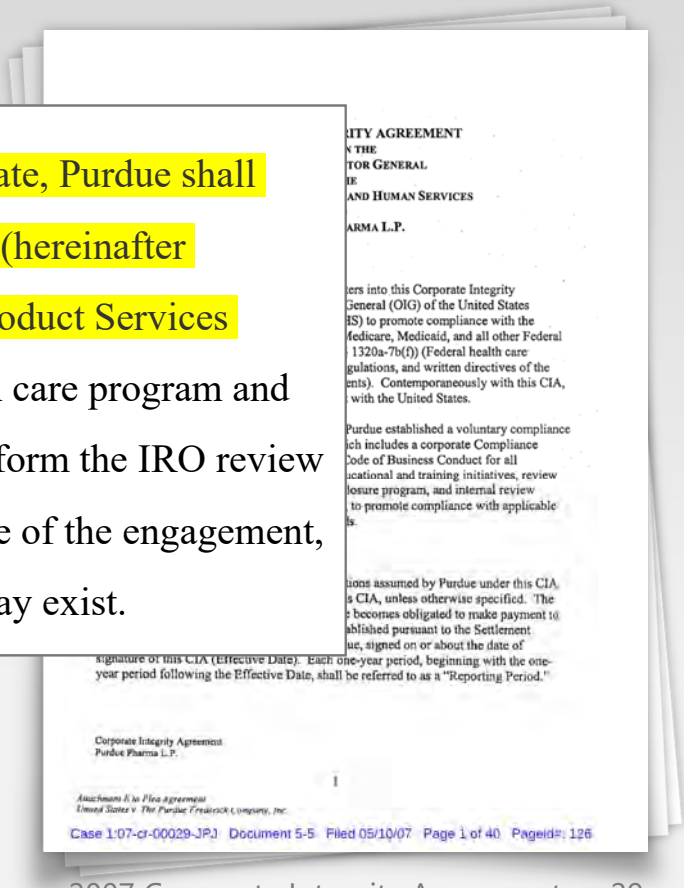
Attachment E to Plea Agreement
United States v. The Purdue Frederick Company, Inc.

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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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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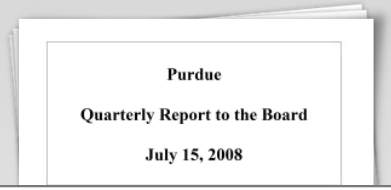
ions assumed by Purdue under this CIA,
s CIA, unless otherwise specified. The
becomes obligated to make payment to
ablished pursuant to the Settlement
ue, signed on or about the date of
signature of this CIA (Effective Date). Each one-year period, beginning with the one-
year period following the Effective 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

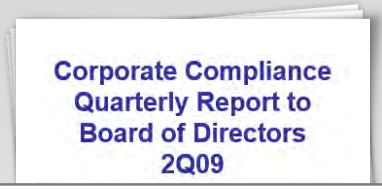
2007 Corporate Integrity Agreement, p. 29

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



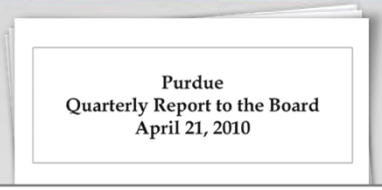
"By letter dated May 2nd we received **confirmation that the OIG was satisfied with Purdue's Implementation Report**, and confirmed that "**it appears that Purdue has successfully implemented the initial requirements of its Corporate Integrity Agreement**."

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



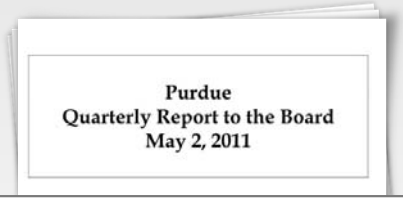
"By May 6th letter, **OIG confirmed Purdue's compliance with the requirements of our CIA** during the first year, based on their review of our Annual Report and other materials."

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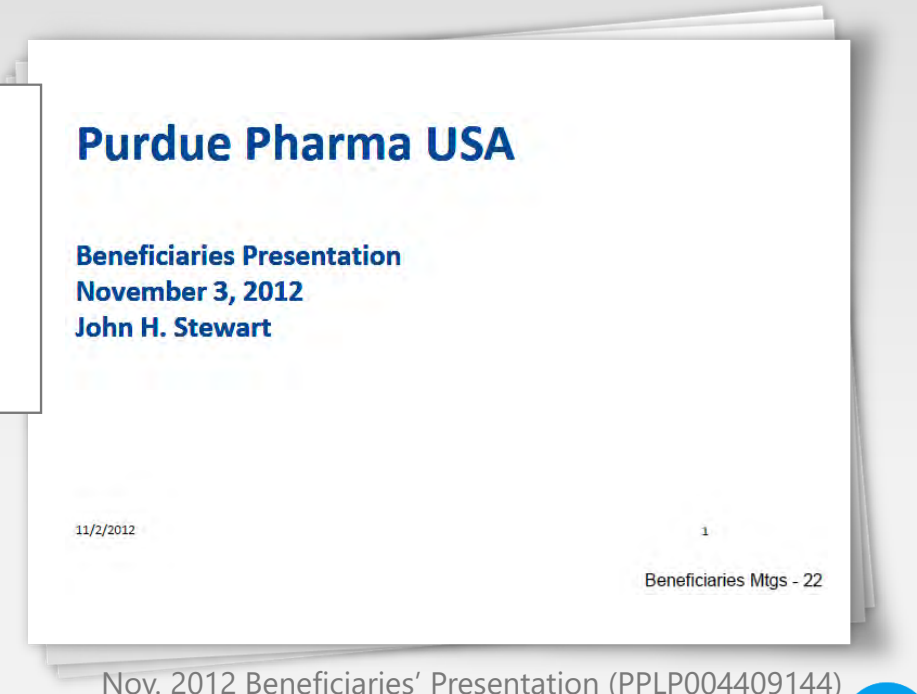
2Q 2012 Quarterly Compliance Report (PPLP004408046, -61)

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

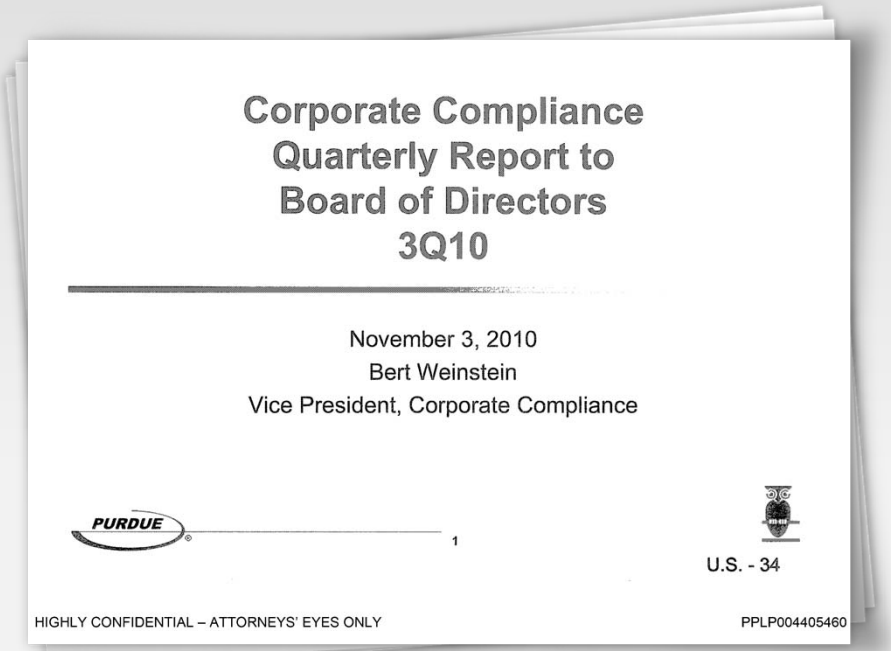
Source: PPLP004416591-98; PPLPC020000167047; PPLPC012000293628

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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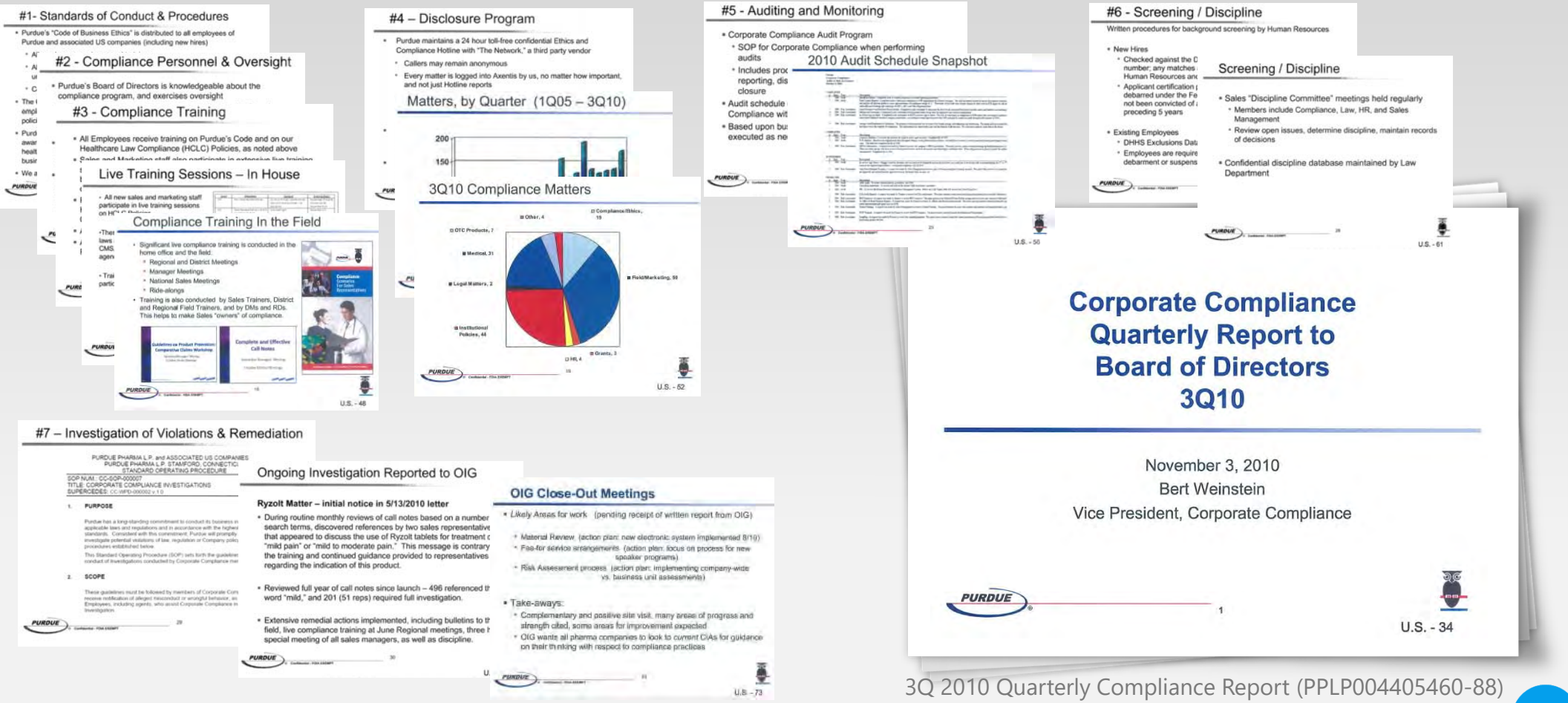
3Q 2010 Quarterly Compliance Report (PPLP004405465-5488)

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.

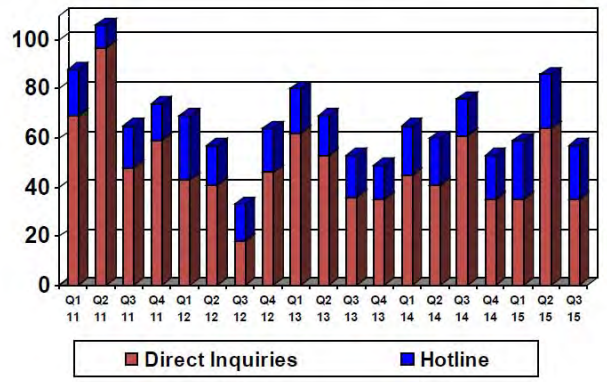
It is noted that none of the matters are significant, and generally concern inquiries by patients, appropriate product messaging by the field, Adverse Events, and preparation of call notes, for which remediation has included coaching, warning letters and bulletins to the field.

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

December 1, 2015

Bert Weinstein

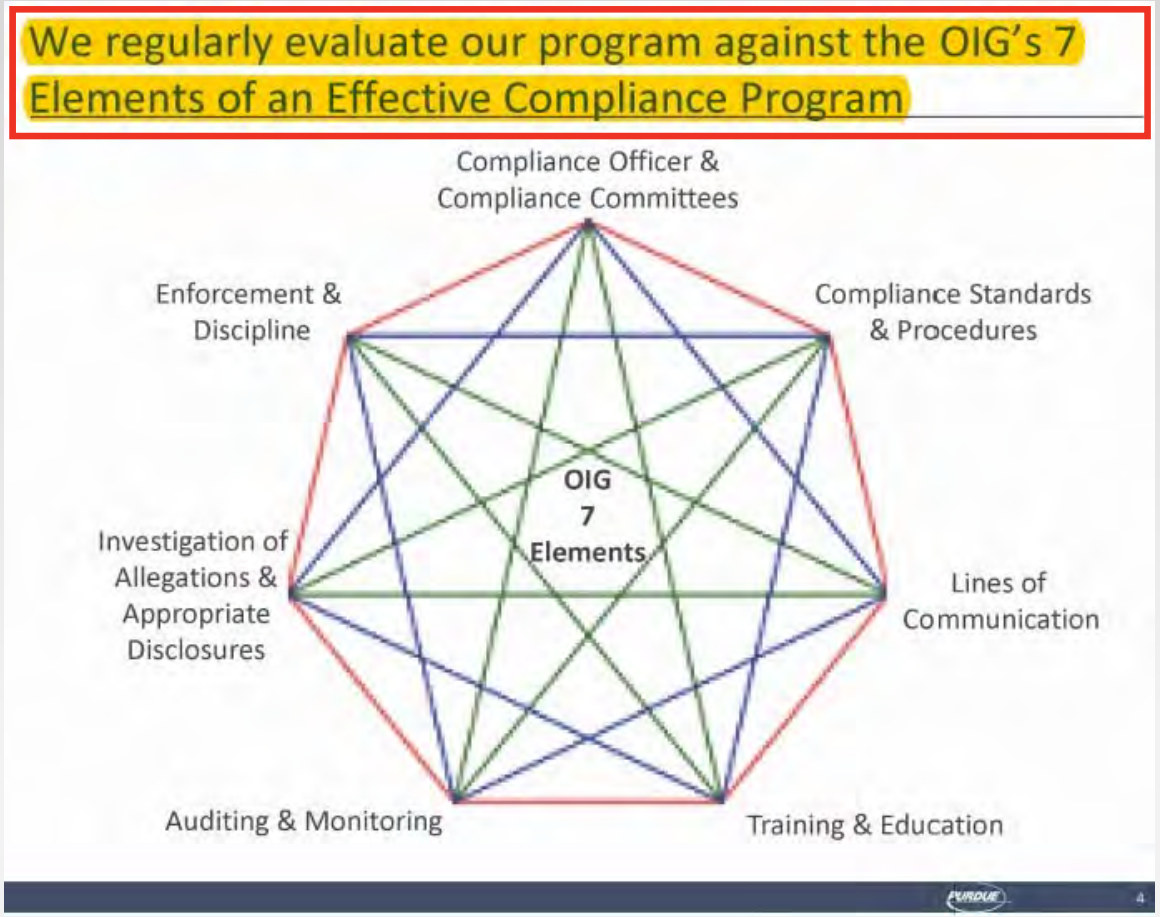
Matters by Quarter (1Q11 – 3Q15)

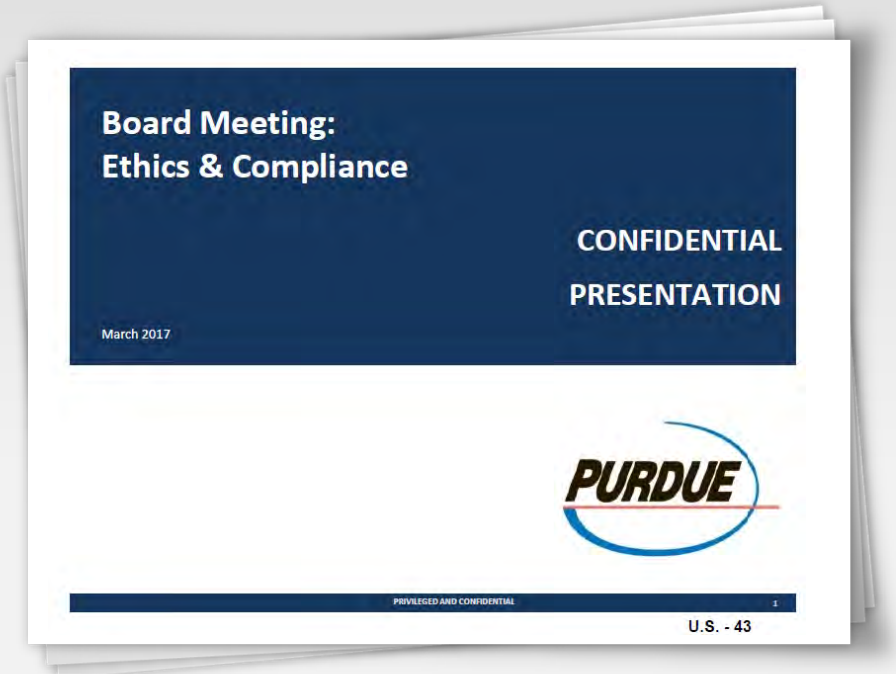


Data through Q3 2015

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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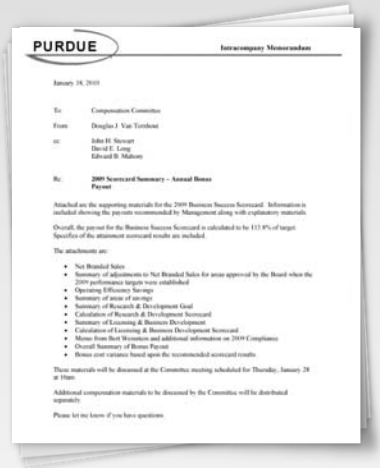
PURDUE Intracompany Memorandum

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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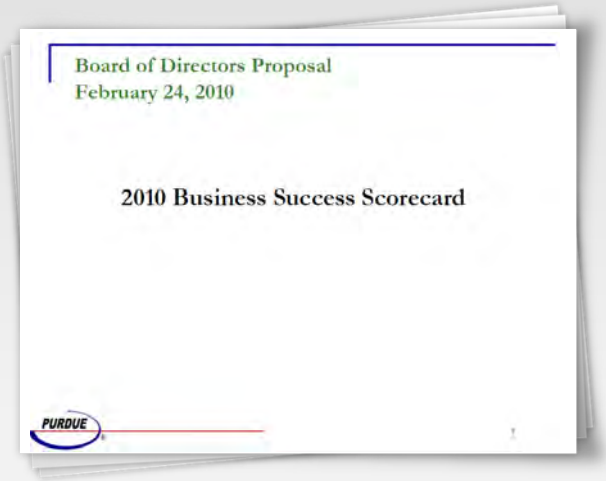

February 24, 2010 BOD Proposal (PURDUE-COR-00028015); Adopted (SCK06079)

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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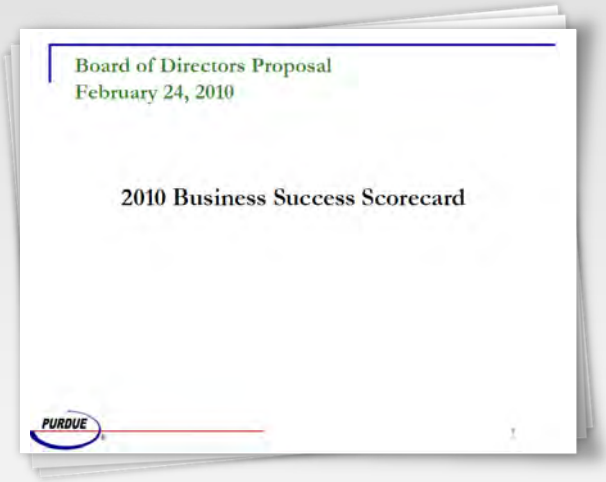

February 24, 2010 BOD Proposal (PURDUE-COR-00028015); Adopted (SCK06079)

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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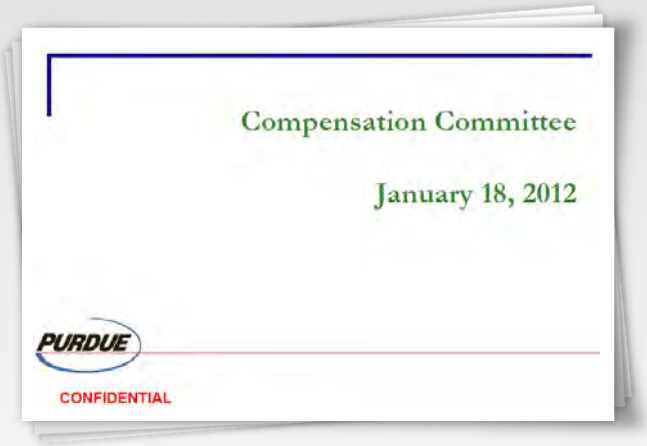

Jan. 18, 2012 BOD Compensation Committee Deck (PPLPUCC9002649696)

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

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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

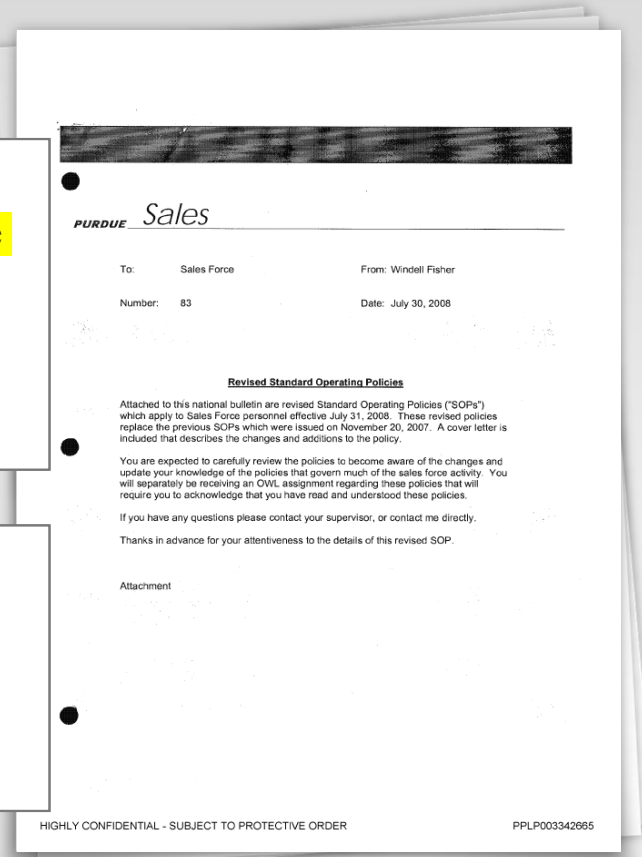
2008 Sales Force SOP Manual:

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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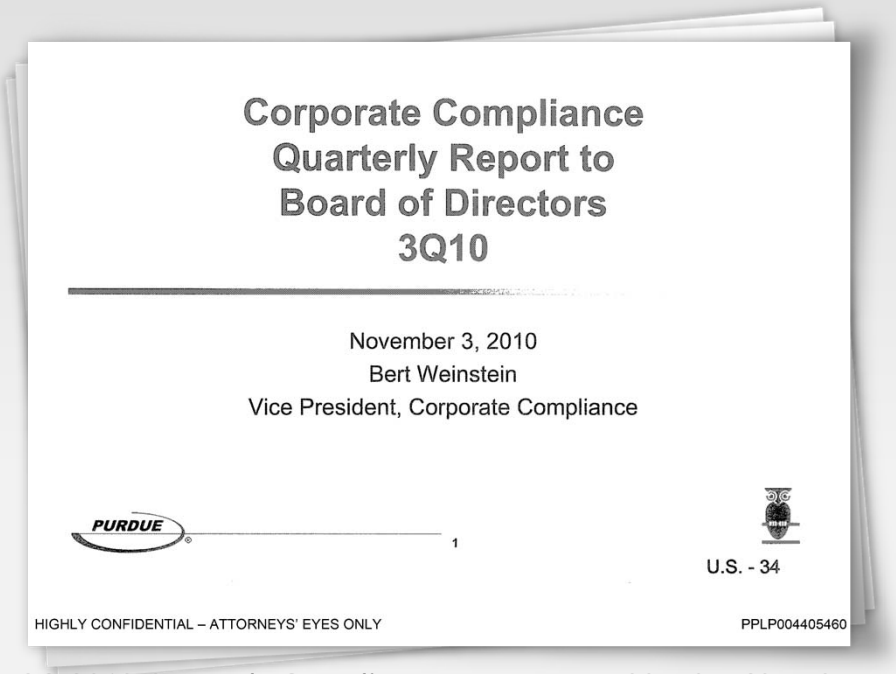
HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY PPLP004405470



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.

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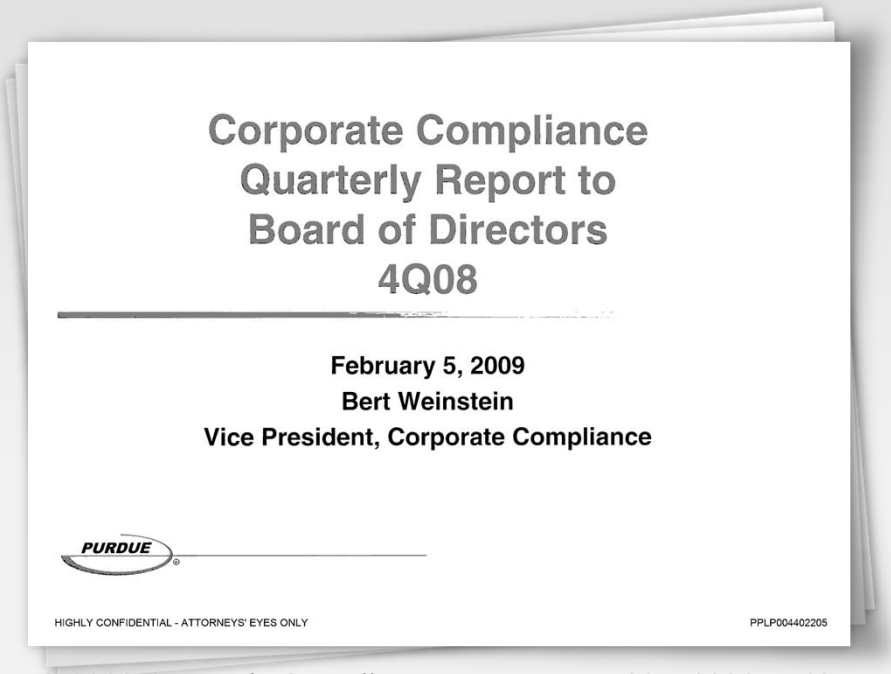
HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY PPLP004402212



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

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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

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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)

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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%

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Quarterly Compliance Report to Board of Directors 4Q2014

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2015

PURDUE

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

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

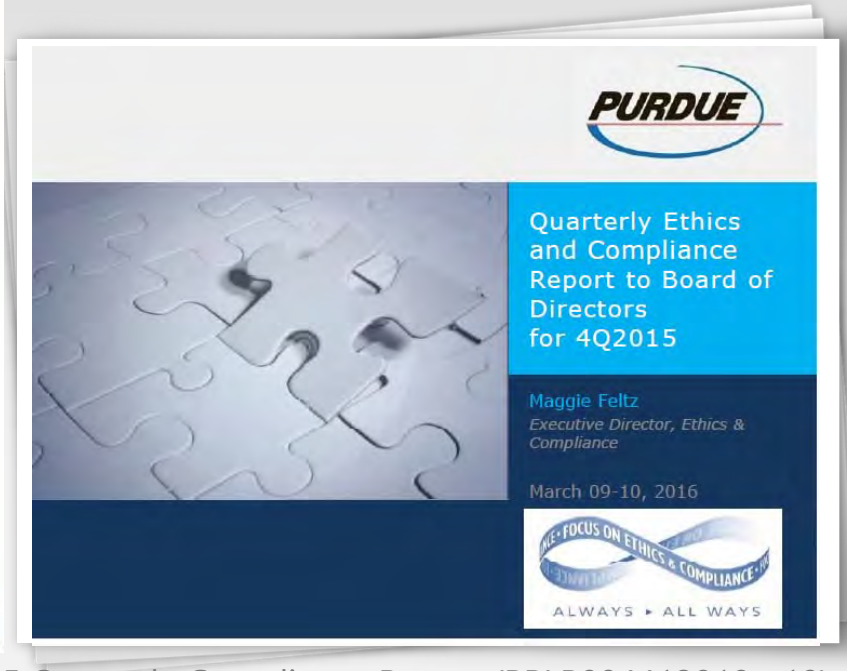
Bottom Line

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.

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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

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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

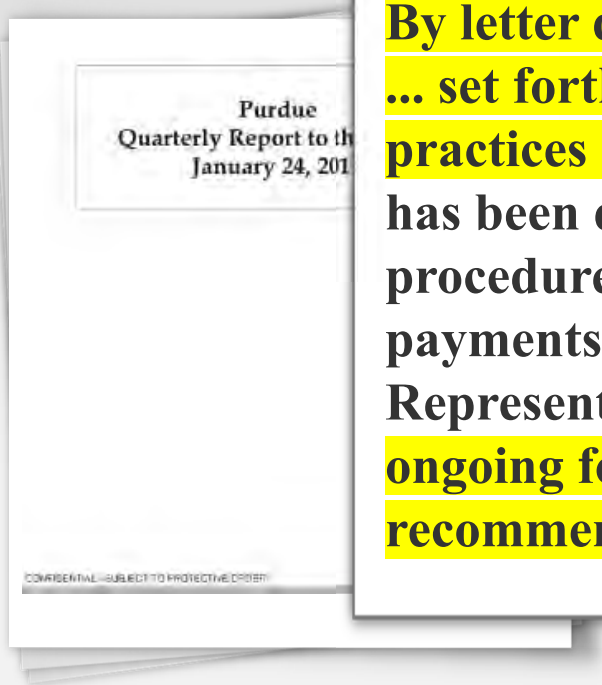
Bert Weinstein
Vice President, Corporate Compliance

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

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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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Quarterly Compliance Report to the Board of Directors for 4Q2013

Bert Weinstein
Vice President, Corporate Compliance
January 16, 2014

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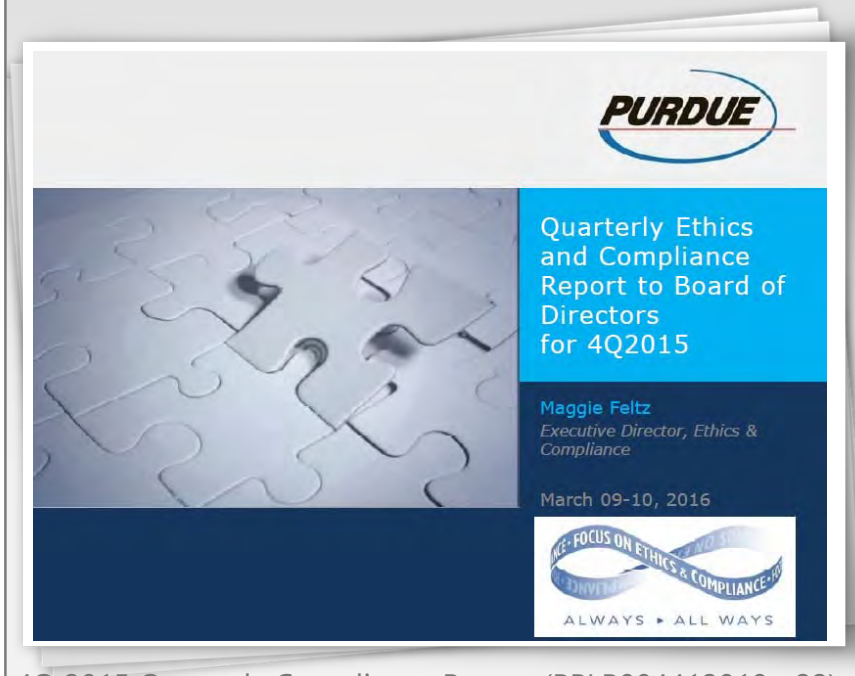
4Q 2013 Quarterly Compliance Report (PPLP004410797, -804)

Board Understood Speakers Program Was Carefully Monitored

2016 Compliance Priorities

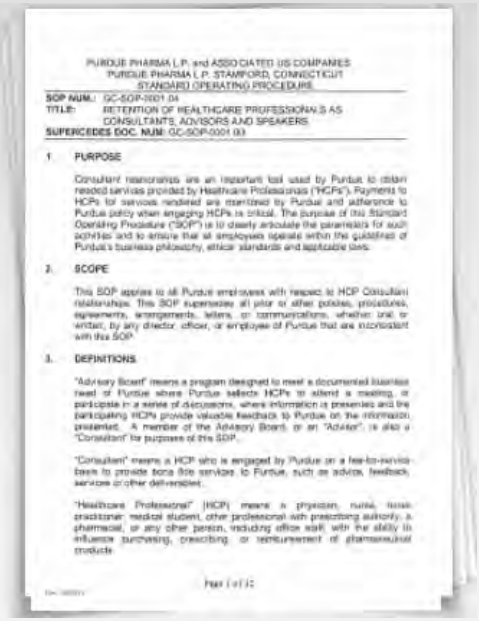
- An annual assessment of the most important areas of compliance risk is conducted each year, with a work stream that follows throughout the year focused on those risks.
- Risks are rated as high, medium and low (no high risks currently)
- Together with senior business heads, we are focusing on four 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

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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

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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

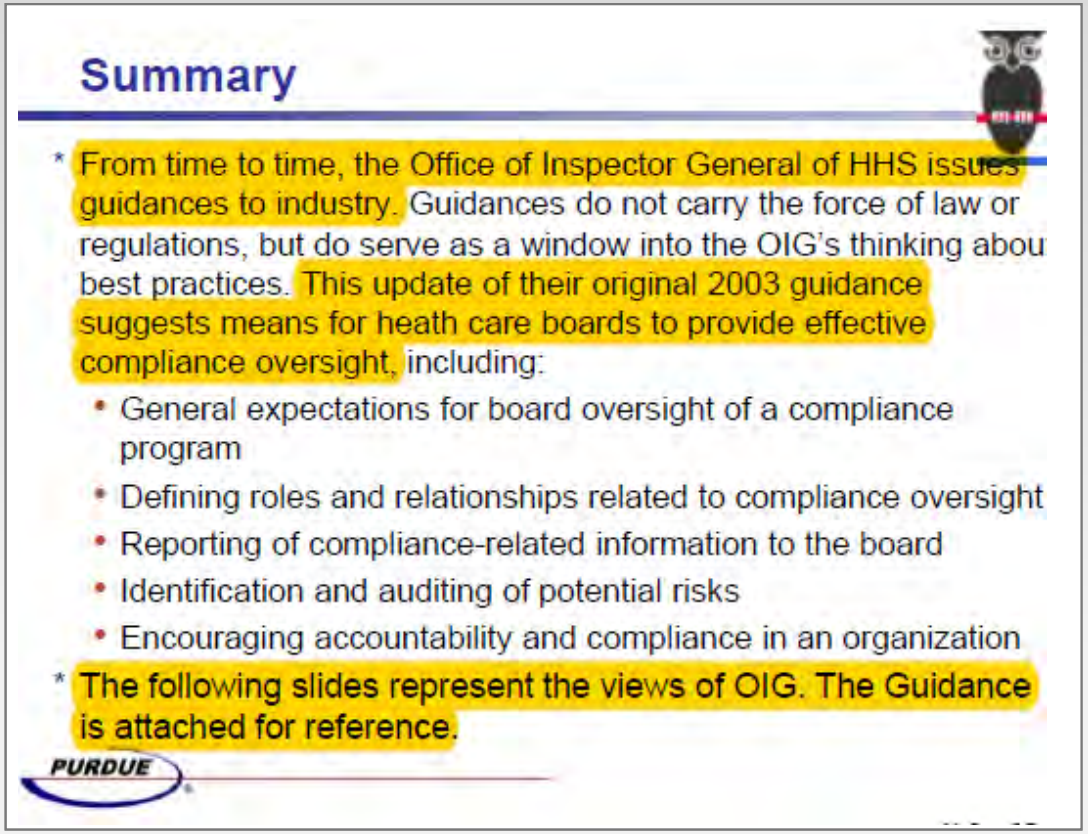
- Reviewed 100 highest *prescribers* of Butrans, 100 highest prescribers of OxyContin, and 100 highest Purdue-*compensated* HCPs in 2014
- Results – *There was no correlation found between Purdue's financial relationships with HCPs and their prescribing of Purdue products*
- For the 10 out of 200 "overlapping" 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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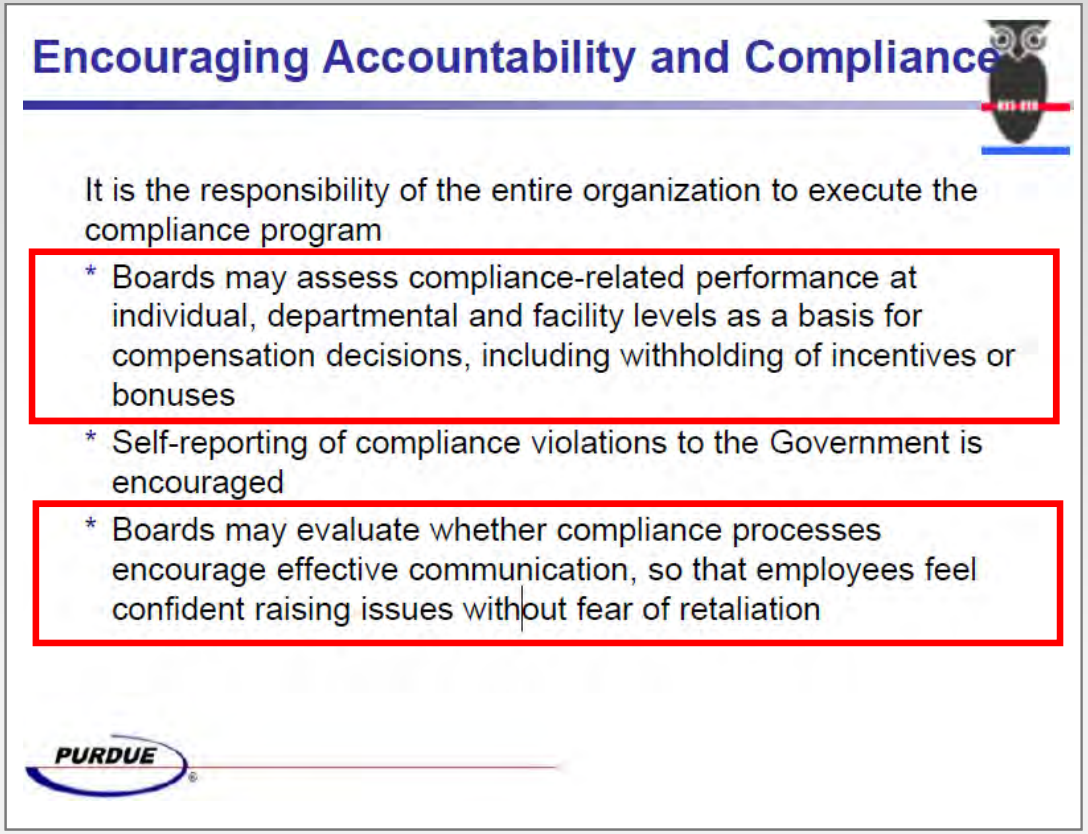

Encouraging Accountability and Compliance

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

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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