

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 2: Marketing

April 26, 2021

Marketing

Board Members Did Not Personally Participate in Marketing

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

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

N.Y. Bus. Corp. Law §717

Board Knew Purdue Submitted All Marketing Materials to FDA

Code of Federal Regulations

Title 21 - Food and Drugs

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

Code of Federal Regulations

Title 21 - Food and Drugs

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

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

§ 314.81 Other postmarketing reports.

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

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

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

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

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

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

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

<https://www.govinfo.gov/content/pk g/CFR-1997-title21-vol5/xml/CFR-1997-title21-vol5-sec314-81.xml>

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



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

Regulatory Procedures Manual November 2019 Chapter 4-Advisory Actions

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

Definitions

Purpose of these procedures:

- a. A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.
- b. An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter. Untitled Letters are intended to cover those circumstances where the Agency has a need to communicate with regulated industry about violations that do not meet the threshold of regulatory significance as described above. The three types of letters related to licensed products that are issued by CBER and CDER, pursuant to subsection 6.3 of Exhibit 4-4-1 do not necessarily fall within this definition of an Untitled Letter; however, they are still Untitled Letters that are covered by the scope of these procedures.

5. Responsibilities

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

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

MAN-000007

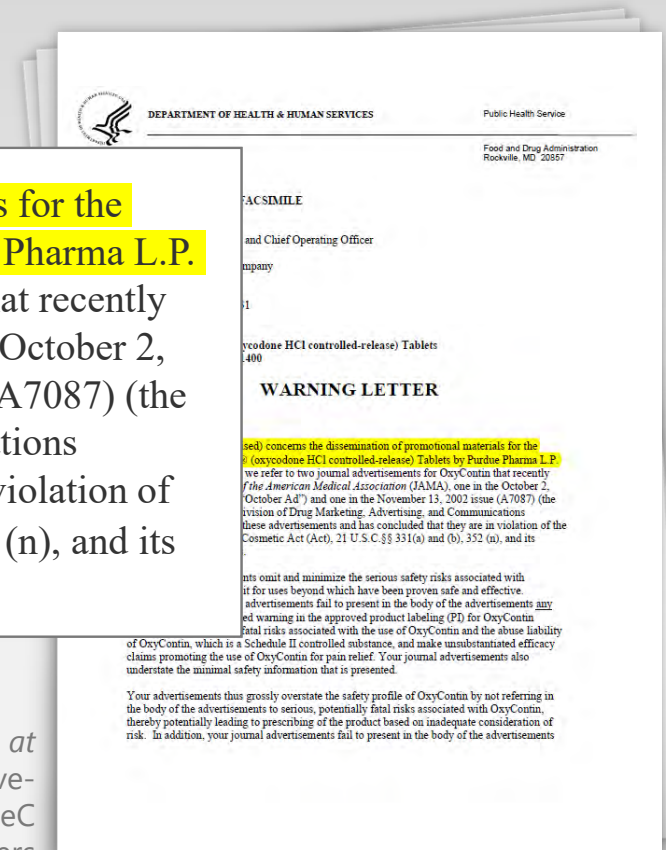
Page 42 of 61

Revision 05

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

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

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




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

More in Warning Letters and Notice of Violation Letters to Pharmaceutical Companies	
Warning Letters 2016	
Warning Letters 2015	
Warning Letters 2014	
Warning Letters 2013	
Warning Letters 2012	
Warning Letters 2011	
Warning Letters 2010	
Warning Letters 2009	
Warning Letters 2008	
Warning Letters 2007	
Warning Letters 2006	
Warning Letters 2005	
Warning Letters 2004	
Warning Letters 2003	
Warning Letters 2002	

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

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



U.S. FOOD & DRUG

ADMINISTRATION

Search

Menu

[Home](#) / [Drugs](#) / [Guidance, Compliance, & Regulatory Information](#) / [Enforcement Activities | FDA](#) / [Warning Letters and Notice of Violation Letters to Pharmaceutical Companies](#) / [Warning Letters 2018](#)

Warning Letters 2018

Share

Tweet

LinkedIn

Email

Print

Warning Letters and Notice of Violation Letters to Pharmaceutical Companies

Warning Letters 2019

Warning Letters 2018

Warning Letters 2017

Warning Letters 2016

Warning Letters 2015

These letters are supplied by the CDER Freedom of Electronic Information Office. This page only covers Office of Prescription Drug Promotion (formerly Division of Drug Marketing, Advertising and Communications) and CDER Headquarters Warning Letters. For District Office Warning Letters see the [Main FDA FOI Warning Letters Page](#). Some of the letters have been redacted or edited to remove confidential information. Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter.


- Office of Prescription Drug Promotion Letters
- Office of Compliance/Immediate Office
- Office of Manufacturing Quality Letters
- Office of Scientific Investigations Letters
- Office of Unapproved Drugs and Labeling Compliance
- Office of Drug Security, Integrity and Recalls

If you wish to obtain available additional information on the current status of an issue in a particular warning letter or notice of violation on this website, please contact the Agency or the recipient of the letter directly. Inquiries to FDA should be sent to:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane, Rockville, MD 20857

Content current as of:
08/08/2019

Regulated Product(s)
Drugs



Allegations Are Unsupported by Cited Documents

Allegation: Board Received Research Contradicting Marketing Material

Massachusetts AG OC ¶179:

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

¹² July 2007.

MA AG Cmplt. ¶179

New York AG FAC ¶388:

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

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

NY AG FAC ¶388

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

July 2007 Board Report:

Norspan – US Submission

Path #1 (submission target 3Q2009)

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

• Path # 1 (submission target 3Q2009)

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

For Path # 1 – BUP3024

Corporate objective for initiating the Clinical Study BUP3024 study has been with a first patient, first visit that occurred on June 27, 2007.

Design and analysis plan for this study was agreed to by FDA through the Special Protocol Assessment (SPA) procedure on May 25, 2007.

We also accepted our proposal to submit two pivotal studies that utilize an adaptive design as the basis for providing substantial evidence of efficacy. Agency's acceptance of our justification for this submission strategy represents a significant achievement for PPLP, and is expected to improve the speed for the demonstration of efficacy required for US approval.

For Path # 1 – BUP3025

BUP3025 protocol and statistical analysis plan have been finalized for submission to FDA through the Special Protocol Assessment (SPA) procedure. BUP3025 is a replicate design of BUP3024, albeit with a population change from chronic low back pain to osteoarthritis of the hip or knee to a population of subjects with chronic low back pain.

Timing of this study is to take place in 4Q07.

4Q4Q2008

Efficacy study – BP96-0604 (Previously completed, submitted and FDA-approved study: A Comparative Study of Buprenorphine TDS, Oxycodone/Paracetamol Tablets qid and Placebo in Patients with Chronic Back Pain)

For Path # 2

Study BP96-0604 is currently being re-analyzed; final results will be available in August 2007.

Additional clinical and statistical experts and external consultants are currently reviewing the re-analysis plan for BP96-0604 and the likelihood of a successful outcome using this study as the second pivotal efficacy study. A final decision regarding the viability of this submission plan will be presented to John Stewart, R&D Operating Committee in September 2007.

1 or Path # 2

Non-approval letter items

Comments have been drafted to 48/50 CM&C deficiency items

Comments have been drafted to 5/12 Clinical deficiency items

2nd Quarter 2007

21

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP004366655

July 2007 Board Report, p. 21 (PPLP004366645)

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

2010 Butrans Label:

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

The Office of Inspector General confirmed compliance for this period

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

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

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

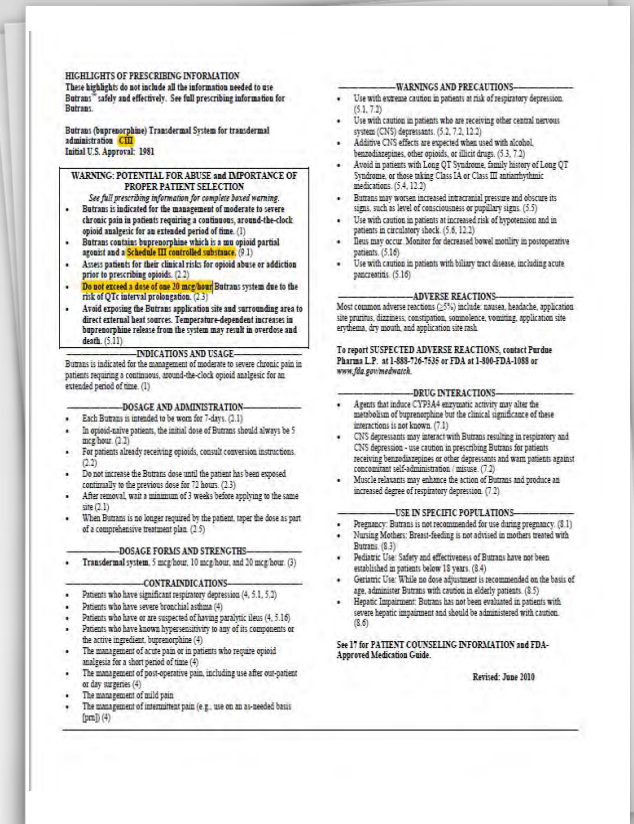
reasons. Of the 256 patients randomized to Butrans, 9% discontinued due to lack of efficacy and 16% due to adverse events. Of the 283 patients randomized to placebo, 13% discontinued due to lack of efficacy and 7% due to adverse events.

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

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

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

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



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

Allegation: Directors Oversaw Payments To High Prescribers

Massachusetts AG OC ¶182:

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

¹⁵ November 2011.

¹⁶ July 2007.

¹⁷ July 2013.

¹⁸ August 2011, November 2011.

¹⁹ April 2010.

New York AG FAC ¶388:

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

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

MA AG OC ¶182

NY AG FAC ¶388

Cited Reports Say Nothing About a Strategy to “Pay High Prescribers”

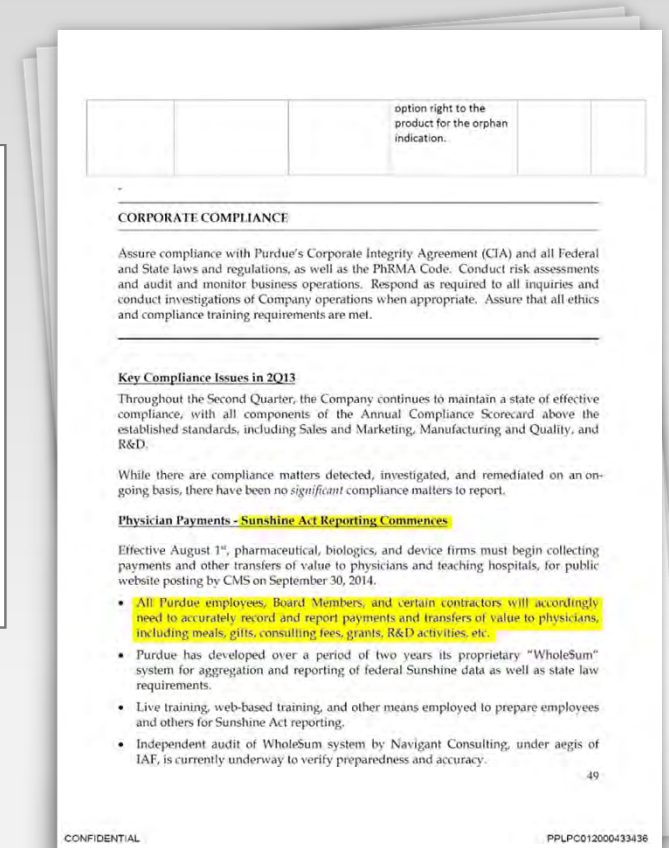
- The reports informed Board of new reporting requirements and spending limits

Physician Payments - Sunshine Act Reporting Commences

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

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

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



July 2013 Board Report, p. 49 (PPLPC012000433388)

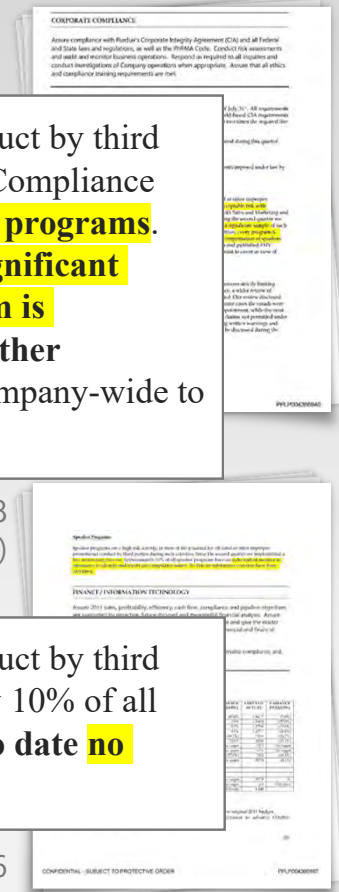
Cited Reports Informed Board Speaker Programs Had Appropriate Controls And Were Monitored For Compliance

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

August 2011 Board Report, p. 28
(PPLP004366913)

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

November 2011 Board Report, p. 26
(PPLP004366871)



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

Massachusetts AG OC ¶183:

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

²⁰ January 2011.

²¹ August 2011.

²² November 2011.

²³ April 2010, July 2010, October 2010, November 2011.

²⁴ April 2010, July 2010, October 2010, November 2011.

²⁵ May 2013 email for board meeting in June 2013

New York AG FAC ¶388:

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

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

MA AG OC ¶183

NY AG FAC ¶388

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

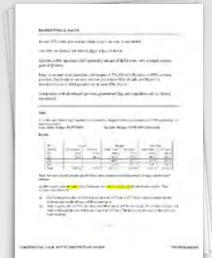
Net sales of the 40 and 80 mg strengths of OxyContin ended 2010 \$85 mm **less than budget**. Sales of these strengths were over budget through the end of October, but sales in November and December were substantially less than budget.

January 2011 Board Report, p. 2 (PPLP004366955)



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

August 2011 Board Report, p. 3 (PPLP004366913)



3Q 2011 year to date actual **net sales** of \$2,213.7 mm were **lower than budget** by \$848.9 mm or 28 %. This variance was driven by: (i) OxyContin gross sales of \$2,077.6 mm that were \$813.4 mm or 28 % below budget mainly due to declining sales in the 40 mg and 80 mg strengths.

November 2011 Board Report, p. 2 (PPLP004366871)



- **OIG confirmed compliance for this period (2010-2011)**

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

April 2010 Board Report:

Take appropriate action on external threats to optimal pain care.

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

EXTERNAL AFFAIRS

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

16

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP004317563

April 2010 Board Report, p. 16 (PPLP004317547)

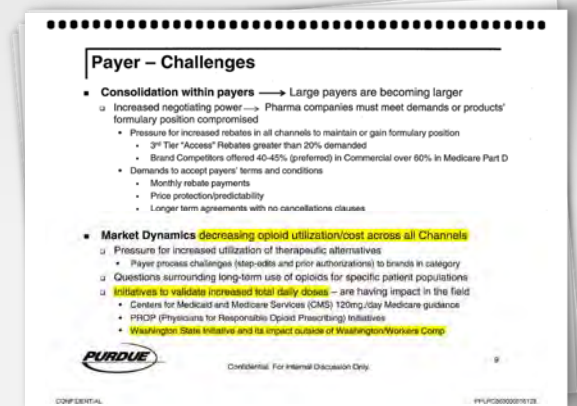
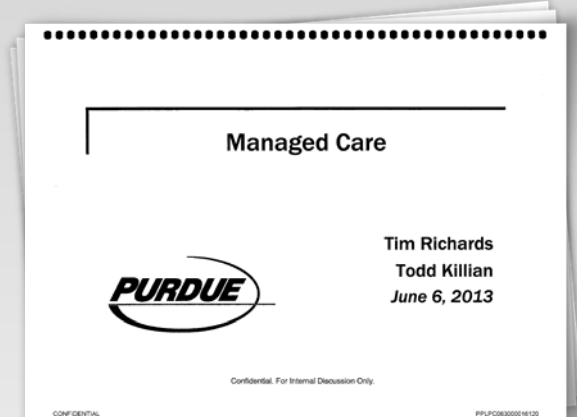
Cited Reports Informed The Board That Legislation Required Validation of Higher Daily Doses — Not Purdue Initiatives To Increase Doses

Board was told market dynamics were driving sales down

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

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

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



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

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

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

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

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

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

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

John,

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

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

Jon Sackler

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

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

-----Original Message-----

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

Jon

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

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

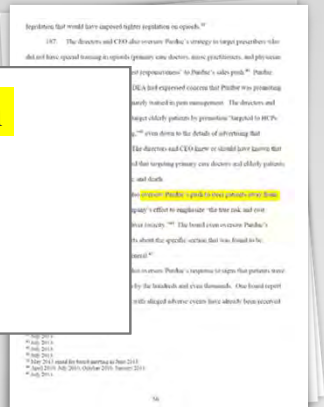
5/28/09 - 6/1/09 Email Chain (PPLPC012000225228)

Allegation: Board Oversight Push Away From Safer Alternatives

Massachusetts AG OC ¶188:

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

⁴³ May 2013 email for board meeting in June 2013.

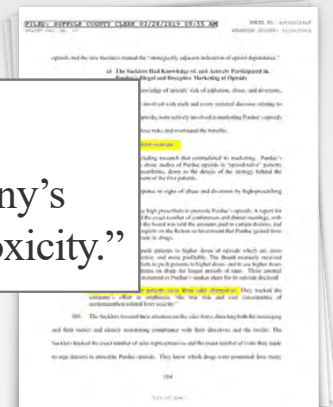


MA AG OC ¶188

New York AG FAC ¶388:

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

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



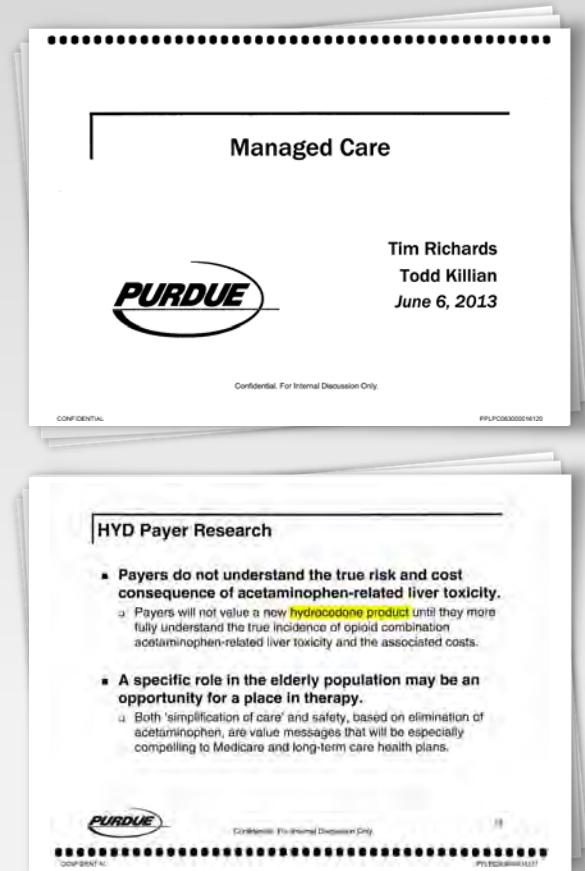
NY AG FAC ¶388

No “Push Away From Safer Alternatives”

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

- **Payers do not understand the true risk and cost consequence of acetaminophen-related liver toxicity.**

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



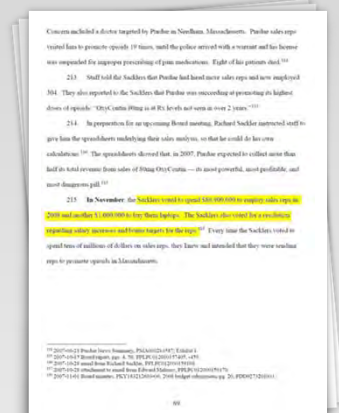
June 2013 Managed Care Board Slides, p. 18 (PPLPC063000016119)

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

Massachusetts AG FAC ¶215:

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

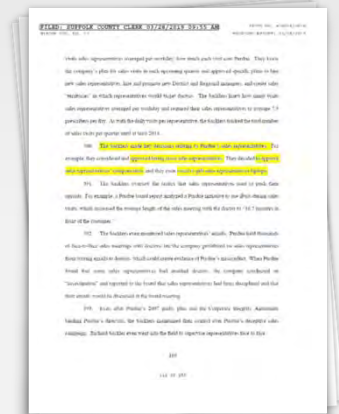
¹¹⁸ 2007-11-01 Board minutes, PKY183212603-06; 2008 budget submission, pg. 20, PDD9273201033.



MA AG FAC ¶215

New York AG FAC ¶390:

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



NY AG FAC ¶390

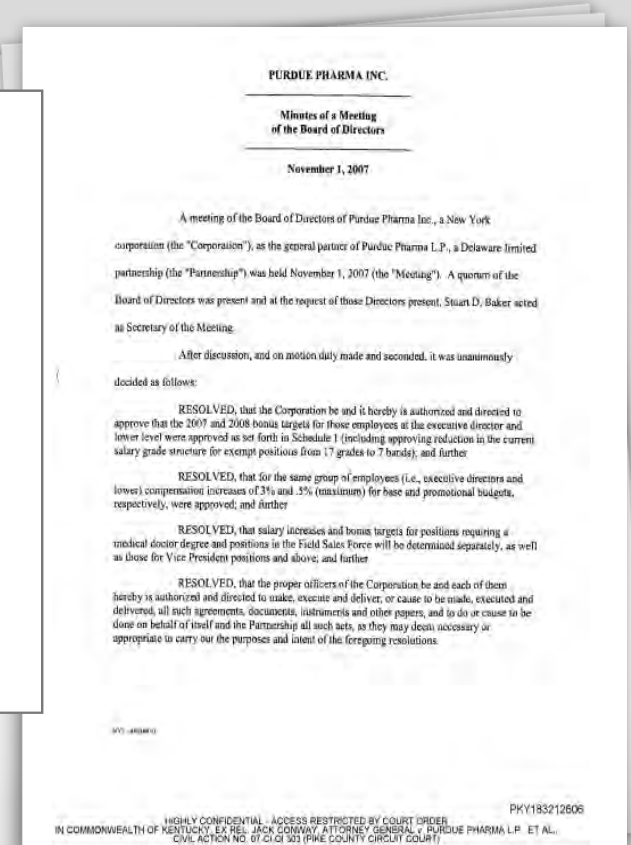
Cited Board Minutes Did Not Address Compensation For Sales Reps, Said Nothing About “Gifting” Laptops

November 1, 2007 Board Minutes:

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

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

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



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

Corporate Integrity Agreement:

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

the requirement that all of Purdue's Covered Persons shall be reported to the Compliance Officer, or other appropriate individual by Purdue, suspected violations of any Federal law, or FDA requirements or of Purdue's own policies as implemented pursuant to Section III.B.2; sequences to both Purdue and Covered Persons of the 1st Federal health care program or FDA policies and procedures as set forth in Purdue's own Policies and Procedures as set forth in Section III.B.2 and the failure to report such violations; and

individuals to use the Disclosure Program described in Purdue's commitment to nonretaliation and to ensure the confidentiality and anonymity with respect to the reporting of violations.

lished, within 120 days after the Effective Date, whether in writing or electronically, that he or she has received, or is to receive, a copy of Purdue's Code of Conduct. New Covered Persons shall complete the required certification within 30 days or within 120 days after the Effective Date, whichever is later.

the Code of Conduct to determine if revisions are necessary. Any revisions shall be implemented within 30 days or within 120 days after the Effective Date, whichever is later. Any revisions shall be implemented in writing or electronically, that he or she has received, or is to receive, a copy of the revised Code of Conduct within 30 days or within 120 days after the Effective Date, whichever is later.

es. To the extent not already accomplished, Purdue shall implement written Policies and Procedures to ensure compliance with the requirements of the Code of Conduct and the compliance program and its implementation. At a minimum, the Policies and Procedures shall include:

The CIA Governed Decisions About Compensation For Sales Reps

HR Standard Business Practices Field Sales Compensation Determination:

- 1.1 The compensation system for the Field Sales Force is composed of payment of base salary and a quarterly bonus. **The compensation structure is based on a variety of factors and is not based exclusively on volume of OxyContin sales.** The Field Sales Force compensation system is managed by the Human Resources Compensation group with input from Sales Management.
- 1.4 There is a Field Force Bonus Review Committee comprised of Purdue senior management from: Sales, Marketing, Finance, Human Resources, Office of the General Counsel and Sales Operations.
- 1.6 **The Field Force Bonus Review Committee reviews and recommends quarterly bonus plan proposals in an effort to provide for a bonus program that rewards the Field Sales Force's efforts to promote Company products in a compliant manner within applicable FDA and federal health care program guidelines** and reflects a pay philosophy that is market competitive.

Field Sales
Compensation Determination
4.2
C: July 11, 2009
July 30, 2008
d may be updated at any
is Force that is based on a
appropriate and responsible
applicable FDA and federal
Medical Marketing
atives, District Managers
Regional Managers and
bonus program only.
3. Compliance with Purdue's Code of business ethics, policies and procedures will
be considered in all compensation related documents and actions.
Sales Force is market
Sales Force are made in a
is composed of payment of
structure is based on a
volume of OxyContin sales. The
by the Human Resources
ment. This includes bonus
plan recommendations, pay administration and the collection of external industry
data to help determine results versus goal. The Sales Operations Department also
the collection of external
information. This information
salary and bonus)
force is paying its sales
determined based on external
the new employee's current
we are conducted annually
or date as may be set.
based on individual
Page 1 of 2

PPLP004433671

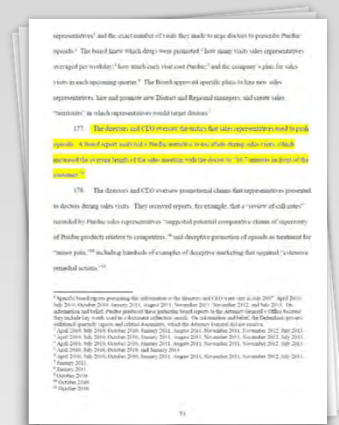
2009 HR SOP (PPLP004433671)

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

Massachusetts AG OC ¶177:

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

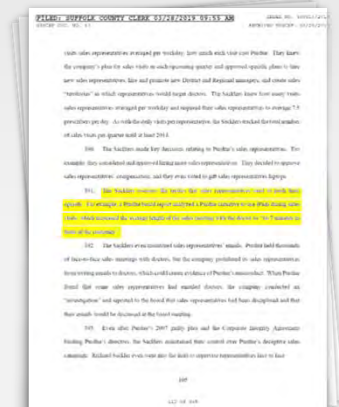
⁸ January 2011.



MA AG OC ¶177

New York AG FAC ¶391:

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

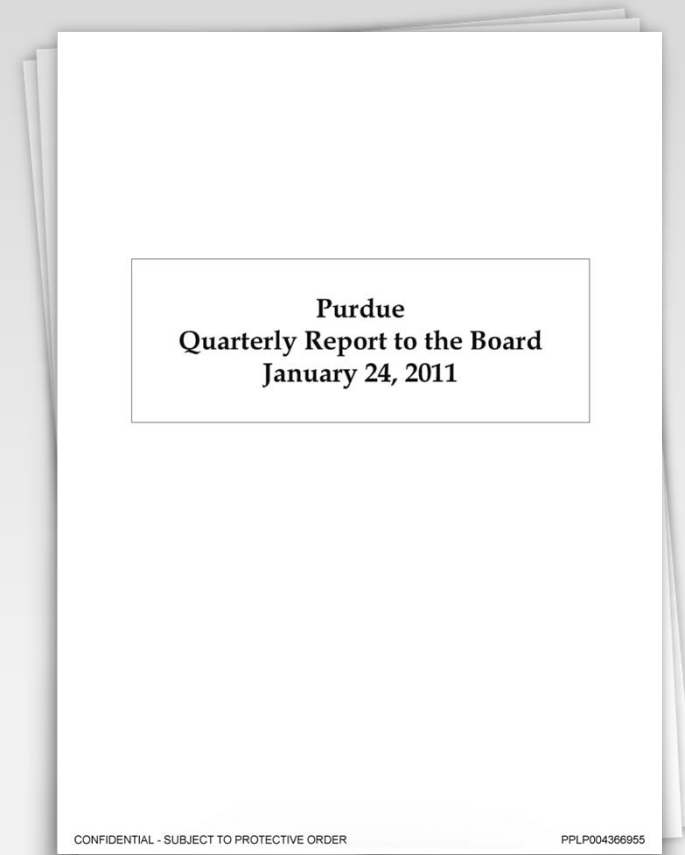


NY AG FAC ¶391

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

The January 2011 Report to the Board:

- Seeks no Board input on the marketing initiatives
 - Informs directors about existing marketing initiatives
 - Makes no reference to iPads
 - Does not describe the substance of any marketing presentation
- **OIG confirmed compliance for 2011**



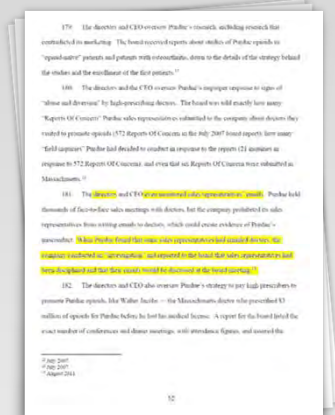
January 2011 Board Report (PPLP004366955)

Allegation: Board Monitored Sales Reps' Emails

Massachusetts AG OC ¶181:

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

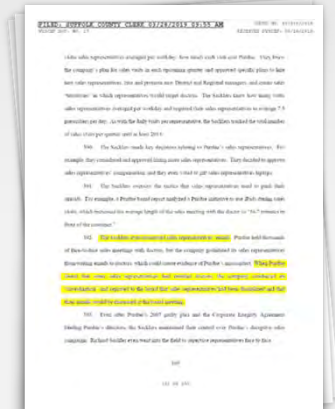
¹⁴ August 2011.



MA AG OC ¶181

New York AG FAC ¶392:

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



NY AG FAC ¶392

Management Monitored Emails To Prevent And Remediate Marketing Violations

August 2011 Board Report:

“Email” Investigation

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

CORPORATE COMPLIANCE

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

Agreement

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

Reportable Events to report to the Office of Inspector General during this quarter:

Requirements

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

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

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

July 21st Board meeting.

28

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP004366940

August 2011 Board Report, p. 28 (PPLP004366913)

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

How Does the Sales Monitoring “System” Work in Practice?

An Example...



22

CONFIDENTIAL

PPLPC012000335554

Emails to Customers

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

Correspondence with HCPs

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

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

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



23

CONFIDENTIAL

PPLPC012000335555



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

Investigation

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

MINOR

MAJOR

Customer reference to Butrans

Rep email including claims

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



24



CONFIDENTIAL

PPLPC012000335556

Outcomes

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



25



CONFIDENTIAL

PPLPC012000335567

- OIG confirmed compliance for 2011**

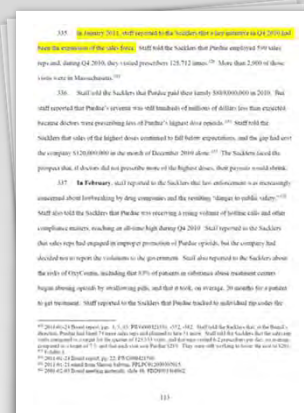
Quarterly Compliance Report 2Q 2011, p. 24-25 (PPLPC012000335414)

Allegation: Board Approved Expansion Of Sales Force

Massachusetts AG FAC ¶335:

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

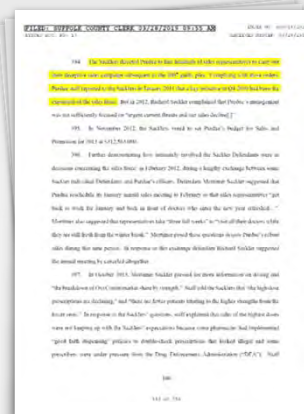
³²⁸ 2011-01-24 Board report, pgs. 4, 5, 35, PWG000421551, -552, -582.



MA AG FAC ¶335

New York AG FAC ¶394:

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



NY AG FAC ¶394

Cited Report Shows Expanded Sales Force Was To Launch Butrans

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

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

Purdue
Quarterly Report to the Board
January 24, 2011

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP004366955

January 2011 Board Report, p. 5 (PPLP004366955)

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

January 2011 Board Report:

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

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

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

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

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

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

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

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

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

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

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

4

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP004366959

January 2011 Board Report, p. 4 (PPLP004366955)

Allegation: Board Set Sales Budget

Massachusetts AG FAC ¶391:

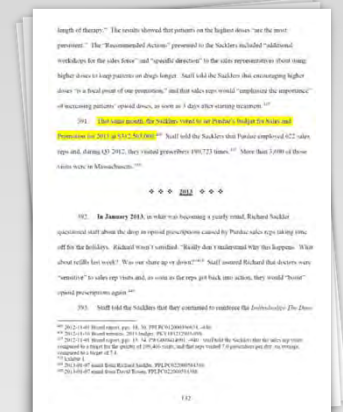
391. That same month, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at \$312,563,000.⁴³⁶

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

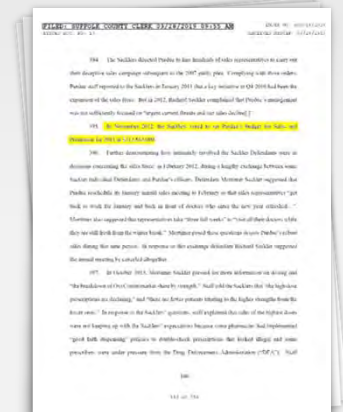
New York AG FAC ¶395:

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

- Setting a budget is not deceptive marketing



MA AG FAC ¶391

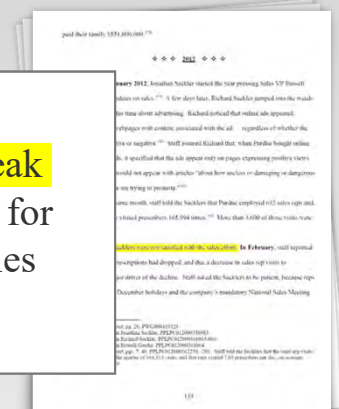


NY AG FAC ¶395

Allegation: Board Was “Intimately Involved” in Sales Force Decisions

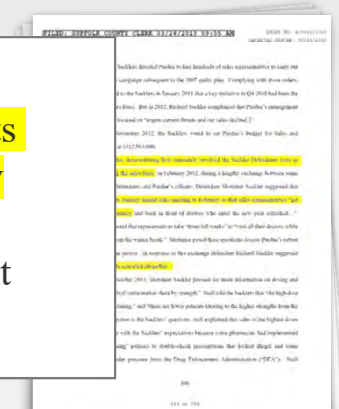
Massachusetts AG FAC ¶368:

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



New York AG FAC ¶396:

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



MA AG FAC ¶368

NY AG FAC ¶396

Cited Email Shows Board Questions About Timing Of Annual Sales Meeting

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

Russ,

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

What do other companies do?

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

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

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

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

- OIG confirmed compliance for 2012**

HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLPC026000095656

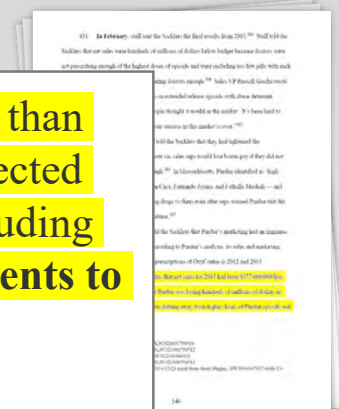
2/7/12 Email Chain (PPLPC026000095656)

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

Massachusetts AG FAC ¶433:

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

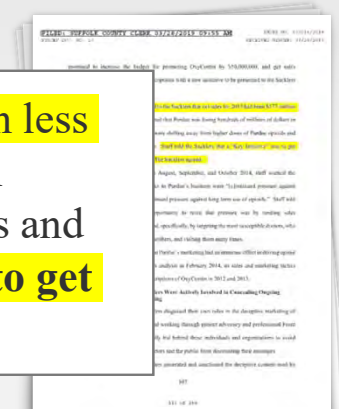
⁵⁰⁸ 2014-02-04 Board report, pgs. 3, 5, 9, 22, PPLPC002000181037, -039, -043, -056.



MA AG FAC ¶433

New York AG FAC ¶398:

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



NY AG FAC ¶398

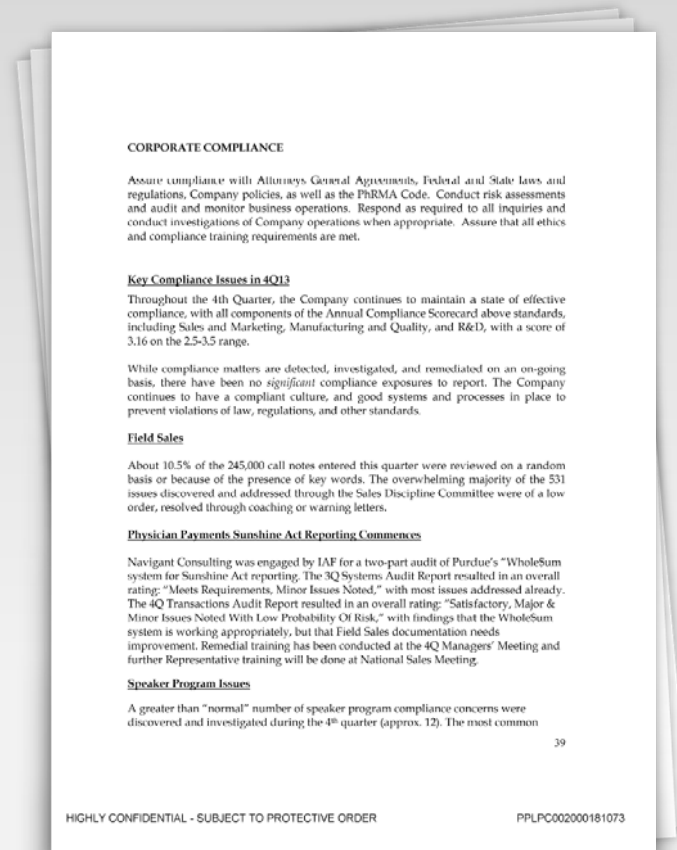
Allegation Juxtaposes Unrelated Passages On Net Sales And An Initiative To Help Patients Take Butrans As Prescribed (“Adherence Program”)

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

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

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

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



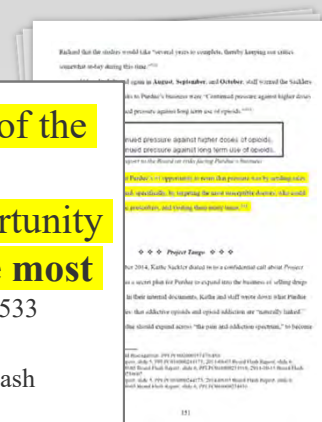
February 2014 Board Report, p. 39 (PPLPC002000181073)

Allegation: Board Informed Purdue Was Targeting “Susceptible” Doctors

Massachusetts AG FAC ¶444:

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

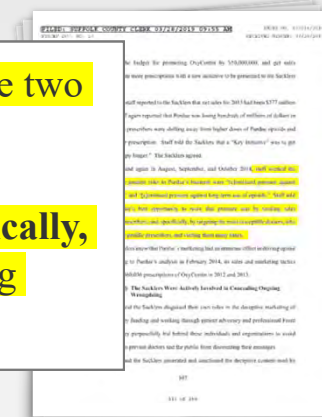
⁵³³. 2014-07-01 Board Flash Report, slide 5, PPLPC016000244173; 2014-08-05 Board Flash Report, slide 6, PPLPC016000250753; 2014-09-05 Board Flash Report, slide 6, PPLPC016000254916.



MA AG FAC ¶444

New York AG FAC ¶399:

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



NY AG FAC ¶399

Cited Flash Reports Say Nothing About Targeting “Susceptible” Doctors

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

OPPORTUNITIES

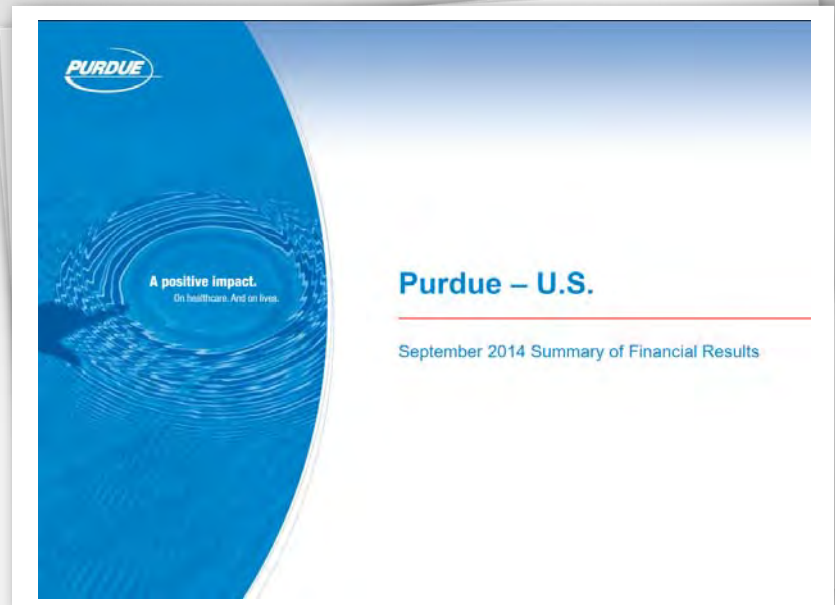
- i. OxyContin AG bottles may sell in slower than Budget. Net sales value of \$180 million of AG product was shipped by Purdue to the counterparties in Q3 2014. The budget assumed that the entire \$180 million would impact Purdue sales in 2014 - our current estimate is that only \$85 million will impact 2014, with \$95 million of net sales impact shifting from 2014 to 2015.
- ii. Medicaid line extension rebate final regulations may be decided favorable to Purdue saving \$243 million. We now expect this matter to be resolved in Q2 2015.
- iii. The E2E effort has resulted in on or very close to budget performance on (1) primary sales call split between products (OxyContin/Butrans), (2) # of sales calls, and (3) % calls on target HCP's (Q3 Actual of 90% vs. budget of 85%). These are all significant improvements since 2013.
- iv. Improved patient access - Purdue is employing many tactics to address patient access issues including collaborating with the National Association of Boards of Pharmacy to develop standard dispensing guidelines, working with wholesalers/retailers to establish thresholds for orders/scripts based on NDC # versus API, and more. Most recently Purdue has been successful with Walgreens in moving to NDC # quotas thereby separating OxyContin from oxycodone IR and other non-abuse deterrent products.
- v. R2R has delivered improved tools such as customer segmentation and contract profitability that will help ensure profitable access and optimization of rebates in the Managed care area (more likely to impact 2015).
- vi. IDN, call center, savings card optimization, prior authorization assistance programs and other initiatives are underway or being evaluated (more likely to impact 2015).

RISKS

- i. Continued pressure against higher doses of opioids.
- ii. Continued pressure against long term use of opioids.
- iii. A new class label for ER opioids includes the following language “reserve OxyContin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate ...”.
- iv. OxyContin rebates will run higher than budget due to an unanticipated contract re-negotiation initiated by United Healthcare. This is reflected in our latest estimates.
- v. The budget does not include any impact that a Teva settlement may have on 2014 results.



7



2014-10-15 Board Flash Report, slide 7 (PPLPC016000259607).

See also 2014-07-01 Board Flash Report, slide 5 (PPLPC016000244173);

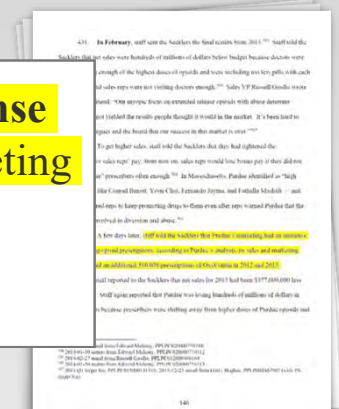
2014-08-05 Board Flash Report, slide 6 (PPLPC016000250753); 2014-09-05 Board Flash Report, slide 6 (PPLPC016000254916).

Allegation: Board Knew Marketing Generated Increased Prescriptions

Massachusetts AG FAC ¶433:

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

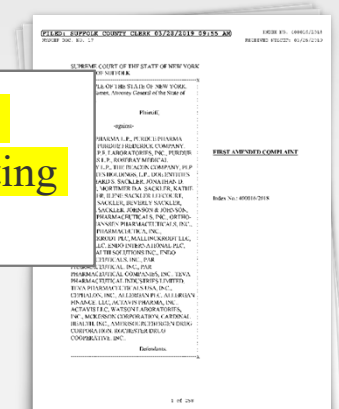
⁵⁰⁸ 2014-02-04 Board report, pgs. 3, 5, 9, 22, PPLPC002000181037, -039, -043, -056.



MA AG FAC ¶433

New York AG FAC ¶400:

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



NY AG FAC ¶400

Reports Of Increased Prescriptions Accompanied By Confirmation Of Compliance

February 2014 Board Report:

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

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

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

CORPORATE COMPLIANCE

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

Key Compliance Issues in 4Q13

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

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

Field Sales

About 10.5% of the 245,000 call notes entered this quarter were reviewed on a random basis or because of the presence of key words. The overwhelming majority of the 531 issues discovered and addressed through the Sales Discipline Committee were of a low order, resolved through coaching or warning letters.

Physician Payments Sunshine Act Reporting Commences

Navigant Consulting was engaged by IAF for a two-part audit of Purdue's "WholeSum" system for Sunshine Act reporting. The 3Q Systems Audit Report resulted in an overall rating: "Meets Requirements, Minor Issues Noted," with most issues addressed already. The 4Q Transactions Audit Report resulted in an overall rating: "Satisfactory, Major & Minor Issues Noted With Low Probability Of Risk," with findings that the WholeSum system is working appropriately, but that Field Sales documentation needs improvement. Remedial training has been conducted at the 4Q Managers' Meeting and further Representative training will be done at National Sales Meeting.

Speaker Program Issues

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

39

HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLPC002000181073

February 2014 Board Report, p. 39 (PPLPC002000181035)

Allegation: The Board Served As “De Facto CEO” of Purdue

Massachusetts AG FAC ¶485:

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

opioid addiction with intravenous drug pumps.⁵⁸⁹ The business was a “strategic fit,” because the business treated the “strategically adjacent indication of opioid use.” The Sacklers were searching for a way to expand their business by selling both for opioid addiction.

♦ ♦ ♦ 2017 ♦ ♦ ♦

The Sacklers met with the Board in February, March, April, June, July, and December.⁵⁹⁰ Landau told the Sacklers that an independent nonprofit had concluded that Naloxone was not a cost-effective way to prevent opioid overdose. Landau told staff what they were doing to fight back to convince doctors and patients.⁵⁹¹

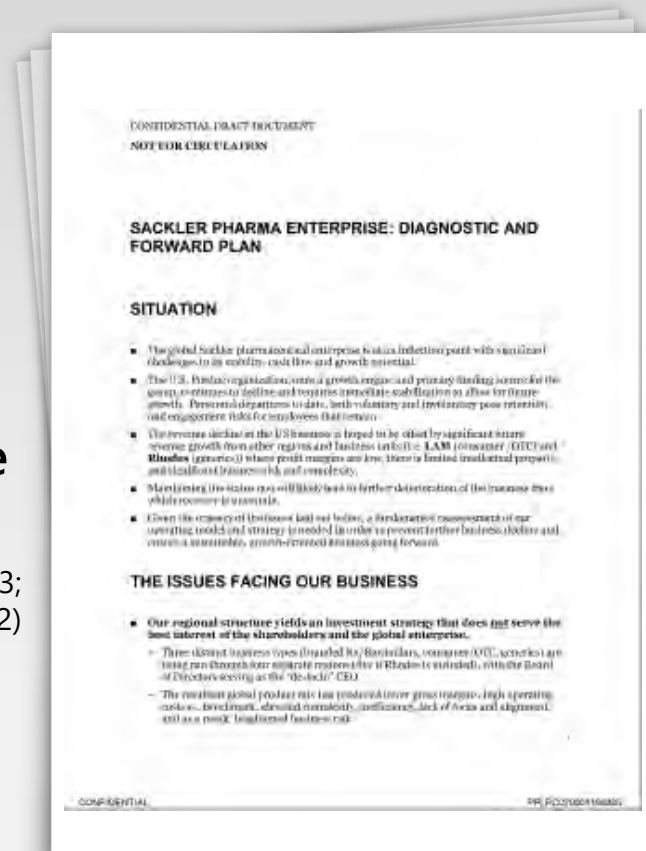
The Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled “SACKLER PHARMA ENTERPRISE.” Landau was careful to acknowledge their power: he acknowledged that Purdue operated with “the Board of Directors serving as the ‘de facto’ CEO.” He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

1. PPLPC02200900230
2. PPLPC02200900233
3. PPLPC02200900233
4. PPLPC02200900233
5. PPLPC02200900233
6. PPLPC02200900233
7. PPLPC02200900233
8. PPLPC02200900233
9. PPLPC02200900233
10. PPLPC02200900233
11. PPLPC02200900233
12. PPLPC02200900233
13. PPLPC02200900233
14. PPLPC02200900233
15. PPLPC02200900233
16. PPLPC02200900233
17. PPLPC02200900233
18. PPLPC02200900233
19. PPLPC02200900233
20. PPLPC02200900233
21. PPLPC02200900233
22. PPLPC02200900233
23. PPLPC02200900233
24. PPLPC02200900233
25. PPLPC02200900233
26. PPLPC02200900233
27. PPLPC02200900233
28. PPLPC02200900233
29. PPLPC02200900233
30. PPLPC02200900233
31. PPLPC02200900233
32. PPLPC02200900233
33. PPLPC02200900233
34. PPLPC02200900233
35. PPLPC02200900233
36. PPLPC02200900233
37. PPLPC02200900233
38. PPLPC02200900233
39. PPLPC02200900233
40. PPLPC02200900233
41. PPLPC02200900233
42. PPLPC02200900233
43. PPLPC02200900233
44. PPLPC02200900233
45. PPLPC02200900233
46. PPLPC02200900233
47. PPLPC02200900233
48. PPLPC02200900233
49. PPLPC02200900233
50. PPLPC02200900233
51. PPLPC02200900233
52. PPLPC02200900233
53. PPLPC02200900233
54. PPLPC02200900233
55. PPLPC02200900233
56. PPLPC02200900233
57. PPLPC02200900233
58. PPLPC02200900233
59. PPLPC02200900233
60. PPLPC02200900233
61. PPLPC02200900233
62. PPLPC02200900233
63. PPLPC02200900233
64. PPLPC02200900233
65. PPLPC02200900233
66. PPLPC02200900233
67. PPLPC02200900233
68. PPLPC02200900233
69. PPLPC02200900233
70. PPLPC02200900233
71. PPLPC02200900233
72. PPLPC02200900233
73. PPLPC02200900233
74. PPLPC02200900233
75. PPLPC02200900233
76. PPLPC02200900233
77. PPLPC02200900233
78. PPLPC02200900233
79. PPLPC02200900233
80. PPLPC02200900233
81. PPLPC02200900233
82. PPLPC02200900233
83. PPLPC02200900233
84. PPLPC02200900233
85. PPLPC02200900233
86. PPLPC02200900233
87. PPLPC02200900233
88. PPLPC02200900233
89. PPLPC02200900233
90. PPLPC02200900233
91. PPLPC02200900233
92. PPLPC02200900233
93. PPLPC02200900233
94. PPLPC02200900233
95. PPLPC02200900233
96. PPLPC02200900233
97. PPLPC02200900233
98. PPLPC02200900233
99. PPLPC02200900233
100. PPLPC02200900233

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

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

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



PPLPC020001106306-15

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

SUMMARY

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

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

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

ENT
Enterprise
WARD PLAN

rmaceutical enterprise is at an inflection point with
o its cash flow, stability, and future.
ization, once a growth engine and primary funding source
ng precipitously, faces intensifying headwinds and
bilization.

the current revenue decline in the US business will be
offset by significant future revenue growth from **LAM** (consumer /OTC) and
Rhodes (generics) where profit margins are low, there is limited intellectual
property and significant business risk and complexity.

Given the urgency of the issues laid out below, a fundamental reassessment of
immediate change is needed in
I ensure a sustainable, growth-

ered an active decision and in my
of the business from which recovery

NESS

y does **NOT** serve the best
shareholders.

/Biosimilars, consumer/OTC,
rate regions (five if Rhodes is
ving as the “de-facto” CEO.

duced lower gross margins, high
% EU, 82% LAM, 30% Canada) vs.
arma), elevated complexity,
and as a result, heightened business

ifferent products across 49 different
bal enterprise generated from only

Requests

PWG004670880

PWG004670879

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

POTENTIAL IDEAS TO UNLOCK SHAREHOLDER VALUE THROUGH AN INTEGRATED GLOBAL ORGANISATION

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

WE NEED A GLOBAL STRUCTURE ALIGNED WITH GOVERNANCE AND PRIORITIES

What we should do:

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

Memorandum to
The Board of Directors

From
Raman Singh

May 15th, 2017

Driving value creation by globalising our current businesses

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

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

STRATEGIC DIAGNOSIS OF WHERE WE ARE AS A GROUP

Exhibit 1: Our net sales and true contribution projections



PPLPC05100317752, PPLPC051000317764

*Marketing Allegations About Richard, Jonathan,
Beverly & David Sackler*

Claimants' Allegations Fall Into 3 Categories

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

True But Irrelevant Allegations

1. Directors received or requested information from management

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

2. Directors were concerned about sales performance

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

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

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

Risk Of Abuse And Addiction Always Prominently Disclosed

WARNING: May be Habit Forming

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

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

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

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

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



Original 1995 OxyContin Label

1995 OxyContin Label (PDD1501070001)

Schedule II: "High Potential For Abuse"

The **Schedule II ㉟** symbol appears prominently.

1995 OxyContin Label (PDD1501070001)

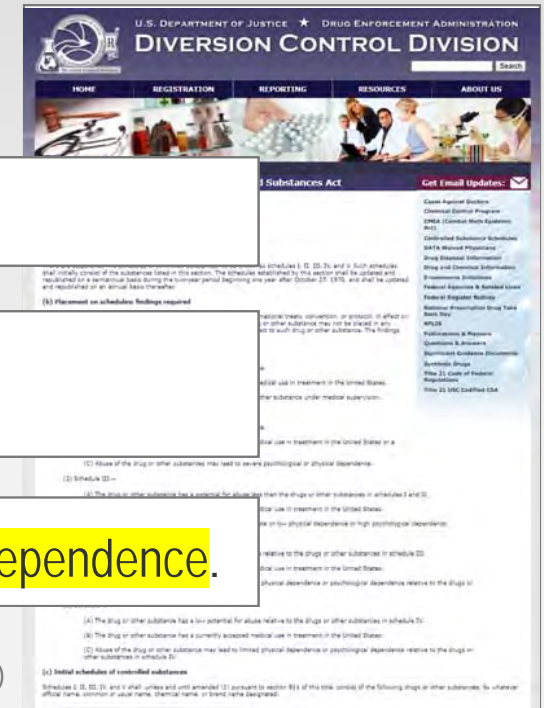


Schedule II:

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

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

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



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

2001 Label Added Black Box Warning

WARNING:

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

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

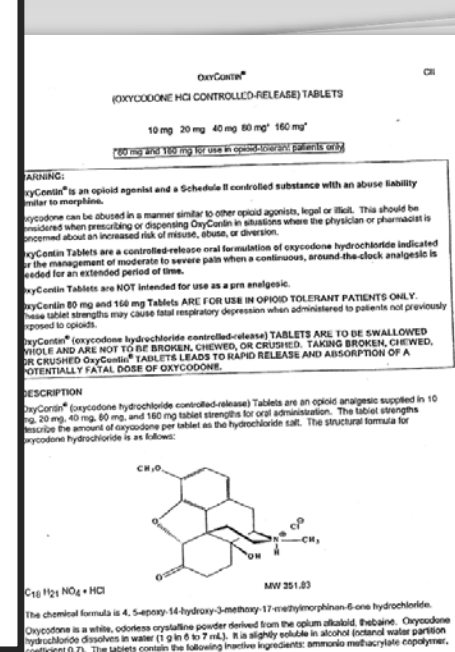
OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These label strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

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

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

FDA Denial of AG Richard Blumenthal Petition (Sept. 9, 2008)

FDA Docket No. FDA-2004-P-0294, at p. 2



July 2001 OxyContin Label, p. 1 (PDD1501070063)

NON-CONFIDENTIAL

PDD1501070063

2001 Label Expanded Prior Warnings About Abuse And Diversion

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

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

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

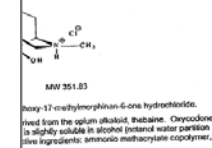
OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone hydrochloride is an opioid agonist, legal or illicit. This should be used in situations where the physician or pharmacist is aware of the potential for diversion. Oxycodone hydrochloride is indicated for the treatment of moderate to severe pain in a continuous, around-the-clock analgesic regimen.

USE IN OPIOID-TOLERANT PATIENTS ONLY. Oxycodone hydrochloride should be administered to patients not previously receiving opioid analgesics.

Tablets are to be swallowed whole, not crushed, broken, chewed, or dissolved. Do not crush, break, chew, or dissolve tablets. Do not use for intravenous or intrathecal administration.

Tablets are an opioid analgesic supplied in 10 mg and 5 mg strengths. The structural formula for oxycodone hydrochloride is as follows:



NON-CONFIDENTIAL

PDD1501070063

July 2001 OxyContin Label, p. 7 (PDD1501070063)

2001 Label Expanded Prior Warnings About Abuse And Diversion

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

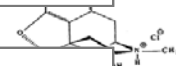
Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

OxyContin®
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

mg* 160 mg*
*For patients only

...ed substance with an abuse liability
...id agonists, legal or illicit. This should be
...ations where the physician or pharmacist is
...ision.
...tion of oxycodone hydrochloride indicated
...ontrols, around-the-clock analgesia is
...nalgesic.
...OPIOID TOLERANT PATIENTS ONLY.
...on when administered to patients not previously
...TABLETS ARE TO BE SWALLOWED
...CRUSHED, TAKING BROKEN, CHEWED,
...RELEASE AND ABSORPTION OF A

Tablets are an opioid analgesic supplied in 10
oral administration. The tablet strengths
chloride salt. The structural formula for



MW 351.83

...y-17-nalbylmorphinan-6-one hydrochloride.
...d from the opium alkaloid, thebaine. Oxycodone
...lightly soluble in alcohol (room temperature)
...ingredients: simonite methacrylate copolymer,

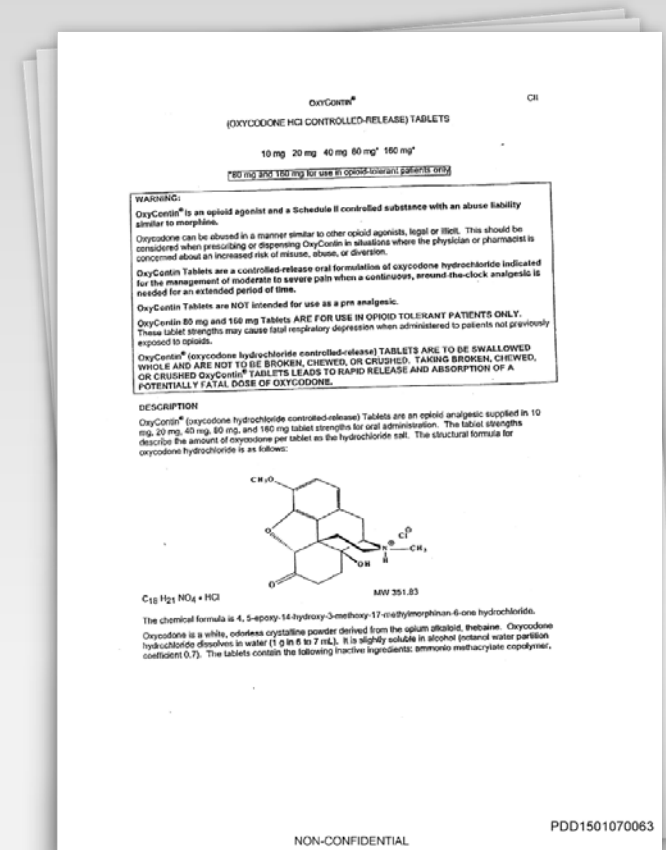
NON-CONFIDENTIAL

PDD1501070063

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

2001 Label Removed And Revised Prior Statements

- Removed statements that “Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug” and that “iatrogenic ‘addiction’ to opioids legitimately used in the management of pain is very rare.”
- Revised label to say that OxyContin is not appropriate for “as needed” pain relief or in the immediate-post operative period if pain is mild or not expected to persist for an extended period of time



July 2001 OxyContin Label (PDD1501070063)

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

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

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

58

Black Box Warnings On Every OxyContin Label Since 2001

2010 Label

WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE

See full prescribing information for complete boxed warning.

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

2010 OxyContin Label, p. 1,
(PDD8901035967)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2014 Label

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

See full prescribing information for complete boxed warning.

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

April 2014 OxyContin Label, p. 1,

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf

2016 Label

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

See full prescribing information for complete boxed warning.

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

2016 OxyContin Label, p. 1,

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf

2018 Label

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

See full prescribing information for complete boxed warning.

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

September 2018 OxyContin Label, p. 1,

Risks Of Addiction, Overdose And Death Continuously Disclosed

2010 Label

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

2010 OxyContin Label, p. 14,
(PDD8901035967)

2014 Label

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

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

2016 Label

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

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

2018 Label

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

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

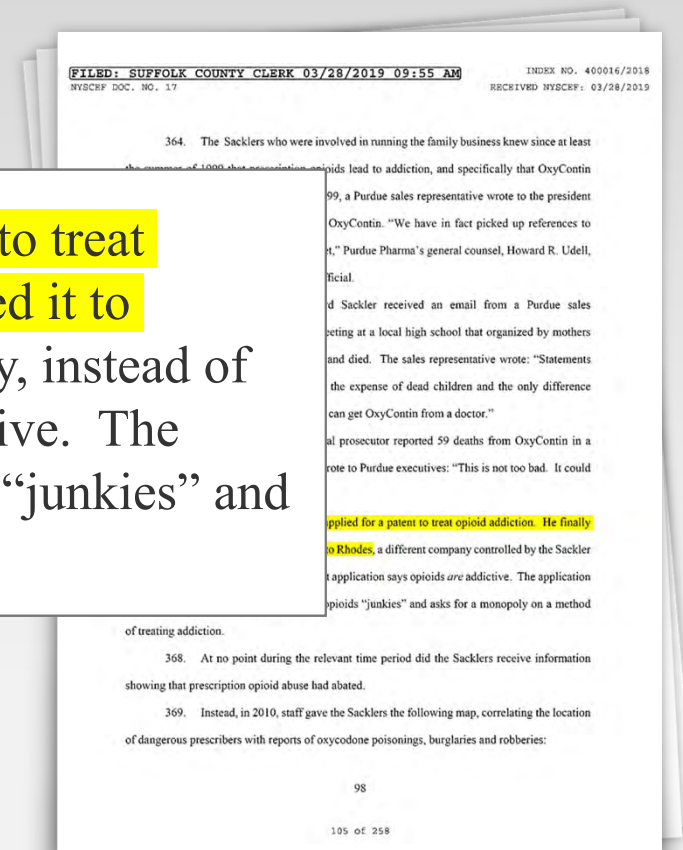
Post-2007 Allegations About Richard Sackler

Allegation: Richard Applied For Patent To Treat Addiction

New York AG FAC ¶367:

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

- False, irrelevant and released

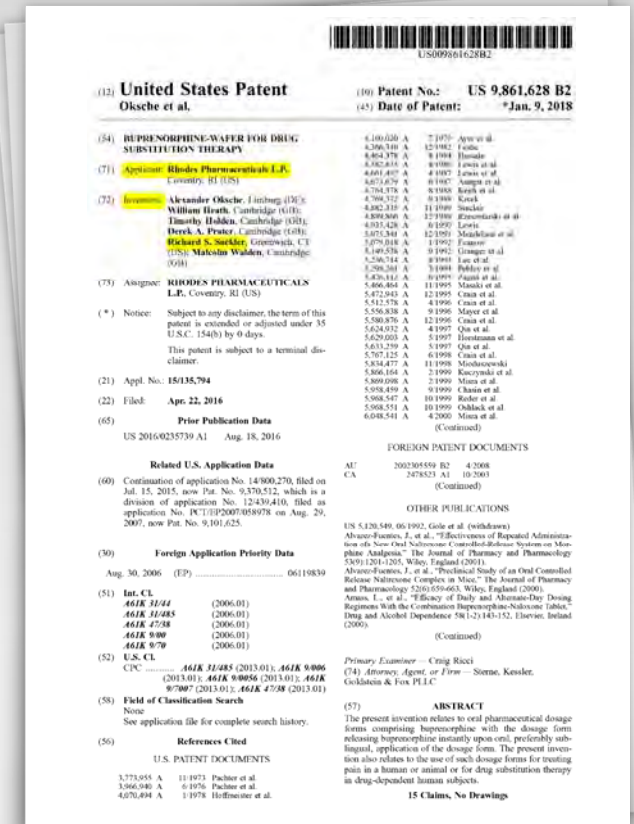


NY AG FAC ¶367

Inventor, Not Applicant

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

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



Patent No. 9,861,628

Purdue Assigned Patent To Rhodes

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

Irrelevant to deceptive marketing claims

ASSIGNMENT AND ASSUMPTION AGREEMENT

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

WITNESSETH:

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

in consideration of the promises and mutual covenants as follows:

Assignor does hereby convey, transfer, assign and deliver unto Assignee, all of Assignor's right, title and interest, in and to all of the patents and patent rights of opiod substitution therapy for treating opiod pain, as set forth on Schedule A attached hereto, and Assignee hereby acknowledges, assigned, its successors and assigns, to its and their own use

As of the Assignment Date, Assignee hereby undertakes, discharge to the extent not heretofore performed, paid obligations of Assignor with respect to the Patent Rights hereby distributed, assigned, to be construed to impose upon Assignee any liability for violation of Assignor with respect to the Patent Rights

prior to the Assignment Date.

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

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

CPH04-1074973.2

PATENT
REEL: 040883 FRAME: 0386

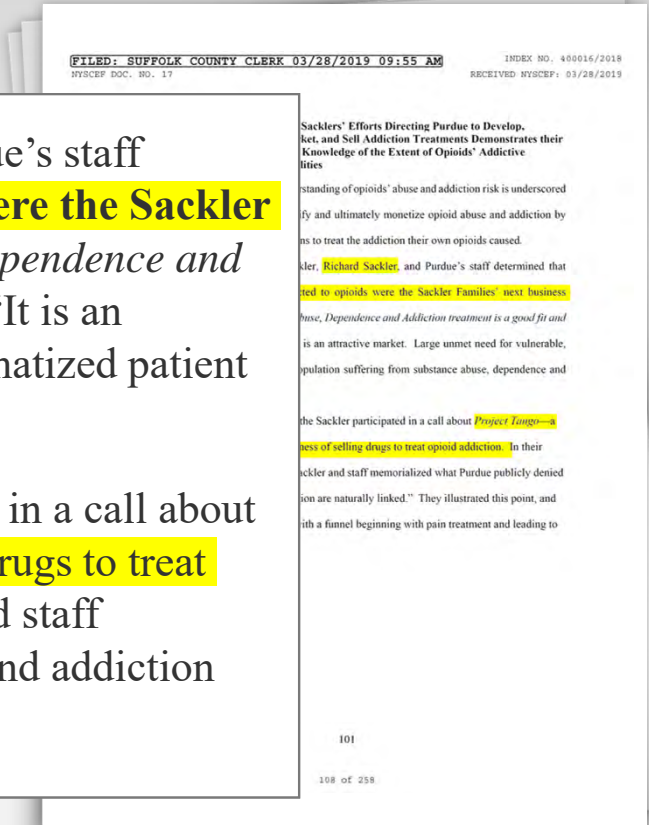
<http://legacy-assignments.uspto.gov/assignments/assignment-pat-43183-387.pdf>

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

New York AG FAC ¶¶377-78:

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

378. In September 2014, Kathe Sackler participated in a call about **Project Tango—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction**. In their internal documents, defendant Kathe Sackler and staff memorialized what Purdue publicly denied for decades: “Pain treatment and addiction are naturally linked.” ...



Not A Family Plan, Not Pursued, Not Relevant

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

Allegation: “Another Version Of *Project Tango*” Two Years Later

New York AG FAC ¶386:

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

- Presented to Board by management
- Never materialized
- Irrelevant to deceptive marketing claims

FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM
RECEIVED: NYC - 11

INDEX NO: 400016/2018
RECEIVED NYSCRF: 03/28/2019

During the presentation, the *Tango* team mapped how patients could get addicted to high prescription opioid analgesics such as Purdue's OxyContin or heroin, and then to the new company's suboxone. The team noted the opportunity to capture patients after patients were done buying suboxone the first time, 40-60% would relapse and

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

could provide \$24M in net sales to Purdue



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

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

103

110 of 258

NY AG FAC ¶386

Allegation: Explored Possibility Of Using PET Scans To Identify Abusers

NY AG FAC ¶374:

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

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

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

INDEX NO. 400016/2018
RECEIVED NYSCEF: 03/28/2019

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

Sackler dictated Purdue's strategy for responding to the
in opioids and addiction to Purdue's opioids: blame and
Sackler wrote in an email: "we have to hammer on the
culprits and the problem. They are reckless criminals."
ing glorified as some sort of populist victim."

essing whether people dependent on opioids "want to be
hing that will totally revise your belief that addicts don't
They get themselves addicted over and over again."
ts] are criminals, and they engage in it with full, criminal
or sympathies?" He further wrote: "This vilification is

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

very interesting

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

100

107 of 258

Allegation: 2011 Ride-Along With Sales Rep

New York AG FAC ¶393:

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

FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM
NYDCRP DOC. NO. 17

INDEX NO. 400016/2019
RECEIVED NYSCEF: 03/28/2019

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

ld target doctors. The Sacklers knew how many visits y and required their sales representatives to average 7.5 per representative, the Sacklers tracked the total number 4.

ecisions relating to Purdue's sales representatives. For ing more sales representatives. They decided to approve hey even voted to gift sales representatives laptops.

e tactics that sales representatives used to push their art analyzed a Purdue initiative to use iPads during sales of the sales meeting with the doctor to "16.7 minutes in

ed sales representatives' emails. Purdue held thousands

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

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

105

115 04 2019

NYAG FAC ¶393; see also *id.* ¶196

2011 Ride-Along With Sales Rep

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

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

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

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



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

Allegation: Report On Tactics To “Push” Butrans Sales

Massachusetts AG FAC ¶¶341-42:

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

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

Purdue: Zero doctors stopped prescribing opioids. Purdue would lose almost 10% of its sales.³⁴⁵

to talk about sales. He
h more than three billion
Sacklers voted to pay

staff sent Richard,
tics reps were using to
a select “core” of
s lobbying to prescribe
“core” include Dr.
ashali.³⁴⁹ Purdue sales
prescriptions, but
way. Dozens of their

he, Mortimer, and
for specific patient
it pushing opioids for
y urged Massachusetts
es in 2011. The reps

1, -809.

³⁴⁹ 2011-05-25 email from Russell Gaudin, PPLPC012000326017.

115

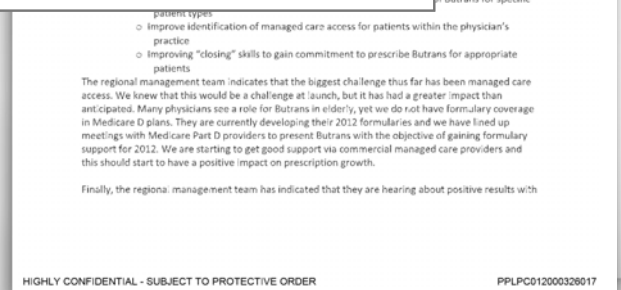
MA AG FAC ¶341

2011 Email: High Level Report On Sales

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

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

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



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

Allegation: Question About Butrans Warning

Massachusetts AG FAC ¶356:

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

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

to promote opioids to doctors alongside
ce President of Sales that a legally-
He asserted that the warning "implies a
en't there." Richard insisted there
oids.³⁶⁵
ur family \$200,000,000.³⁶⁶
If scrambled to prepare responses to
out launching a generic version of
the Sackler recommended looking at the
in to see if Purdue could identify more
anges in market share for opioids,
ring more ways for Richard Sackler to
ard:

utatives, you may want to
consider attending one of the upcoming conventions where we will
be attending. At each of the ones listed below, we will have a
promotional booth for OxyContin & Butrans. In addition, we are
sponsoring educational programs for Butrans and OxyContin in the
form of a "Product Theater."

This would provide you the opportunity to be on the convention
floor, observing numerous presentations being provided by our
representatives and see a wide range of interactions over the course
of a day. In addition, we can arrange for one-on-one meetings with
key opinion leaders who are attending, many of them are approved
consultants/advisors for us and you can have some open
conversations regarding the market, perceptions around Butrans

³⁶⁵ 2011-07-20 email from Richard Sackler, PPLPC001000091102.

³⁶⁶ 2011-06-24 Board minutes, PKCY183212924-925.

³⁶⁷ 2011-06-28 email from Edward Mabony, PPLPC012000331343; attachment PPLPC012000331345.

2011 Email: Question About Butrans Warning

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

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

From: Baumgartner, Todd
Sent: Thursday, July 21, 2011 1:36 PM ...

Dr. Richard, Gary and all,

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

, Gary
7/21/11 1:36 PM
From: Sackler, Dr Richard; Gasdia, Russell
To: John H. (US); Landau, Dr. Craig; Innaurato, Mike; Fanelli, Richard
Subject: Butrans FPI - Follow-Up on Post-Op Contraindication

very helpful.

Baumgartner, Todd
7/21/11 1:36 PM
From: Sackler, Dr Richard; Gasdia, Russell
To: John H. (US); Landau, Dr. Craig; Innaurato, Mike; Fanelli, Richard
Subject: Butrans FPI - Follow-Up on Post-Op Contraindication

Gary and all,

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

Bullets in the Contraindications section of the Butrans FPI are as follows:

- the management of acute pain or in patients who require opioid analgesia for a short period of time
 - management of post-operative pain, including use after out-patient or day surgeries
 - management of mild pain
 - management of intermittent pain (e.g., use on an as-needed basis [prn])
- As of this week, I went back through our correspondence to jog my memory on the negotiations. We originally proposed text similar to what ultimately appeared in the INDICATIONS AND USAGE section of the Butrans label. On April 5, we received FDA's initial comments to our original proposal and at that time they had placed these CONTRAINDICATIONS. We submitted a counter proposal to FDA on April 22 where we went back in the INDICATIONS AND USAGE section, under the sub-heading, "LIMITATIONS OF USE" and included this proposal as well.
- Guidance on labeling for Warnings, Precautions, Contraindications, etc. (January 2006) states: **"The risks of the drug should be contraindicated only in those clinical situations for which the risk clearly outweighs any possible therapeutic benefit. Only known hazards, and not potential hazards, must be listed."** The Guidance further specifies that a contraindication is appropriate for "Likely Clinical Situations" including where: **"The risks of the drug that the drug should never be used in a selected subset of the larger population are such that the risks clearly outweigh any possible therapeutic benefit and the drug should never be used in that subset, a contraindication for use of the drug in that subset should be included."**

- No suggestion of impropriety

CONFIDENTIAL

PPLPC00100091100

7/20/11 Emails w/R. Sackler (PPLPC00100091102)

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

Massachusetts AG FAC ¶376:

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

ment of sales: “Anything you can do to reduce the direct contact of
ation is appreciated.”⁴⁰⁰ A week later, Richard wrote to sales
timize them for U.S. sales being “among the worst” in the world.⁴⁰¹
a, staff sent the Sacklers a revised 2012 budget that cut the proposed
om \$472,500,000 to \$418,200,000.⁴⁰²
aturday morning, Richard Sackler wrote to marketing staff, demand-
nded release pain medications for the past twelve years and an
Monday night.⁴⁰³ Gasdia and Stewart stood by helpless, writing: “Do let
⁴⁰⁴ Later that month, staff created for Richard a historical summary of
OxyContin sales. Eleven of the key events in sales history were changes
sales force — all known to Richard because the Sacklers had ordered
ys later, staff sent Richard Sackler an assessment of recently-improved
Richard that the increase in prescriptions was caused by tactics that
pushing opioids for elderly patients with arthritis (“proper patient
ing doctors to use higher doses of opioids (“quick titration”).⁴⁰⁵ In the
would study, document, and expand the use of higher doses to increase
ped to kill people in Massachusetts.
Sackler wrote that he was not satisfied with a report on sales and

⁴⁰⁰ 2012-02-07 email from Russell Gasdia, PPLPC012000368569.
⁴⁰¹ 2012-02-10 email from Richard Sackler, PPLPC012000368823.
⁴⁰² 2012-01-05 email from Edward Mahoney, PPLPC012000368627.
⁴⁰³ 2012-03-17 email from Richard Sackler, PPLPC012000369328.
⁴⁰⁴ 2012-03-18 email from Russell Gasdia, PPLPC012000369328.
⁴⁰⁵ 2012-03-28 presentation, PPLPC012000371063.
⁴⁰⁶ 2012-03-28 email from David Rosen, PPLPC012000371301.

2012 Email Concerns Butrans, Does Not Mention Elderly Or Arthritis

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

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

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

Thanks,
David

CONFIDENTIAL

PPLPC012000371301

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

Allegation: Demand For Details About Sales And Marketing

Massachusetts AG FAC ¶304:

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

ed prescribers in Massachusetts. Indeed, every day. During Q1 2010, Purdue sales reps mes.²⁶⁹ the sales visits. In April 2010, staff reported edue \$219, and they were working to lower ssachusetts, the costs were far higher. an updated 10-year plan for growing scklers expected Purdue to pay their family at 20. Beginning on page one, staff emphasized “will require significant salesforce support” and the number of reps they would require. med for each rep to visit prescribers 1,540 visits at a cost of \$212 per visit. He by 2015. To reach the Sacklers’ vince doctors to switch patients from oid, and Butrans would become a billion- if just before the July 4th holiday weekend to hard directed them to send to the Board gram.” with instructions to “get this out

Key Assumptions pg. 6, PPLPC012000277155-169, -

101

- True but irrelevant

MA AG FAC ¶304

2010 Email: Request For Written Presentation On Five Topics

From: Sackler, Dr Richard

To: JHS (US)

Cc: Gasdia, Russell; Landau, Dr. Craig; Tavares, Lino; edm; Boer, Peter; Lewent, Judy; Pickett, Cecil; Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Dr Raymond R; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer D.A.; Sackler, Theresa

Sent: Thu Jul 01 13:41:33 2010

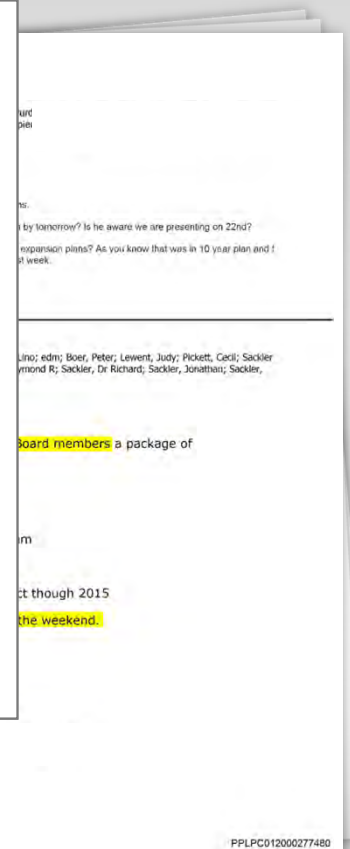
Subject: Norspan

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

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

Please try and get this out before the weekend.

- Butrans, not OxyContin
- OIG confirmed compliance for 2010



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

Allegation: 2011 Meeting With Sales Reps At Butrans Launch

Massachusetts AG FAC ¶328:

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

325. Staff also told the Sacklers that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories.³⁰⁶ The Sacklers voted to spend \$158,086,000 to employ sales reps in 2011.³⁰⁷

326. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and "owners, officers, and managers will especially face even more serious scrutiny in the future."³⁰⁸

by their family \$260,000,000.³⁰⁹

❖ ❖ ❖

t with sales reps for several days at the

ld promote Purdue's newest opioid.³¹⁰

to demand a briefing on how the sales visits

ence and intelligence
are we encountering the
ell are we overcoming it.

and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?"³¹¹

329. Richard's interventions into sales tactics made employees nervous. When Richard followed up to ask for information "tomorrow," CEO John Stewart tried to slow things

³⁰⁶ 2010-11-10 Executive Committee notes, PPLPC012000209854.

³⁰⁷ 2010-11-03 Board minutes, 2011 budget, PKY185212865; 2010-11 budget submission, pg. 18, PDD9273201306.

³⁰⁸ 2010-11-10 Executive Committee notes, PPLPC012000209855; 2010-11-10 Slideshow presentation by Bert Weinstein, slide 7, PPLPC012000209866.

³⁰⁹ 2010-12-02 Board minutes, PKY185212869-70.

³¹⁰ 2011-01-21 email from Russell Gasda, PPLPC012000308393.

³¹¹ 2011-01-30 email from Richard Sackler, PPLPC021000352206.

2011 Email Contains No Suggestion of Improper Marketing

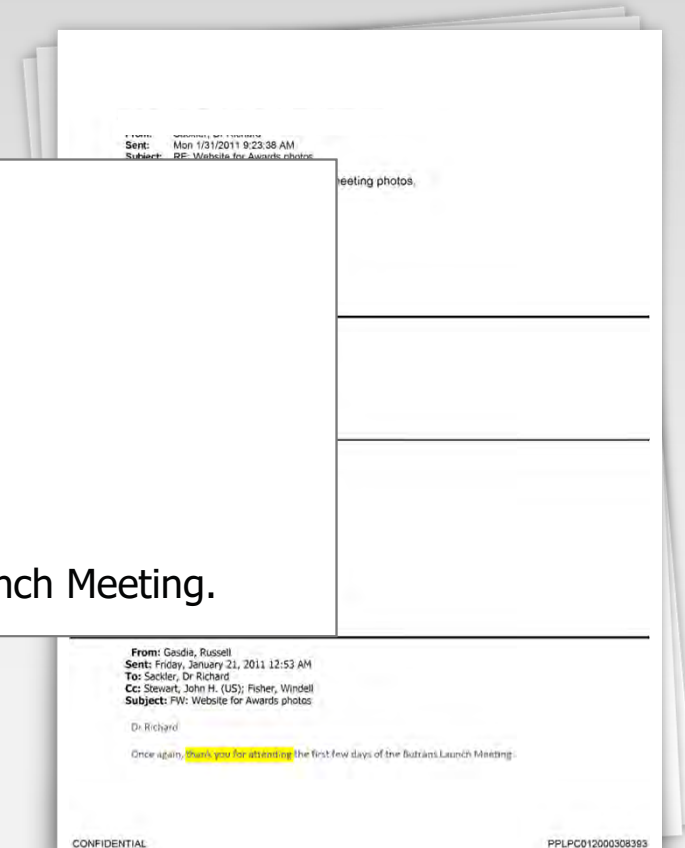
- True but irrelevant

From: Gasdia, Russell
Sent: Friday, January 21, 2011 12:53 AM
To: Sackler, Dr Richard
Cc: Stewart, John H. (US); Fisher, Windell
Subject: FW: Website for Awards photos

Dr Richard

Once again, **thank you for attending** the first few days of the Butrans Launch Meeting.

- Butrans, not OxyContin
- **OIG confirmed compliance for 2011**



1/21/11 Email from R. Gasdia (PPLPC012000308393)

Allegation: Request For Information About Butrans Sales

Massachusetts AG FAC ¶328:

328. Richard quickly followed up with sales management to demand a briefing on how the sales visits were going in the field: “I’d like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?”

- True but irrelevant

325. Staff also told the Sacklers that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories.³⁰⁶ The Sacklers voted to spend \$158,086,000 to employ sales reps in 2011.³⁰⁷

326. Staff also reported to the Sacklers that drug company leaders can be punished for

s will especially face even more serious

by their family \$260,000,000.³⁰⁹

❖ ❖ ❖

st with sales reps for several days at the

old promote Purdue’s newest opioid.³¹⁰

to demand a briefing on how the sales visits

ence and intelligence

, are we encountering the
well are we overcoming it,
, or worse than when we

cs made employees nervous. When

w,” CEO John Stewart tried to slow things

³⁰⁶ 2010-11-10 Executive Committee notes, PPLPC012000299854.

³⁰⁷ 2010-11-03 Board minutes, 2011 budget, PKY185212865; 2010-11 budget submission, pg. 18, PDD9273201306.

³⁰⁸ 2010-11-10 Executive Committee notes, PPLPC012000299855; 2010-11-10 Slideshow presentation by Bert Weinstein, slide 7, PPLPC012000299866.

³⁰⁹ 2010-12-02 Board minutes, PKY185212869-70.

³¹⁰ 2011-01-21 email from Russell Gasda, PPLPC012000308393.

³¹¹ 2011-01-30 email from Richard Sackler, PPLPC021000352206.

2011 Email Requests Info About HCP Reactions To Butrans

From: Sackler, Dr Richard
To: JHS (US); Gasdia, Russell
Sent: Sun Jan 30 09:48:18 2011
Subject: Going to LTS briefing on Butrans distribution, sales response, etc.

Next week, I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?

From: Gasdia, Russell
Sent: Sunday, January 30, 2011 11:13 AM
To: Sackler, Dr Richard; JHS (US)
Subject: Re: Going to LTS briefing on Butrans distribution, sales response, etc.

We are developing an exec summary report. ...

Top line - things are going VERY WELL. Little resistance, high interest, people feel training prepared them to handle 99% of questions with remaining 1 % they know where to go for support.

- Butrans, not OxyContin
- OIG confirmed compliance for 2011

3 AM
n Butrans distribution, sales response, etc.
y report. I conducted a conf call with all regional mgrs and
as well as overview of feedback by Wed.
Little resistance, high interest, people feel training prepared
remaining 1% they know where to go for support.

trans distribution, sales response, etc.
ing on the field experience and intelligence
re we doing, are we encountering the resistance
well are we overcoming it, and are the
r, or worse than when we marketed

is that I'm going to LTS and will want to give an
er Hoffmann. I'll suggest timing soon.

CONFIDENTIAL

PPLPC021000352206

(PPLPC012000308371)

Allegation: "This Is Bad"

Massachusetts AG FAC ¶198:

198. The Sacklers' directions shot through the company with dangerous force. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field. When **Richard Sackler wrote to managers, "This is bad,"** to criticize the sales of Purdue's Butrans opioid, the managers in turn drafted a warning for employees: ...

- **Butrans, not OxyContin**
- **2012 email concerning sales, not marketing**
- **OIG confirmed compliance for this period**

their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

Conduct From The 2007 Judgment Until Today

ment to 2018, the Sackler controlled Purdue's deceptive sales any to hire hundreds more sales reps to visit doctors ed that sales reps repeatedly visit the most prolific prescribers. ctors to prescribe more of the highest doses of opioids. They ents on opioids longer and then ordered staff to use them. ut doctors suspected of misconduct, how much money Purdue em Purdue had reported to the authorities. They sometimes else in the entire company, so staff had to create special ler even went into the field to promote opioids to doctors and management was so intrusive that staff begged for relief. The y the CEO:

"Anything you can do to reduce the direct contact of Richard into the organization is appreciated."⁹⁴

198. The Sacklers' directions shot through the company with dangerous force. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field. When **Richard Sackler wrote to managers, "This is bad,"**⁹⁵ to criticize the sales of Purdue's Butrans opioid, the managers in turn drafted a warning for employees:

⁹⁴ 2012-02-07 email from Russell Gasdia, PPLPC012000368569.
⁹⁵ 2012-02-07 email from Richard Sackler, PPLPC012000368430.

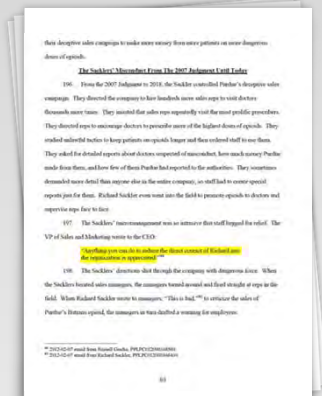
Allegation: Alleged “Micromanagement”

Massachusetts AG FAC ¶197:

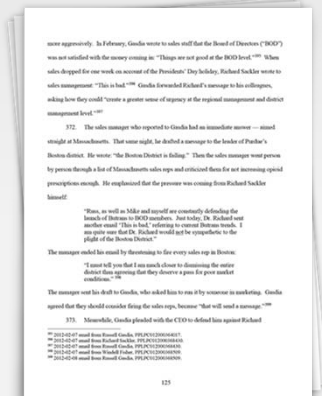
197. The Sacklers’ micromanagement was so intrusive that staff begged for relief. The VP of Sales and Marketing wrote to the CEO: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.”

Massachusetts AG FAC ¶373:

373. Meanwhile, Gasdia pleaded with the CEO to defend him against Richard Sackler’s micromanagement of sales: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.” A week later, Richard wrote to sales management again to criticize them for U.S. sales being “among the worst” in the world.



MA AG FAC ¶197



MA AG FAC ¶373

First 2012 Email: Richard Irked Management With Information Requests

March 7, 2012 email from R. Gasdia to J. Stewart

This is taking a lot of David's energy, almost every day. I can assure you that Mike and Windell are fully focused on improving these results. It isn't constructive to spend too much time on this as opposed to expending energy with my department of identifying the problem, developing the solutions and gaining implementation.

Anything you can do to reduce the direct contact of Richard into the organization is appreciated. I realize he has a right to know and is highly analytical, but diving into the organization isn't always productive.

- Butrans, not OxyContin
- Sales, not marketing
- **OIG confirmed compliance for this period**

Stewart, John H.
J. Gasdia, Russell
Wed, 3/8/2012 8:48:53 AM
Copy of Butrans Weekly Report 2-24-12-RS.xlsm

12, at 6:37 AM, "Stewart, John H."

on this virtually every day, some with more success than others. You are right the ultimate solution, and in the meantime when RSS does ask for data - I find it just give it to him, but at the same time repeat what I've felt.

David to keep copying me on his replies to RSS, since it is those that spur me to respond directly.

J. Gasdia, Russell
Wed, March 07, 2012 1:35 PM
John H. (US)
Copy of Butrans Weekly Report 2-24-12-RS.xlsm

taking a lot of David's energy, almost every day. I can assure you that Mike and I are fully focused on improving these results. It isn't constructive to spend too time on this as opposed to expending energy within my department of identifying problem, developing the solutions and gaining implementation. Anything you can do to reduce the direct contact of Richard into the organization is appreciated. I realize he has a right to know and is highly analytical, but diving into the organization isn't always productive.

From: Sackler, Dr Richard
Sent: Wednesday, March 07, 2012 11:39 AM
To: Rosen, David (Marketing)
Cc: Stewart, John H. (US); Gasdia, Russell; Insaurato, Mike; Fisher, Windell; Condon, Donna
Subject: Re: Copy of Butrans Weekly Report 2-24-12-RS.xlsm

This is bad. This will extend the period of plateau by more than one week, but maybe by two or three, even if next week is up.

Please take the notations of 1.5% etc off on the Butrans US Dollar

CONFIDENTIAL

PPLPC012000368569

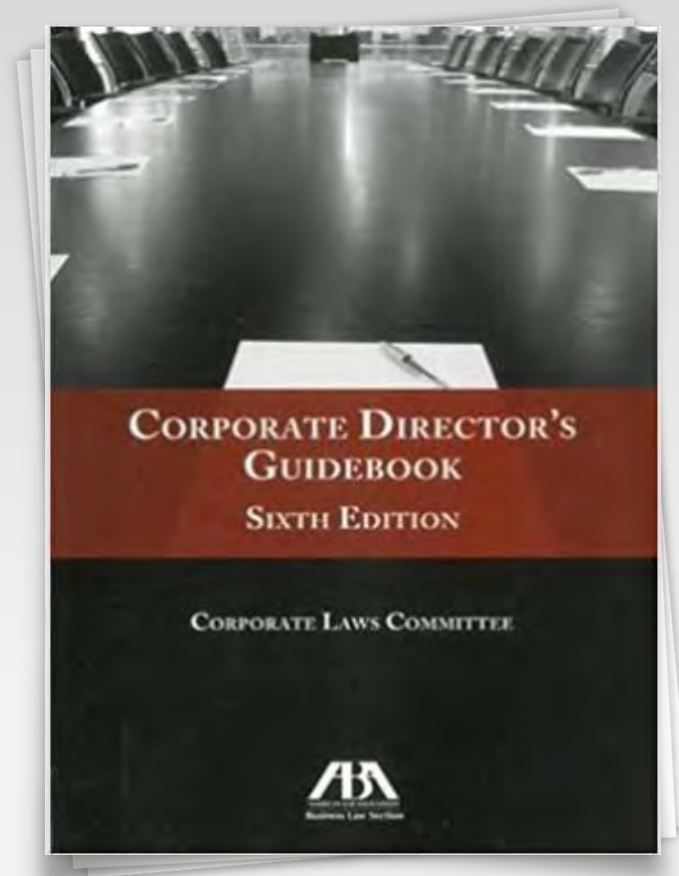
3/7/12 Email from R. Gasdia (PPLPC012000368569)

Information Requests From Directors Are Important To Good Corporate Governance

ABA BUS L. SEC., CORPORATE DIRECTOR'S GUIDEBOOK at 17 (6th ed. 2011):

"[A]ll directors have both legal and customary rights of access to the information and resources needed to do the job. Among the most important are the rights:

- to inspect books and records;
- to request additional information reasonably necessary to exercise informed oversight and make careful decisions...."



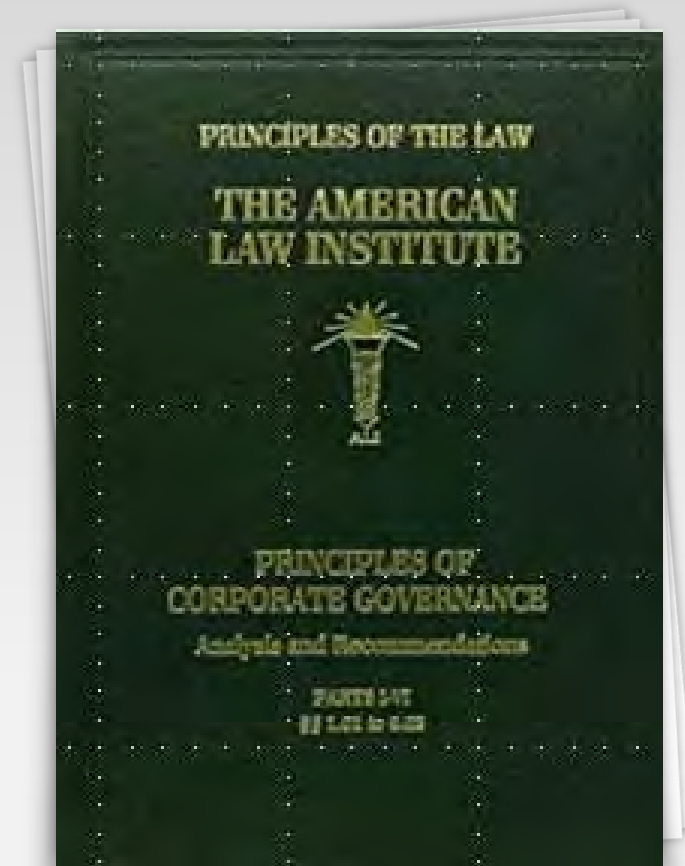
Information Requests From Directors Are Important To Good Corporate Governance

ALI PRINCIPLES OF CORPORATE GOVERNANCE:

§ 3.02(a): “The board of directors of a publicly held corporation should perform the following functions: ***

“(2) Oversee the conduct of the corporation's business to evaluate whether the business is being properly managed”

§ 3.03: “Every director has the right ... to inspect and copy all books, records, and documents of every kind ... of the corporation and of its subsidiaries”



Second 2012 Email: Concern About Butrans Sales Trajectory

From: "Rosen, David (Marketing)"
Date: Fri, 9 Mar 2012 10:16:48 -0500
To: "Richard S. Sackler"
Cc: John Stewart, "Gasdia, Russell", "Innaurato, Mike", "Fisher, Windell"
Subject: Butrans SAS analysis

Hi, Dr. Richard. Based on your request, here is a summary our SAS analysis of the share data trends.

From: Sackler, Dr Richard
Sent: Saturday, March 10, 2012 5:41 PM
To: Rosen, David (Marketing)
Cc: Stewart, John H. (US); Gasdia, Russell; Innaurato, Mike; Fisher, Windell
Subject: Re: Butrans SAS analysis

This is reassuring, but the fact remains that the trajectory is much less than plan and on a unit/capita basis among the worst of all the Butrans launches.

- Butrans, not OxyContin
- OIG confirmed compliance for this period

Stewart, John H.
David (Marketing)
7/12/2012 9:12:04 AM
Butrans SAS analysis

spreadsheet with both Rx's and \$ versus the international launches. I also believe that
st factors in the EU is that hydrocodone/APAP is not on the market.

Russell
March 11, 2012 5:02 PM
John H. (US)
(Marketing)
Butrans SAS analysis

and provide context as it relates to international results. It's my understanding that
Europe and Australia sell for far less than US. Rx's alone are not the only comparison. If we want more
efficiently lower our prices through deeper rebates and in increased Rx's. Also, the
our market and competition shows that this is the second best such in the history of
Rx's and the best first year in dollars.

at 12:36 PM, "Stewart, John H."

Richard is still commenting on the Butrans Rx trajectory. It has been some
time I have been into the international prescription data, but as I recall – the US
price isn't "amongst the worst" of all countries, or am I wrong.

By, have you also looked at the international comparison on a \$ per capita
since in many other countries the product is priced far lower than it is here (and
even in reference to prices of competitive products in those countries).

and no need for an immediate reply.

Sackler, Dr Richard
March 10, 2012 5:41 PM
(Marketing)
Cc: Stewart, John H. (US); Gasdia, Russell; Innaurato, Mike; Fisher, Windell
Subject: Re: Butrans SAS analysis

This is reassuring, but the fact remains that the trajectory is much
less than plan and on a unit/capita basis among the worst of all

3/10/12 Email from R. Sackler (PPLPC012000368823)

Allegation: Richard Pushed To Sell Highest Doses

Massachusetts AG FAC ¶232:

232. **Richard Sackler did not back off. Instead, he pushed staff to sell**

more of the highest doses of opioids and get more pills in each prescription. That

same Saturday night, Richard sent Gasdia yet another set of instructions, directing him

to identify tactics for “exceeding 2007 Rx numbers on an adjusted basis (adjusted for

strength and average number of tablets per Rx).” The very next day, Gasdia was

writing up plans for how adding sales reps, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

¹⁴⁵ “John, I know it is tricky, but Dr. Richard has to back off pushing people in all directions, creating a lot of pressure and stress. I will draft a realistic in his expectations and it is very understand.”¹⁴⁵

back off. Instead, he pushed staff to sell more of the pills in each prescription. That same Saturday night, instructions, directing him to identify tactics for adjusted basis (adjusted for strength and average number of tablets per Rx). Gasdia was writing up plans for how adding sales reps, more intermediate doses of OxyContin could help increase

ed through on his weekend threat that he would have the later, Richard circulated his own sales analysis to the his high in the Board agenda,” and proposed that he and e annual plan as well as the 5-year plan for Purdue’s

than, Kathe, and Mortimer Sackler were also pushing staff klers that they would use opioid savings cards to meet the ts at the same level in 2008 as in 2007, “in spite of all the staff identify the “pressures” and provide “quantification of

¹⁴⁵ 2008-03-08 email from Russell Gasdia, PPLPC012000174127.

¹⁴⁶ 2008-03-08 email from Richard Sackler, PPLPC012000175157.

¹⁴⁷ 2008-03-09 email from Russell Gasdia, PPLPC012000174161.

¹⁴⁸ 2008-03-10 email from Richard Sackler, PPLPC023000164605.

¹⁴⁹ 2008-03-09 email from Edward Mahoney, PPLPC012000175155-156.

¹⁵⁰ 2008-03-11 email from Kathe Sackler, PPLPC012000175155.

2008 Email Concerns Higher Sales, Not Higher Doses

From: Sackler, Dr Richard

To: Stewart, John H. (US); Gasdia, Russell

Cc: sdb; Rosen, David; edm; Sackler, Dr Kathe; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer JR

Sent: Sat Mar 08 17:12:45 2008

Subject: Card program

I would suggest that based upon Russ' description of the McKesson program that would replace the existing program, we **limit the presentation on this part of the agenda to the budget** that you want to be in principle be allocated to extending a program. This will **shorten the presentation to a simple set of slides showing budget and + Rx's above the existing provisional plan**. Please give these Rx's on an adjusted or KG basis. Ed and David Rosen can help here.

Please **identify this as a means to reach for the increasing trajectory of Rx's and exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)**.

Please indicate your agreement or disagreement with this proposal.

strengths as well. Kadian is growing and continues to be heavily promoted. Both Endo and Alpharma sales forces larger than ours.

confident that our additional reps will have a positive impact, our new strengths will have a positive impact and we will identify programs to increase the likelihood of patients who are prescribed OxyContin fill the Rx and pay for the brand.

ed a few days to get data together and assess the McKesson program. It will not be done over the weekend.

Original Message -----

From: Sackler, Dr Richard
To: Stewart, John H. (US); Gasdia, Russell
Cc: Rosen, David; edm; Sackler, Dr Kathe; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer JR

Sent: Sat Mar 08 17:12:45 2008
Subject: Card program

I would suggest that based upon Russ' description of the McKesson program that would replace the existing program, we limit the presentation on this part of the agenda to the budget that you want to be in principle be allocated to extending a program. This will shorten the presentation to a simple set of slides showing budget and + Rx's above the existing provisional plan. Please give these Rx's on an adjusted or KG basis. Ed and David Rosen can help here.

Please identify this as a means to reach for the increasing trajectory of Rx's and exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx).

Please indicate your agreement or disagreement with this proposal.

Richard S. Sackler, M.D.

Redacted

- 2008 email urges higher sales, not higher doses
- **OIG confirmed compliance for 2008**

CONFIDENTIAL TREATMENT REQUESTED
NOT FOR CIRCULATION/COMMITTEE MEMBERS AND STAFF ONLY

PURDUE-COR-00007345

3/8/08 Email from R. Sackler (PPLPC012000175155, -157)

Allegation: Board Directed Sales Force Hike; Richard Concerned About Sales

New York AG FAC ¶394:

394. The Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign subsequent to the 2007 guilty plea. Complying with those orders, Purdue staff reported to the Sacklers in January 2011 that a key initiative in Q4 2010 had been the expansion of the sales force. But in 2012, Richard Sackler complained that Purdue's management was not sufficiently focused on "urgent current threats and our sales decline[.]"

- **OIG confirmed compliance for this period**

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

INDEX NO. 405016/2018
RECEIVED NYSCEF: 03/28/2019

due to hire hundreds of sales representatives to carry out
to the 2007 guilty plea. Complying with those orders,
January 2011 that a key initiative in Q4 2010 had been the
Richard Sackler complained that Purdue's management
urgent threats and our sales decline[.]

Sacklers voted to set Purdue's budget for Sales and

intimately involved the Sackler Defendants were in
February 2012, during a lengthy exchange between some
's officers, Defendant Mortimer Sackler suggested that
meeting to February so that sales representatives "get
front of doctors who enter the new year refreshed..."
es take "three full weeks" to "visit all their doctors while
Mortimer posed these questions despite Purdue's robust
to this exchange defendant Richard Sackler suggested

er Sackler pressed for more information on dosing and
by strength." Staff told the Sacklers that "the high dose

prescriptions are declining, and there are fewer patients titrating to the higher strengths from the
lower ones." In response to the Sacklers' questions, staff explained that sales of the highest doses
were not keeping up with the Sacklers' expectations because some pharmacies had implemented
"good faith dispensing" policies to double-check prescriptions that looked illegal and some
prescribers were under pressure from the Drug Enforcement Administration ("DEA"). Staff

106

113 of 258

NY AG FAC ¶394

Allegation: No “Paper Trail”

Massachusetts AG FAC ¶228:

228. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue’s patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids are safer for patients. Mortimer Sackler suggested that Purdue conduct similar studies to find out whether reformulated OxyContin was really safer before selling it to millions of patients. He wrote to Richard Sackler: “Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up ...? Shouldn’t we have studies like this ...?” The Sacklers decided not to do the research because they wanted the profits from a new product, regardless of whether the deaths continued. **Richard didn’t want a paper trail, so he instructed Mortimer to call him**, and CEO John Stewart met with his staff to plan how to phrase a carefully worded reply. Later that month, Stewart wrote to Richard that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.”

...ained that two sales reps hired in the 2008 expansion
rescriptions in Massachusetts that they were among
... rewarded them with bonuses and all-expense-paid trips
... samples to motivate other reps to sell more opioids.¹²⁷
... and intended that the sales reps would push higher doses
... i, Richard Sackler directed Purdue management to
... strength, giving higher measures to higher strengths.”¹²⁸
... kler on the instruction. The Sacklers knew higher doses
... as the 1990s, Jonathan and Kathie Sackler knew that
... high doses of an opioid are used for long periods of

... e Sacklers voted to pay former CEO and criminal convict
... as one of several multi-million-dollar payments to the
... loyalty and protect the Sackler family.
... orking on a crush-proof reformulation of OxyContin in
... The Sacklers learned that another company was planning
... proof opioids are safer for patients.¹²⁹ Mortimer Sackler
... studies to find out whether reformulated OxyContin was
... s of patients. He wrote to Richard Sackler: “Purdue should
... search and should be generating the research to support

Stipok pg. 120, 2018-03-01 deposition of Timothy Quinlan pg. 99
PLPC012000170948-040
D1701785443
22
w. pg. 2, PLPC012000180022:
PC013000241041

74

MA AG FAC ¶228

2008 Email Requests A Phone Call To Discuss A Study

From: Sackler, Dr Richard

Sent: Tuesday, February 12, 2008 8:26 PM

To: Sackler, Mortimer JR

Cc: Stewart, John H. (US)

Subject: RE: Columbia University - Abuser Tamper Testing

My sentiments exactly the first time I read it. But you should read it again. If you do and ask yourself what it means, I think you may come to a very different conclusion, as I now have.

The reason I sent it to you was that it was presented more than a year ago and perhaps to surprise, no one broke down the door to take over the product. We know that they have back-burnered the project, so when you reread it, ask yourself why it didn't generate a licensee.

We should talk about it. Give me a call at home.

- Innocuous email about a Columbia University study
- OIG confirmed compliance for 2008

(CN=RECIPIENTS/CN=79393526); Landau,
(CN=LANDAU)

g

ply to this. Will you be in the

But you should read it again. If
you may come to a very different

ented more than a year ago and
e down the door to take over the
red the project, so when you
licensee.

ic.

From: Sackler, Mortimer JR
Sent: Tuesday, February 12, 2008 8:05 PM
To: Sackler, Dr Richard; Stewart, John H. (US)
Subject: Re: Columbia University - Abuser Tamper Testing

Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up

CONFIDENTIAL

PPLPC013000244843

2/12/08 Email from R. Sackler (PPLPC013000244843)

Allegation: Demands To Get Patients On Higher Doses, For Longer Times

Massachusetts AG FAC ¶240:

240. On April 18, the Sacklers voted to increase the 2008 budget for Sales and Promotion to \$155,802,000. Then, Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard wanted to know: how many Purdue patients had insurance that would let them take unlimited quantities of Purdue opioids; how many patients were limited to 60 tablets per month; and how many patients had any limit on the number of tablets or dose or number of tablets per day. He demanded that sales staff be assigned to answer his questions "by tomorrow morning." When the sales staff pleaded for a few more hours to collect the data, Richard agreed to give them until the end of the day.

nger patients, staff reported to the Sacklers that
s highest doses provided \$23,964,122 per year, or 2.8% of
prescription data on over 500,000 individual prescribers
confirm that Massachusetts constituted approximately
5, 2007, the Sacklers paid their family approximately

s voted to increase the 2008 budget for Sales and
Richard Sackler sent Sales VP Russell Gasdia a series of
patients to take higher doses and stay on opioids for
: how many Purdue patients had insurance that would let
e opioids; how many patients were limited to 60 tablets
any limit on the number of tablets or dose or number of
s staff be assigned to answer his questions "by tomorrow
ded for a few more hours to collect the data, Richard
day.¹⁶⁰
acklers more ideas about ways to promote Purdue's
cklers' own plan, which Richard had written out as CEO:
drugs by stigmatizing people who become addicted.

"KEY MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse."

¹⁵⁵ 2016-04-13 Q1 2016 Commercial Update, slide 74, PPLPC016000286167.
¹⁵⁶ Purdue Drug Units Dispensed by HCP, Product, and Strength, PWG003984518-45.
¹⁵⁷ 2.8% of \$4,000,000,000 is \$112,000,000.
¹⁵⁸ 2008-04-18 Board minutes, PKY183212634-37.
¹⁵⁹ 2008-04-22 email from Richard Sackler, PPLPC012000179497.
¹⁶⁰ 2008-04-22 email from Richard Sackler, PPLPC012000179679.

2008 Email: Insurance Questions

From: Sackler, Dr Richard

Sent: Tuesday, April 22, 2008 11:51 AM

To: Gasdia, Russell; Innaurato, Mike

Subject: Covered lives

Importance: High

What is the status of covered lives now with OxyContin?

Of these, how many are:

1. limited to 60 tablets/month of any strength
2. limited to number of tablets/dose
3. limited to number of tablets/day

please assign to get me this information by tomorrow morning.

Sackler, Dr Richard[DrR]
Gasdia, Russell
Tue 4/22/2008 11:52:17 AM
Re: Covered lives
already requested an update
Original Message -----
Sackler, Dr Richard
Gasdia, Russell; Innaurato, Mike
Tue Apr 22 11:51:16 2008
Re: Covered lives
is the status of covered lives now with OxyContin?
se, how many are:
limited to 60 tablets/month of any strength
limited to number of tablets/dose
limited to number of tablets/day
assign to get me this information by tomorrow morning.

CONFIDENTIAL

PPLPC012000179497

4/22/08 Email from R. Sackler (PPLPC012000179497)

- No promotion of higher doses
- Email asks about insurance limitations on the number of tablets per month covered
- OIG confirmed compliance for 2008

Allegation: Demands To “Boost” Sales

Massachusetts AG FAC ¶260:

260. In July, staff told the Sacklers that Purdue employed 429 sales reps. Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to “boost” them. He asked for the topic to be added to the agenda for the Board.

Sacklers that Purdue employed 429 sales reps.¹⁹² Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to “boost” them. He asked for the topic to be added to the agenda for the Board.¹⁹³ Sackler convened a meeting of Board members and staff to discuss the decline in sales. Staff is doing and planning to do to reverse the decline in sales. Staff estimated that \$200,000,000 in profit was at stake.¹⁹⁴ At the time, the 80mg OxyContin pill was far-and-away Purdue’s best selling product. It contained more kilograms of active ingredient in the 80mg dose than all other brands of oxycodone.¹⁹⁵ Sackler discussed with staff about their newest OxyContin sales campaign, which was set to launch in 2009. The campaign set the pattern that Purdue would follow for future sales campaigns. To make it easy for sales reps to sell more pills, the campaign materials emphasized the “range of tablet strengths,” and said: “You can adjust your patient’s dose every 1 to 2 days.”

Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.¹⁹⁷

¹⁹² 2009-07-20 Board report, pg. 19, PPLPC012000233249.

¹⁹³ 2009-07-20 email from Richard Sackler, PPLPC012000232016.

¹⁹⁴ 2009-08-12 email from Richard Sackler, PPLPC012000234970-971; see also 2009-08-10 email from John Stewart, PPLPC012000234801 (“Richard has asked me about this at least 5 times over the past few weeks”).

¹⁹⁵ 2009-08-19 Board slides, slide 7, PPLPC012000235543.

¹⁹⁶ 2009-08-12 email from Russell Gaudin, PPLPC012000235039.

¹⁹⁷ 2009-08-19 Board slides, slides 12, 16, PPLPC012000235543; *Options* marketing materials, PMA000189015.

2009 Emails: No Demands To “Boost” Sales

From: Sackler, Dr Richard

Sent: Wednesday, October 07, 2009 8:21 AM

To: Stewart, John H. (US)

Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

John,

Are we continuing to make progress with OER and OxyContin® tablets?

- Email asks about progress with sales
- No reference to boosting sales
- OIG confirmed compliance for 2009

Sackler, Dr Richard
Thursday, October 08, 2009 8:54 AM
Gasdia, Russell
RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

be provided?

Sackler, M.D.
77
85 cell
65 home

Russell
y, October 08, 2009 8:42 AM
Dr Richard
John H. (US)
Oxycodone-ER Stocking Report for Week Ending August 28,

In the monthly reports that will be provided

From: Sackler, Dr Richard
Sent: Thursday, October 08, 2009 8:35 AM
To: Gasdia, Russell
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

I'd like to see the reports of the comparative position of oxycodone ER over time.
These spot reports don't really inform me adequately.

Richard S. Sackler, M.D.

From: Gasdia, Russell
Sent: Wednesday, October 07, 2009 10:16 PM
To: Stewart, John H. (US); Sackler, Dr Richard
Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28,

HIGHLY CONFIDENTIAL

P4571328

PDD9316309168

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

10/8/09 Email from R. Sackler (PDD9316309168)

2009 Emails: No Demands To “Boost” Sales

From: Sackler, Dr Richard

Sent: Thursday, October 08, 2009 8:35 AM

To: Gasdia, Russell

Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

I'd like to see the reports of the comparative position of oxycodon ER over time. These spot reports don't really inform me adequately.

From: Gasdia, Russell

Sent: Thursday, October 08, 2009 8:42 AM

To: Sackler, Dr Richard

Cc: Stewart, John H. (US)

Subject: RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

That will be in the monthly reports that will be provided

- Appropriate request for adequate information
- OIG confirmed compliance for 2009

Sackler, Dr Richard
Thursday, October 08, 2009 8:54 AM
Gasdia, Russell
RE: Oxycodone-ER Stocking Report for Week Ending August 28, 2009

be provided?

Sackler, M.D.

777

54

54

Russell
ay, October 08, 2009 8:42 AM
Dr Richard
John H. (US)
Oxycodone-ER Stocking Report for Week Ending August 28,

That will be in the monthly reports that will be provided

Sackler, Dr Richard
ay, October 08, 2009 8:35 AM
Russell
Oxycodone-ER Stocking Report for Week Ending August 28,

see the reports of the comparative position of oxycodon ER over time.
reports don't really inform me adequately.

Sackler, M.D.

777

54

54

Russell
ay, October 07, 2009 10:16 PM
John H. (US); Sackler, Dr Richard
Oxycodone-ER Stocking Report for Week Ending August 28,

HIGHLY CONFIDENTIAL

P4571328

PDD9316309168

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

10/8/09 Emails w/R. Sackler (PDD9316309168)

Allegation: Decision Not To Acquire Insomnia Drug

Massachusetts AG FAC ¶318:

318. In August, the Sacklers continued to focus on the sales force. That month, they decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales reps from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales reps' meetings with prescribers was too great a risk, and the Sacklers decided not to go through with the deal.

Purdue employed 491 sales reps and
s.²⁹¹ More than 2,500 of those visits
ers that Purdue had paid their family

on the sales force. That month, they
risk that promoting it could distract
concluded that "loss of focus" in sales
Sacklers decided not to go through

se of OxyContin. Staff told them that
wallowing it — which a crush-proof
the Sacklers that data from the
higher rates of "doctor-shopping" for
prescription monitoring program
on multiple prescribers — an
and death.

about the Board's July 2010 decision
plement the decision, adding 125

²⁹¹ 2010-07-27 Board report, pgs. 5, 27, PWG000422481, -503. Staff told the Sacklers that the target for visits was 142,687; that reps visited 7.0 prescribers per day, on average, compared to the target of 7.5; that the average cost of a visit was \$219; and that they were still working to lower the cost to \$201.

²⁹² Exhibit 1.

²⁹³ 2010-07-27 Board report, pg. 18, PWG000422494.

²⁹⁴ 2010-08-14 email from Richard Sackler, PPLPC012000283047.

²⁹⁵ 2010-08-16 email from Stuart Baker, PPLPC012000283342-43; 2010-08-19 presentation by Paul Coplan, slides 7, 31, PPLPC012000283469.

2010 Email: Concern About Launching Two Products Simultaneously

From: Sackler, Dr Richard

Sent: Saturday, August 14, 2010 7:26 PM

To: JHS (US)

Cc: Dolan, James; Boer, Peter; Lewent, Judy; Pickett, Cecil; Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Dr Raymond R; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer D.A.; Sackler, Theresa

Subject: FW: Hi -- Somaxon urgent!

Importance: High

... I'm not sure when Silenor will launch, but assuming it is close to the Butrans launch, the question is raised how can we successfully launch two products at the same time with the same reps? The complexities of loss of focus on the calls seems great. But if there were a way to do it, and if we could negotiate a deal that would give us options to commit only after we saw success, it would be a sweet deal for us.

il, Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Mortimer D.A.; Sackler, Theresa, Dolan, Mallin, William

had with Somaxon/Silenor below – and at the the Silenor deal (at least not right now) because parate salesforce of approximately 175 persons preparing for the Butrans launch. We can't support Silenor with the same salesforce that will launch Butrans and also detail OxyContin.

a readout on the driving study being conducted ber/November), and while we are optimistic – ve outcome. As such, we are cautious about nt in Silenor/insomnia product marketing – ll be approved and ready for launch in Q4-2011

of your early negative impressions toward the

marketing success closely, and if we get a nce and the Intermezzo driving study – look to panies together – with our having a substantial

ownership share.

John

From: Sackler, Dr Richard

Sent: Saturday, August 14, 2010 7:26 PM

To: JHS (US)

Cc: Dolan, James; Boer, Peter; Lewent, Judy; Pickett, Cecil; Sackler Lefcourt, Ilene; Sackler, Dr Kathe; Sackler, Dr Raymond R; Sackler, Dr Richard; Sackler, Jonathan; Sackler, Mortimer D.A.; Sackler, Theresa

Subject: FW: Hi -- Somaxon.....urgent!

Importance: High

I had a call from Mary Tanner about Somaxon last week. During the same call, she said that Horizon was for sale and to learn more about this given our relationship with Horizon through our license of Lodotra in Europe and potentially in Asia as well. However, I never got a chance to finish the call.

CONFIDENTIAL

PPLPC012000283046

8/14/10 Email from R. Sackler (PPLPC012000283047)

Allegation: Criticism For Not Targeting High Potential Prescribers

Massachusetts AG FAC ¶353:

353. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales reps to target "non-high potential prescribers." "How can our managers have allowed this to happen?" Richard insisted that sales reps push the doctors who prescribed the most drugs.

a meeting about sales tactics with Richard for first thing the next morning.³⁵⁸ Richard would not wait until the morning and instructed Gasdia to call him that same day.³⁵⁹

353. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales reps to target "non-high potential prescribers." "How can our managers have allowed this to happen?"³⁶⁰ Richard insisted that sales reps push the doctors who

were followed, Richard Sackler demanded to be sent into and wanted a week shadowing Purdue sales reps, two reps Purdue's Chief Compliance Officer, warning that Richard posed a potential compliance risk."³⁶² Compliance replied: "LOL."³⁶³ Richard insisted that sales reps push the doctors who in marketing stayed secret, staff instructed: "Richard

³⁵⁸ 2011-06-16 email from Russell Gasdia, PPLPC012000329607.

³⁵⁹ 2011-06-16 email from Richard Sackler, PPLPC012000329621.

³⁶⁰ 2011-06-16 email from Richard Sackler, PPLPC012000329706.

³⁶¹ 2011-06-16 email from Russell Gasdia, PPLPC012000329706.

³⁶² 2011-06-16 email from Russell Gasdia, PPLPC012000329494 ("Based on our discussions, perhaps you could sit down with JS on your thoughts. Also, I haven't spoken to him about RS going to field with reps. Perhaps you could also say something to JS and indicate I came to you for counsel as I saw this as a potential compliance risk?").

³⁶³ 2011-06-16 email from Bert Weinstein, PPLPC012000329722.

2011 Email: Sales Call Focus, Not Marketing

From: Gasdia, Russell
Sent: Thursday, June 16, 2011 9:24 AM
To: Sackler, Dr Richard
Subject: Feedback from District Manager Advisory Council – FYI

- The manager's all felt that we can improve in our call focus and frequency on high-potential prescribers

From: Richard Sackler
Date: Thu, 16 Jun 2011 16:44:58 -0400
To: "Gasdia, Russell"
Cc: "JHS (US)"
Subject: RE: Feedback from District Manager Advisory Council – FYI

1 Above suggests that we are calling on non-high potential prescribers. How can our managers have allowed this to happen? ...

- Appropriate inquiry about sales call focus
- OIG confirmed compliance for 2011

Gasdia, Russell/
Sackler, John H. (US)
6/16/2011 5:40:10 PM
Feedback from District Manager Advisory Council - FYI

which was one of the things I had planned on speaking with you about tomorrow.

Sackler, Dr Richard
6/16/2011 4:46 PM

Cc: JHS (US)
Subject: Re: Feedback from District Manager Advisory Council - FYI

thing. Who have you chosen for me to go to the field with the week after meetings? Where are they? Can we conveniently do two reps each day? I travel to get to the right place as I probably should do.

Sackler, Dr Richard
6/16/2011 16:44:58 -0400
Subject: RE: Feedback from District Manager Advisory Council - FYI

quantitative. May all be true but insignificant. How have you tried to use elements? Using or misleading in our message that causes physicians to think of I thought that we were careful to make clear this is not for the most patients. The manager's all felt that we can improve in our call focus and frequency on high potential prescribers.

gests that we are calling on non-high potential prescribers. How can our managers have allowed this to happen?

1. We are seeing that where we focus our efforts with greater call frequency, we see a great number of Rx per MD. This is not a surprise; but now that we have a few months of call data as well as Rx data, we see a pretty clear correlation. (This will be presented next week at the Mid-Year meeting)

What is the evidence that calling on more physicians with higher frequency will produce more sales? I must say that I don't find this convincing as a major cause of our underperformance. Isn't it the case that reps call more frequently on their

CONFIDENTIAL

PPLPC012000329706

(PPLPC012000329706)

Allegation: Study Of Savings Card For Cholesterol Drug

Massachusetts AG FAC ¶363:

363. In September, Richard Sackler directed staff to study a savings card program for a widely-used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids. That same month, the Sacklers voted to pay their family \$140,800,000 more.

and OxyContin. Finally, you could observe the Product Theaters we are implementing.³⁶⁸

360. In July, staff assured the Sacklers that Purdue prohibited sales reps from writing their sales pitches to prescribers in email.³⁶⁹

361. In August, staff told the Sacklers that Purdue employed 640 sales reps and, during Q2 2011, they visited prescribers 189,650 times.³⁷⁰ More than 4,500 of those visits were in Massachusetts.³⁷¹

ed to the Sacklers that, in the first seven months of 2011,³⁷²

Sackler directed staff to study a savings card program for (not an addictive narcotic) to learn how Purdue could use it

Sacklers voted to pay their family \$140,800,000 more.³⁷⁴

ed the Sacklers that Purdue still employed 640 sales reps
scribers 189,698 times.³⁷⁵ More than 4,100 of those visits
lead, the Sacklers voted to spend \$162,682,000 to employ

he Sacklers that, in the first nine months of 2011, Purdue

³⁶⁸ 2011-07-26 email from Russell Gasdia, PPLPC012000336250.

³⁶⁹ 2011-07-21 Board meeting presentation, PPLP004406488-490.

³⁷⁰ 2011-08-03 Board report, pgs. 6, 42, PWG000420318, -354. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 187,950 visits; and that reps visited 7.2 prescribers per day, on average, compared to a target of 7.0.

³⁷¹ Exhibit 1.

³⁷² 2011-08-03 Board report, pg. 29, PWG000420341.

³⁷³ 2001-09-28 email from Richard Sackler, PPLPC012000345892.

³⁷⁴ 2011-09-01 Board minutes, PKY183212927-928.

³⁷⁵ 2011-11-09 Board report, pgs. 5, 41, PWG000419307, -343. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 189,525 visits; and that reps visited 7.2 prescribers per day, on average, compared to a target of 7.0.

³⁷⁶ Exhibit 1.

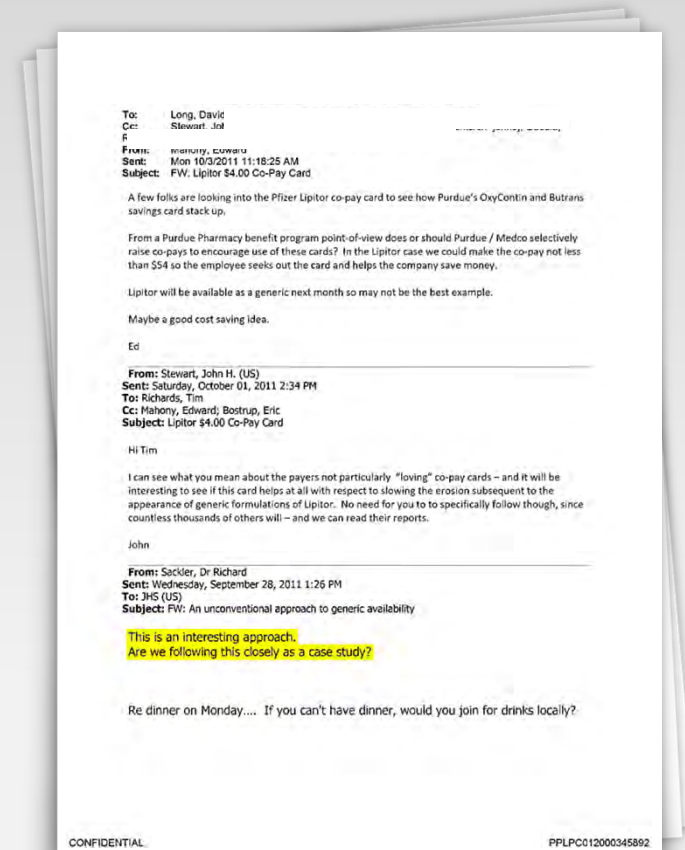
³⁷⁷ 2011-11-18 Board minutes, 2012 budget, PKY183212941-942; 2012 budget submission, pg. 22, PDD9273201436.

2011 Email Forwards Article About Lipitor Savings Card

From: Sackler, Dr Richard
Date: Wednesday, September 28, 2011 1:26 PM
To: JHS (US)
Subject: FW: An unconventional approach to generic availability

This is an interesting approach.
Are we following this closely as a case study?

- Email forwards article about Lipitor savings card
- OIG confirmed compliance for 2011



9/28/01 Email from R. Sackler (PPLPC012000345892)

Allegation: Request For Savings Card Details

Massachusetts AG FAC ¶219:

219. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter “Sales VP”), demanding information about Purdue’s opioid savings cards. Richard asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings card scheme. Richard sent Gasdia a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.

❖ 2008 ❖ ❖ ❖

ld the Sacklers that Purdue still employed 304 sales reps promoting higher doses of opioids: “OxyContin 80mg rs that, in 2007, Purdue’s net sales were just over \$1 npany had planned. OxyContin was more than 90% of s that Purdue received 689 Reports of Concern about in Q4 2007, and they conducted only 21 field inquiries cklers that they received 83 tips to Purdue’s compliance I not report any of them to the authorities.¹²⁰ s that they promoted Purdue opioids at the Pharma Pain Program in Boston on November 1 and at and policies in Boston on October 31.¹²¹ e details on tactics for pushing sales. Richard Sackler of Sales and Marketing (hereinafter “Sales VP”), piod savings cards. Richard asked Gasdia how long h savings they offered a patient, and whether there had briefed on the opioid savings card scheme. Richard sent o make sure he understood the sales tactic down to the

¹¹⁷ 2008-01-15 Board report, pgs. 4, 22, 24, PDD8901733977, -995, -997.
¹¹⁹ 2008-01-15 Board report, pg. 18, 24, PDD8901733980, -997.
¹²³ 2008-01-15 Board report, pg. 16, PDD8901733989.

2008 Email Seeks Clarification Due To Typo

From: Sackler, Dr Richard

To: Gasdia, Russell

Sent: Wed Jan 30 18:25:10 2008

Subject: RE: Teva looks to be done

... **I don't get the \$500?** If the Rx is \$1000 and the patient is obligated to pay 30% of that, the card handles 30% of 1000 or \$300-\$10? That seems to be a very serious obligation.

To: Sackler, Dr Richard

From: Gasdia, Russell

Sent: Thur 1/31/2008 8:28:39 AM

Subject: Re: Teva looks to be done

My fault. It was a typo. It is 50 not 500. You have it right at 50 above the first 10. They are good for up to 5 Rxs.

Sorry for the confusion

d
28, 2007 11:55 AM
; edm
end me the excel spread sheets for the preview
?

ard
28, 2007 11:51 AM
me the excel spread sheets for the preview

I don't know why I got the tables as pictures rather than embedded spread sheets, but I want to do some calculations and can't do it on what you sent.

ckler, M.D.
77 O
86 H
05 C
0

CONFIDENTIAL

PPLPC012000159169

1/30/08 Emails from R. Sackler (PPLPC012000168321)

- Email seeks clarification of typo in prior email
- **OIG confirmed compliance for 2008**

Allegation: Questions About Sales And Marketing

Massachusetts AG FAC ¶269:

269. At the Board meeting that month, Kathe and Richard Sackler asked staff to “identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;” and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales.²¹¹ The McKinsey report instructed sales reps to maximize profits by “emphasizing [the] broad range of doses” — which was code for pushing the doses that were highest and most profitable.

payments could often be kept secret. Some of the Sacklers were concerned that doctors would

be disclosed.²⁰⁸

,628,000 to employ sales reps in
e sales projections.²⁰⁹ They also
another \$1,000,000, and to pay
y Purdue's opioids.²¹⁰

Richard Sackler asked staff to
identify specific programs that Sales and Marketing will implement to profitably grow the OER

in light of competition; provide analytics
around why/how the proposed increase in share-of-voice translates into sales and profitability
growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but
only retaining 30% of ongoing patients;” and give the Sacklers a copy of a report from
McKinsey on tactics to increase OxyContin sales.²¹¹ The McKinsey report instructed sales reps
to maximize profits by “emphasizing [the] broad range of doses” — which was code for pushing

the doses that were highest and most profitable.
d staff, “What are OxyContin's
Avinza, Nucynta and Duragesic?
reported to all the Sacklers a list
of questions, including that OxyContin

purportedly reduces pain faster, has less variability in blood levels, and works for more pain

²⁰⁸ 2009-10-19 email from John Stewart, PPLPC032000114702.

²⁰⁹ 2009-11-03 Board minutes, PKY183212802-804; 2009-11 budget submission, pg. 12, PDD0273201222.

²¹⁰ 2009-11-20 Board minutes, PKY183212814; 2009-11-25 Board minutes, PKY183212815.

²¹¹ 2009-11-02 budget presentation, PPLPC012000249328; 2009-12-22 email from Edward Mahony, PPLPC012000249327 (“a list of questions raised at the November Board meeting and answers or actions on each”).

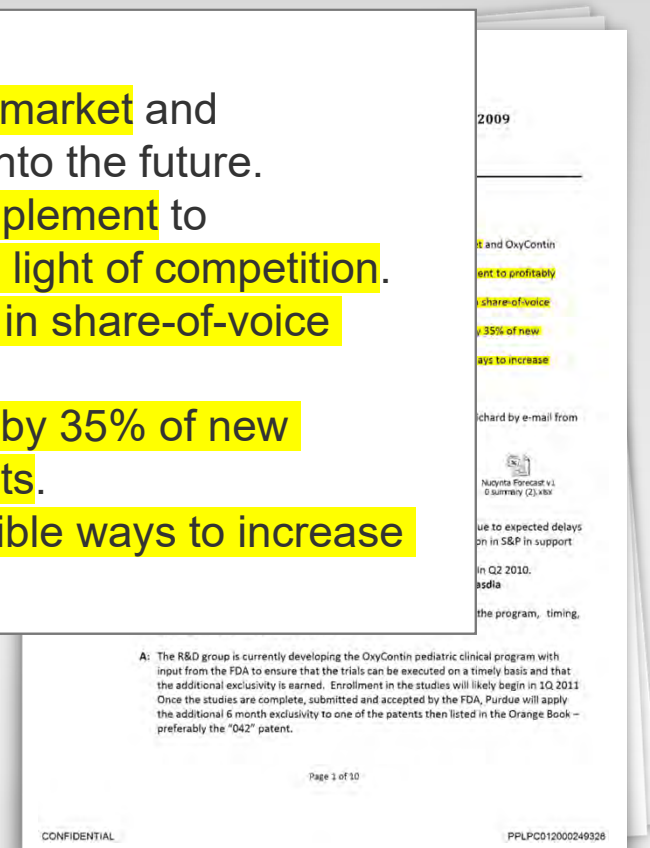
²¹² 2009-10-26 steering committee meeting presentation by McKinsey, slide 19, PPLPC018000346294.

2009 Document: Director Questions About Sales, Marketing Programs

Q: Dr. Richard and Dr. Kathy asked for:

- i. a detailed review of the long acting SEO market, the OER market and OxyContin growth rate for purposes of projecting into the future.
- ii. identify specific programs that Sales and Marketing will implement to profitably grow the OER market and OxyContin in light of competition.
- iii. provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth.
- iv. clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients.
- v. provide a copy of the OxyContin McKinsey report on possible ways to increase OxyContin sales and market share.

- Appropriate inquiries from directors
- OIG confirmed compliance for 2009



11/2-3/09 Budget Presentation Notes (PPLPC012000249328)

Allegation: Secret Memo To Keep Money Flowing To Family

Massachusetts AG FAC ¶237:

237. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

235. In April, staff told the Sacklers that Purdue employed 304 sales reps. Staff

obtained data showing which pharmacies stocked Purdue received 853 Reports of Concern about abuse and 8, and they had conducted only 17 field inquiries in Sacklers that they received 83 tips to Purdue's compliance report any of them to the authorities.¹⁵¹ Sacklers that they promoted Purdue's opioids at Tufts Health sk Management in Boston on March 27.¹⁵² Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer sep money flowing to their family. Richard wrote that concentration of risk." After the criminal investigations ard wrote that it was crucial to install a CEO who would be hift their loyalties rapidly under stress and temptation can eypoint." Richard recommended John Stewart for CEO roposed that the family should either sell Purdue in 2008 the profits out of the business and "distribute more free

¹⁵¹ 2008-03-15 Board report, pgs. 17, 23, 24, 27, PDD8901724450, -456, -457, -460.

¹⁵² 2008-03-15 Board report, pg. 16, PDD8901724449.

¹⁵³ 2008-04-18 email and attached memo from Richard Sackler, PDD9316300629-631.

Cited Document: Confidential Memo About CEO Hiring

- CEO loyalty in context of sale of business or recap
- No reference to prior criminal investigation

Re: CEO Considerations

The Purdue CEO and his top team are thus in an interesting and potentially conflicted position. Under some circumstances, such as a merger with a public company, they may gain exceptional opportunities to increase personal wealth through equity packages. On the other hand, they may at the end of the day gain only the one-time benefits specified in change-of-control or severance agreements.

- “Concentration of risk” — wealth in single company dependent on single product with 2013 patent cliff
- “Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement....”
- The only litigation risk discussed concerns patent exclusivity for OxyContin

Possible investors in, or acquirers of, Purdue will view the top management team differently. Passive investors will include the competence of this team and its long-term commitment to the Company as an element of value. On the other hand, some strategic buyers would contemplate synergies and intend to replace executives in due course with their own people and systems.

h interesting and
is merger with a public
crease personal wealth
at the end of the day gain
l or severance
nd on whether they are
well positioned to
bly, there will be intense
the Company.

er dinner — becomes a
People who will shift their
he a liability from the
bly strong in this

the cash flow afforded by

The primary metric and source of value over the medium term is EBITDA through our period of exclusivity, currently estimated to be through 2013. [It must be remembered that we need to start pediatric studies to earn the additional 6 months of patent life early enough to assuredly accomplish approval.] This must be protected through operational excellence and astute positioning versus potential competitors.

There seem to be a few opportunities to extend the franchise to 2015 or beyond.

these projects would be extremely valuable.

Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement, and employee loss of confidence in a period of turbulence.

Priority 2. Building an organization and business systems that will improve efficiency and decision-making, while trimming redundant procedures or staff

The revitalization and reorganization of the Company, including top executive ranks, is a priority. In particular, the absence of a Chief Scientific Officer to coordinate and prioritize R&D programs is a major gap, and the question has been raised whether Business Development should be led by a more seasoned executive if we are to

HIGHLY CONFIDENTIAL

P4572311

PDD9316314310

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

4/08 CEO Considerations Memo, p. 2 (PDD9316314309)

Allegation: Question About OxyContin's Clinical Advantages

Massachusetts AG FAC 1270:

270. At the same meeting, Richard Sackler also asked staff, “What are OxyContin’s clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?” In response, staff reported to all the Sacklers a list of purported advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. These were all improper, unfair, and deceptive claims that Purdue had admitted were prohibited.

- Appropriate questions about competitive products

Some of the Sacklers were concerned that doctors would
Purdue if the payments were disclosed.²⁰⁸
Sacklers voted to spend \$121,628,000 to employ sales reps in
were designated to review the sales projections.²⁰⁹ They also
pay Howard Udell up to another \$1,000,000, and to pay
claims by people harmed by Purdue’s opioids.²¹⁰
that month, Kathe and Richard Sackler asked staff to
s and Marketing will implement to profitably grow the OER
t and OxyContin in light of competition; provide analytics
se in share-of-voice translates into sales and profitability
pect to OxyContin being used by 35% of new patients, but
nts;” and give the Sacklers a copy of a report from
Contin sales.²¹¹ The McKinsey report instructed sales reps
[the] broad range of doses” — which was code for pushing
profitable.²¹²
Richard Sackler also asked staff, “What are OxyContin’s
S Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic,
ated.” In response, staff reported to all the Sacklers a list
in over competing products, including that OxyContin
purportedly reduces pain faster, has less variability in blood levels, and works for more pain

²⁰⁸ 2009-10-19 email from John Stewart, PPLPC032000114702.

²⁰⁹ 2009-11-03 Board minutes, PKY183212802-804; 2009-11 budget submission, pg. 12, PDD0273201222.

²¹⁰ 2009-11-20 Board minutes, PKY183212814; 2009-11-25 Board minutes, PKY183212815.

²¹¹ 2009-11-02 budget presentation, PPLPC012000249328; 2009-12-22 email from Edward Mahoney, PPLPC012000249327 (“a list of questions raised at the November Board meeting and answers or actions on each”).

²¹² 2009-10-26 steering committee meeting presentation by McKinsey, slide 19, PPLPC018000346294.

2009 Document: Request For Information, Not Direction, About Marketing

Q: What are OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?

A: OxyContin has the following advantages vs. the other above products:

- OxyContin has been studied in more pain syndromes (e.g., LBP, OA, neuropathic pain) with demonstrated efficacy and published results
- Prompt onset of analgesia
- Less variability in blood levels

... Methods of communication

i. Most of the differences above are published in the Full Prescribing Information or in the medical literature and, as such, can be provided to clinicians in various formats to provide clinicians with the information.

- “Full Prescribing Information” is FDA-approved label
- OIG confirmed compliance for 2009

Allegation: Demands For Sales Trends

Massachusetts AG FAC ¶230:

230. In March, Richard Sackler dug into Purdue's strategy for selling more OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early Sunday morning; Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later and pleaded with Richard: "I have done as much as I can." The employee explained that he needed to attend to family visiting from out of town. Richard responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales reps. Meanwhile, Richard met with John Stewart to discuss his analysis of the weekend's data and new graphs Richard had made.

dug into Purdue's strategy for selling more
ing staff to turn over thousands of pieces of data about
the kilograms of active drug from the number of
doses.¹⁴⁰ Staff delivered the data early Sunday
instructions for new data that he wanted that same
ditional data only a few hours later and pleaded with
The employee explained that he needed to attend to
and responded by calling him at home, insisting that the
g that he would have the Board reject it.¹⁴³ On
to prepare for meeting with Richard, highlighting that
only be achieved by hiring more sales reps.
at to discuss his analysis of the weekend's data and
as struggling to handle the pressure. When Richard
questions to answer on a Saturday (and copied Hene,
Sackler), Gasdia wrote to John Stewart:

12000174478;
C012000174477;
12000174201;
12000174202. A month earlier, when an employee did not answer
ing church service, Richard immediately contacted the CEO to
s, PPLPC012000171496. Richard then wrote that he expected
e next day (President's Day) even though Purdue was closed.
12000171511. See also 2006-11-02 email from Mike Insaurto,
Stewart, PPLPC012000174476.

2008 Email Requests Information About Sales Forecast

From: Sackler, Dr Richard
Sent: Sunday, March 09, 2008 12:13 PM
To: Rosen, David
Cc: Innaurato, Mike; Gasdia, Russell; Mahony, Edward; Gadski, Kimberly
Subject: RE: OxyContin Rx data with Kg graphs
Importance: High

Thanks for the quick turn around. This looks very different and much more encouraging, doesn't it? I'm really excited to dig into the data

I assume you've validated and spreadsheet and have checked the equations, but I wonder if you could touch it up a bit.

1. Change the scale on the charts from all strengths to fill the charts as we did in my office so everything will fit.

...

5. Anything else you think is worthy of considering in setting out a forecast.

I trust that the \$'s you show are net, but if this isn't feasible don't mix and match them unless you have to. Either gross or net (net preferred since our rebates are rising).

Can you conveniently do this this morning?

hard. I have put most of the things together that you asked for. A couple of comments:

to do the trend analysis, I needed to put together new charts, because Excel did not let me split the trend lines the way you requested unless I laid them out differently. You will see the trend analysis tabs. In each of the trend analyses, the solid black line is the pre 2006 trend, the dotted black line is the trend from Jan 06 to present, and the bold blue line represents Jan 04 to present. You will see in just about all of the starting Jan 06, there was an inflection point and the growth was significant. More recently, the growth has flattened. You can mouse over the equations to determine to which line each corresponds. The \$/Kg and Rx/Kg charts are the first two in the worksheet. The \$/Rx worksheet vacillates a bit due to the fact that we have assumed a generic price 20% of brand price. In terms of dollars, they are all gross. I believe Finance can supply our blended rebate to factor into the analysis.

At I have done as much as I can in the limited time I have today and Mike and Russ have that I attend to family obligations. I have family who are in from out of town (and I have a last three weekends). The extrapolation to 2009 will take some time, and I can happily attend to it tomorrow AM.

Thank you for the opportunity to do this work and enjoyed our conversation this morning.

Sackler, Dr Richard
Sent: Sunday, March 09, 2008 12:13 PM
To: Rosen, David
Cc: Innaurato, Mike; Gasdia, Russell; Mahony, Edward; Gadski, Kimberly
Subject: RE: OxyContin Rx data with Kg graphs
Importance: High

Thanks for the quick turn around. This looks very different and much more encouraging, doesn't it? I'm

excited to dig into the data

I assume you've validated and spreadsheet and have checked the equations, but I wonder if you could touch it up a bit.

- Sales, not marketing
- OIG confirmed compliance for 2008

CONFIDENTIAL

PPLPC012000174204

(PPLPC012000174202)

Allegation: “What Is Happening???”

Massachusetts AG FAC ¶258:

258. In June, Richard Sackler asked sales staff how a competing drug company had increased sales: “What is happening???” Staff replied that it was all about sales reps: “They have 500 reps actively promoting to top decile MDs ... Their messaging is ‘we are not OxyContin,’ alluding to not having the ‘baggage’ that comes with OxyContin. Interestingly, their share is highest with MDs we have not called on due to our downsizing and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%.”

¹⁸⁵ 2009-05-08 corporate compliance quarterly report to the Board IQ09, slide 6, PPLPC029000274906 (“Compliance was not monitoring against the ‘five full days’ requirement”).
¹⁸⁶ 2009-07-30 Board report, pg. 16, PPLPC012000233246.
¹⁸⁷ 2009-05-08 corporate compliance quarterly report to the Board IQ09, slide 14, PPLPC019000275103.
¹⁸⁸ 2009-06-12 email from Richard Sackler, PPLPC021000235124.
¹⁸⁹ 2009-06-13 email from Russell Gasdia, PPLPC021000235124.
¹⁹⁰ 2009-06-16 email from Pamela Taylor, PPLPC012000226604; 2009-05-20 Executive Committee notes, PPLPC012000226606.
¹⁹¹ 2009-06-26 Board minutes, PKY183212742.

Irrelevant 2009 Email Requests Information About Competitor's Sales

From: Sackler, Dr Richard
To: Stewart, John H. (US); Gasdia, Russell
Sent: Fri Jun 12 14:40:31 2009
Subject: FW: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Huge increase in Opana sales, it appears.

What is happening???

From: Sackler, Dr Richard
To: Gasdia, Russell; Stewart, John H. (US)
Cc: Innaurato, Mike
Sent: Sun Jun 14 20:46:06 2009
Subject: RE: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Thank you.

What is your planned market share ratio OxyContin® tablets : Opana for 2009 and 2010? Please calculate and advise if you haven't developed this metric.

To: Galski, Kim
From: Rosen, David (Marketing)
Sent: Tue 6/16/2009 10:39:35 AM
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Between you and me, one of the more meaningless calculations you have ever done! :)

From: Galski, Kimberly
To: Gasdia, Russell; Innaurato, Mike; Rosen, David (Marketing)
Sent: Tue Jun 16 11:36:09 2009
Subject: FW: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Sorry for the confusion, but here is what was requested.

I've gone back and calculated based on Rx's and our total market forecast that was done for the 10 year plan.

Oxycodone ER is 29% of SEO's in 2009 and 27% in 2010.
Opana ER is 2% of SEO's in both years.
The ratio is 5:1 in 2009 and 4:1 in 2010.

Kim

From: Gasdia, Russell
Sent: Tuesday, June 16, 2009 1:33 AM
To: Galski, Kimberly; Innaurato, Mike
Cc: Rosen, David (Marketing)
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

Yes

From: Galski, Kimberly
To: Gasdia, Russell; Innaurato, Mike
Cc: Rosen, David (Marketing)
Sent: Mon Jun 15 21:22:38 2009
Subject: Re: Opana-ER Monthly Sales (Jan 08-Mar 09) ramp up.xls

The forecast that was sent to him was dollars, but we don't have a full market forecast by dollars. We don't tend to focus on dollars because of generics and the difference in dollar value with branded products. Oxy gaining even small share of OER Rx's drives a huge share change in dollars.

Would it be okay if I provided the answer in Rx's?

Kim

From: Gasdia, Russell
To: Galski, Kimberly; Innaurato, Mike
Cc: Rosen, David (Marketing)
Sent: Mon Jun 15 21:08:51 2009

CONFIDENTIAL

PPLPC021000235122

- **OIG confirmed compliance for 2009**

6/14/09 Emails w/R. Sackler (PPLPC021000235122)

Massachusetts AG FAC ¶261:

He emphasized that \$200,000,000 in profit was at stake. At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (about 1,000 kilograms: literally a ton of oxycodone).

advertise the *Options* campaign in medical journals

¹⁹⁷ 2009-08-19 Board slides, slides 12, 16, PPLPC012000235543; *Options* marketing materials, PMA000189015.

2009 Email: Invitation To Informational Board Meetings

From: Sackler, Dr Richard

Sent: Wed 8/12/2009 10:22:30 AM

Subject: Meetings Monday next

Non-malignant uses of forodesine T-cell diseases.xls

We are having two interesting meetings next week and I'm sharing this with Board members who are interested in attending. Both will inform the Board on matters that will come to the Board in the coming weeks and months.

... The second meeting - and this meeting is next week but isn't yet confirmed for Monday morning - will be a presentation of all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market, that is the oxycodone ER market. In addition, it will be a look at the update sales for 2009 and a budget target for 2010.

- Appropriate information-gathering by directors
- OIG confirmed compliance for 2009

O=F
O=F
PUI
/CO=
net/
PUP
net/
net.
T

Sackler, Dr Richard

Wed 8/12/2009 10:22:30 AM

at: Meetings Monday next

Non-malignant uses of forodesine T-cell diseases.xls

We are having two interesting meetings next week and I'm sharing this with Board members who are interested in attending. Both will inform the Board on matters that will come to the Board in the coming weeks and months.

Scheduled now at 1330 is a meeting with Infinity to understand their perception of value of the US rights for forodesine and the entire forodesine program. I emphasize program because this includes many other possible uses beyond cancer. Currently our rights are limited to neoplastic diseases, but if we buy out all the rights, we and BioCryst agree that we would get all compounds and all indications. Infinity is interested in all the diseases, both malignant and non-malignant. If we acquire WW rights and cleave the US rights (malignant only or malignant and non-malignant) Infinity, we will be in a very complex negotiation indeed. [One possibility is to take more stock in Infinity as part of the compensation for giving the license.]

The second meeting - and this meeting is next week but isn't yet confirmed for Monday morning - will be a presentation of all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market, that is the oxycodone ER market. In addition, it will be a look at the update sales for 2009 and a budget target for 2010. We now can say with some assurance that OxyContin tablets will be the entire market when one takes account of the settlement stocks, which will be 10 or 20% of the current trend of the total marketplace. Thus the value to us of

* See email attachment.

CONFIDENTIAL

PPLPC012000234970

8/12/09 Email from R. Sackler (PPLPC012000234970)

Allegation: Direction To Send Weekly Sales Reports

Massachusetts AG FAC ¶266:

266. In October, staff told the Sacklers that Purdue had expanded its sales force by 50 territories and now employed 475 sales reps. Richard Sackler directed staff to send him weekly reports on OxyContin sales. No one in the company received reports that often, so staff were not sure how to reply. Staff considered telling Richard that there were no weekly reports, but they decided to make a new report just for him instead. The CEO also instructed the Sales Department to report to the Sacklers with more explanation about its activities.

ing with sales staff, Richard Sackler asked for the raw data
staff had not responded within five minutes, he asked

lers voted to pay their family \$173,000,000.²⁰¹ But
staff were not selling Purdue's opioids aggressively
staff predicted a decline in OxyContin sales when he

he Sacklers that Purdue had expanded its sales force by 50
reps.²⁰² Richard Sackler directed staff to send him

No one in the company received reports that often, so

staff considered telling Richard that there were no weekly
report just for him instead.²⁰³ The CEO also instructed

sacklers with more explanation about its activities.²⁰⁷

sacklers and staff discussed federal sunshine legislation
disclose drug companies' payments to doctors. Purdue
s opioids — including doctors in Massachusetts — but the

PPLPC023000236021-022.
b-772.
PPLPC012000240032
016000007322, -339.

²⁰¹ 2009-10-08 email from Robert Barnome, PPLPC012000241515; see also PPLPC022000283453.
²⁰² 2009-10-08 email from David Rosen, PPLPC012000241515 ("Hi, guys... Someone needs to alert Dr. Richard that we no longer do a weekly report. Can either one of you help ..."). 2009-10-08 email from Dipu Jiwala, PPLPC012000241526 ("we have not been providing the OxyContin weekly report since May 09"). 2009-10-08 email from Richard Sackler, PPLPC012000241586 ("I'd like to have the weekly updates."). 2009-10-08 email from David Rosen, PPLPC012000241586 ("If we do as dr. richard requests, we will be adding work and providing him near worthless data"). 2009-10-08 email from Russell Gandia, PPLPC012000241586 ("Tell her not to respond"). 2009-10-08 email from John Stewart, PPLPC012000241647; 2009-10-09 email from Rob Barnome, PPLPC022000283690 ("For the record, my concerns regarding workload and being able to meet demands of all the reporting, primary research, ad loses while maintaining quality and reasonable levels of group morale remain.").
²⁰³ 2009-10-20 email from John Stewart, PPLPC012000242813.

2009 Email: Request To Be Added To Weekly Circulation

From: Sackler, Dr Richard

Sent: Thursday, October 08, 2009 12:08 PM

To: Jinwala, Dipti

Subject: RE: Oxycodone ER Rx's

Please add me to the weekly circulation.

- Irrelevant 2009 email asks for weekly sales reports
- OIG confirmed compliance for 2009

To: Innaurato, Mike
From: Rosen, David (Marketing)
Sent: Thu 10/8/2009 2:16:11 PM
Subject: RE: Oxycodone ER Rx's

Ok

From: Gasdia, Russell
To: Rosen, David (Marketing); Innaurato, Mike
Sent: Thu Oct 08 13:33:20 2009
Subject: RE: Oxycodone ER Rx's

Dipti can respond that we have not been providing a weekly report since May and we have migrated to monthly reports.

From: Rosen, David (Marketing)
Sent: Thursday, October 08, 2009 12:57 PM
To: Innaurato, Mike; Gasdia, Russell
Subject: FW: Oxycodone ER Rx's
Importance: High

Hi, guys. Please see below. Someone needs to alert Dr. Richard that we no longer do a weekly report. Can either one of you help with this?

From: Barmore, Robert
Sent: Thursday, October 08, 2009 12:55 PM
To: Rosen, David (Marketing)
Subject: FW: Oxycodone ER Rx's

Thoughts?

Rob

From: Jinwala, Dipti
Sent: Thursday, October 08, 2009 12:54 PM
To: Barmore, Robert
Subject: FW: Oxycodone ER Rx's

Rob,

Dr. Richard wants me to add him to the weekly distribution but there is no weekly distribution for the OxyContin weekly report. The weekly reports has been discontinued since May 09.

Dipti

CONFIDENTIAL

PPLPC012000241515

10/8/09 Email from R. Sackler (PPLPC012000241515)

Allegation: Request For Spreadsheets Underlying Sales Analysis

Massachusetts AG FAC ¶214:

214. In preparation for an upcoming Board meeting, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin — its most powerful, most profitable, and most dangerous pill.

Concern included a doctor targeted by Purdue in Needham, Massachusetts. Purdue sales reps visited him to promote opioids 19 times, until the police arrived with a warrant and his license

ing of pain medications. Eight of his patients died.¹¹⁴

that Purdue had hired more sales reps and now employed ers that Purdue was succeeding at promoting its highest s at Rx levels not seen in over 2 years.¹¹⁵

pcoming Board meeting, Richard Sackler instructed staff to their sales analysis, so that he could do his own.

owed that, in 2007, Purdue expected to collect more than mg OxyContin — its most powerful, most profitable, and

cklers voted to spend \$86,900,000 to employ sales reps in hem laptops. The Sacklers also voted for a resolution targets for the reps.¹¹⁶ Every time the Sacklers voted to ales reps, they knew and intended that they were sending etts.

¹¹⁴ 2007-06-21 Purdue News Summary, PMA000283587, Exhibit L.

¹¹⁵ 2007-10-15 Board report, pgs. 4, 58, PPLPC012000157405, -459.

¹¹⁶ 2007-10-28 email from Richard Sackler, PPLPC012000159168.

¹¹⁷ 2007-10-28 attachment to email from Edward Mooney, PPLPC012000159170.

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

Irrelevant 2007 Request For Underlying Sales Data

From: Sackler, Dr Richard
Sent: Sunday, October 28, 2007 11:51 AM
To: edm
Subject: please send me the excel spread sheets for the preview

I don't know why I got the tables as pictures rather than embedded spread sheets, but I want to do some calculations and can't do it on what you sent.

- **OIG confirmed compliance for this period**

From: Mahony, Edward
Sent: Sunday, October 28, 2007 11:55 AM
To: Sackler, Dr Richard; edm
Subject: RE: please send me the excel spread sheets for the preview

Do you mean sales?

office
call

From: Richard
Sent: Sunday, October 28, 2007 11:51 AM

send me the excel spread sheets for the preview

why I got the tables as pictures rather than embedded spread
want to do some calculations and can't do it on what you

Sackler, M.D.

CONFIDENTIAL

PPLPC012000159168

10/28/07 Email from R. Sackler (PPLPC012000159168)

Allegation: Direction To Management Re Measuring Sales

Massachusetts AG FAC ¶226:

226. The Sacklers also knew and intended that the sales reps would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to “measure our performance by Rx's by strength, giving higher measures to higher strengths.”

He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when “high doses of an opioid are used for long periods of time.”

d that two sales reps hired in the 2008 expansion
reputations in Massachusetts that they were among
warded them with bonuses and all-expense-paid trips
les to motivate other reps to sell more opioids.¹²⁷
intended that the sales reps would push higher doses
Richard Sackler directed Purdue management to
high, giving higher measures to higher strengths.”¹²⁸
on the instruction. The Sacklers knew higher doses
the 1990s, Jonathan and Kathe Sackler knew that
doses of an opioid are used for long periods of
Sacklers voted to pay former CEO and criminal convict
ne of several multi-million-dollar payments to the
lity and protect the Sackler family.
ing on a crush-proof reformulation of OxyContin to
Sacklers learned that another company was planning
of opioids are safer for patients.¹²⁹ Mortimer Sackler
ies to find out whether reformulated OxyContin was
patients. He wrote to Richard Sackler: “Purdue should
ch and should be generating the research to support

¹²⁷ 2018-02-18 deposition of Catherine Yates Speck pg. 120; 2018-03-01 deposition of Timothy Quinn pg. 99.
¹²⁸ 2008-02-13 email from Richard Sackler, PPLPC012000170948-949.
¹²⁹ 1997-03-12 memo from John Stewart, PDD1701785443.
¹³⁰ 2008-02-14 Board minutes, PKY131212622.
¹³¹ 2007-10-26 Sales & Marketing presentation, pg. 2, PPLPC012000159022.
¹³² 2008-02-07 email from Robert Kaiko, PPLPC013000244844.

Irrelevant 2008 Email Suggests Sales Performance Metric

February 13, 2008 email from Richard to J. Stewart and others

Let's measure our performance by Rx's by strength, giving higher measures to higher strengths an especially the new strengths.

- **OIG confirmed compliance for 2008**

From: Gasdia, Russell
Sent: Thur 2/14/2008 9:07:32 AM
Subject: RE: OxyContin trade inventory stoichiometry.xls

Ed

Trade inventory does take into account the new strengths and OTR. Kim has that factored into the calculations.

Also, others may want to weigh in on valuing the higher strengths versus lower strengths. With the rep bonus plan we have been very careful to not over incentivize reps to promote the higher strengths over the lower strengths. All strengths are important to the overall success of the brand. Also, I would think that the further people are from impacting the demand, the less of an incentive plan this becomes...I do
Generating appropriate demand is my department's responsibility.

2/13/2008 8:33 PM
g. David

inventory stoichiometry.xls

rs. factory sales is interesting. Russ and I will get the data

2/13/2008 8:33 PM

From: Sackler, Dr Richard
Sent: Wednesday, February 13, 2008 7:29 PM
To: Stewart, John H. (US); Mahony, Edward; Lona, David; Pearl Meyer; Joseph A. Sorrentino; Mortimer JR; Richard; Sackler, Jonathan; Sackler,
Subject: OxyContin trade inventory stoichiometry.xls

<< File: OxyContin trade inventory stoichiometry.xls >>

This spreadsheet demonstrates the enormous difficulty in forecasting 2008 shipments only allowing for inventory shifts in the trade.
We haven't layered on this the impact of the new strengths and OTR.

General performance measure for 2008 --

CONFIDENTIAL

PPLPC012000170948

2/13/08 Email from R. Sackler (PPLPC012000170948)

Allegation: Instruction To Find Answers “Before Tomorrow”

Massachusetts AG FAC ¶229:

229. Meanwhile, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau. Mortimer demanded answers to a series of questions about why sales would not grow. Richard chimed in at 8:30 p.m. to instruct the staff to find answers “before tomorrow.” Staff emailed among themselves about how the Sacklers’ demands were unrealistic and harmful and then decided it was safer to discuss the problem by phone.

our formulation. Why are we playing catch up ...? Shouldn't we have studies like this ...?¹³³

The Sacklers decided not to do the research because they wanted the profits from a new product.

ed. Richard didn't want a paper trail, so he instructed

Stewart met with his staff to plan how to phrase a carefully

Stewart wrote to Richard that reformulating OxyContin “will

taking too many pills.”¹³⁵

Jonathan, Kathe, Mortimer and Richard Sackler projections

plateau.¹³⁶ Mortimer demanded answers to a series of

row.¹³⁷ Richard chimed in at 8:30 p.m. to instruct the staff

Staff emailed among themselves about how the Sacklers’

and then decided it was safer to discuss the problem by

PPLPC013000244843-844.

“LPC013000244843 (“My sentiments exactly the first time I read it
to yourself what it means. I think you may come to a very different
about it. Give me a call at home.”); 2008-02-13 email from John

“C012000172201. Five years later, Purdue published two studies
included the crush-proof tablets lowered the risks of addiction,
a use. One was a single-session research study conducted by three
consultant to assess “the attractiveness” of the crush-proof tablets to
road users were interviewed by two researchers. “This study did not
valuations, and no drugs were administered.” Participants’ answers to
to-proof tablets “might be less attractive to recreational opioid
concluded that “among the available opioid products that we included
crush-proof OxyContin tablets) to be the least attractive, the least
likelihood for tampering and the lowest street value.”
the same Purdue authors, 29 volunteers snorted OxyContin (original
per a seven-day treatment phase and rated the drugs. The study

concluded that “reformulated OxyContin has a reduced abuse potential compared to the original formulation upon
intranasal administration.” PTN000002031, -2044. Purdue amended its OxyContin label to reference these studies
in 2013.

¹³³ 2008-02-26 email from Edward Mahony, PPLPC012000172585; attachment PPLPC012000172587.

¹³⁴ 2008-02-26 email from Mortimer Sackler, PPLPC12900172674.

¹³⁵ 2008-02-26 email from Richard Sackler, PPLPC12000172674.

¹³⁶ 2008-02-26 email from John Stewart, PPLPC012000172677.

Irrelevant 2008 Email Requests Information About Sales, Not Marketing

From: Sackler, Dr Richard

Sent: Tuesday, February 26, 2008 8:32 PM

To: Sackler, Mortimer JR; Mahony, Edward; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe

Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam

Subject: RE: Bank Presentation 02272008 v6.ppt

Ed, if you can repair this before tomorrow, it would be very welcome.

- **OIG confirmed compliance for 2008**

From: Mahony, Edward
Sent: Tuesday, February 26, 2008 9:50 PM
To: Sackler, Dr Richard; Sackler, Mortimer JR; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe
Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam
Subject: RE: Bank Presentation 02272008 v6.ppt

Dr Richard please see my response.

Best Regards,

From: Sackler, Dr Richard
Sent: Tuesday, February 26, 2008 8:32 PM
To: Sackler, Mortimer JR; Mahony, Edward; Stewart, John H. (US); sdb; Strassburger, Philip; Dolan, James; Gasdia, Russell; Sackler, Jonathan; Sackler, Dr Kathe
Cc: Fogel, David; Bostrup, Eric; Lowne, Jon; mcm; Shum, Sam
Subject: RE: Bank Presentation 02272008 v6.ppt

CONFIDENTIAL

PPLPC012000172673

2/26/08 Email from R. Sackler (PPLPC012000172674)

Allegation: Request For Monthly Sales Reports

Massachusetts AG FAC ¶293:

293. In March, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes. The report showed that Purdue was selling more pills of its 80mg OxyContin (the highest dose) than any other dose, and that the highest dose pills were responsible for the greatest share of Purdue's revenue by far.

293. In March, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes.²⁶² The report

showed that Purdue was selling more pills of its 80mg OxyContin (the highest dose) than any other dose, and that the highest dose pills were responsible for the greatest share of Purdue's

revenue by far. Sackler that a key selling point for OxyContin compared to a competitor could be used by patients who had not taken opioids previously for opioid-naïve patients who had not taken them, putting patients at risk.

Purdue voted to pay their family another \$141,000,000.²⁶⁵ Sackler that they were pushing back against the demand to limit high doses of opioids. They told the Sacklers that they asked doctors to consult with specialists before

Purdue was pushing high doses with great success. At that time, a spokesman in Massachusetts, Walter Jacobs, had a patient

on twenty-four pills of 80mg OxyContin per day — almost a hundred times more drug than the starting dose on the label. For all of 2010, 73% of the OxyContin pills that Jacobs prescribed were the highest-dose 80mg pills. Purdue paid Jacobs to give presentations to other doctors so that his dangerous prescribing practices would spread.

²⁶² 2010-03-15 emails from Richard Sackler and Mike Innurato, PPLPC012000262889.

²⁶³ 2010-03-11 January 2010 OxyContin monthly report, slides 10, 15, PPLPC012000262892.

²⁶⁴ 2010-03-17 Executive Committee notes, PPLPC012000267960.

²⁶⁵ 2010-04-01 Board minutes, PKY183212829.

²⁶⁶ 2010-04-21 Board report, pg. 16, PWG600423155.

Irrelevant 2010 Email Requests Monthly Information Not Seen In A Year

From: Sackler, Dr Richard

Sent: Monday, March 15, 2010 4:39 PM

To: Stewart, John H. (US)

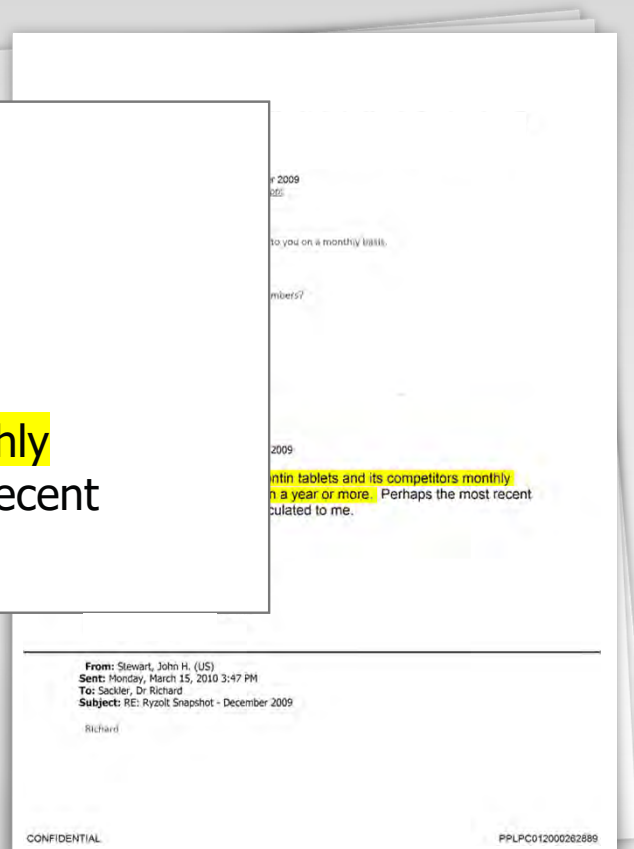
Cc: Gasdia, Russell; Innaurato, Mike

Subject: RE: Ryzolt Snapshot - December 2009

Can we continue to get OxyContin tablets and its competitors monthly information. I haven't seen it in a year or more. Perhaps the most recent editions of these could be circulated to me.

- **OIG confirmed compliance for 2010**

3/15/10 Email from R. Sackler (PPLPC012000262889)



Allegation: Question About Pharmacy Stocking Increase Plan

Massachusetts AG FAC ¶220:

220. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they couldn't get up to 4 bottles or more.

smallest details.¹²² Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.¹²³

220. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they couldn't get up to 4 bottles or more.¹²⁴

didn't only sweat the small stuff. They also made the fundamental and then to expand it. At Purdue, hiring more sales reps was not a problem. Selling opioids door-to-door, in visits to doctor's offices and throughout the state, was the business of the company. The Sacklers themselves made the decisions about what would be and what it would do.

¹²² 2008-01-30 emails from Richard Sackler, PPLPC012000168321-322.

¹²³ 2008-02-09 email from John Stewart, PPLPC012000170262 (opioid savings cards "were singled-out for presentation since they are an extraordinary item in the budget and there is good data showing a positive impact on OxyContin utilization").

¹²⁴ 2008-02-19 email from Richard Sackler, PPLPC004000150467.

Irrelevant 2008 Questions About Pharmacy Stocking Calculations

From: Sackler, Dr Richard

Sent: Tuesday, February 19, 2008 7:24 PM

To: Mahony, Edward; Stewart, John H. (US); Gasdia, Russell; Fogel, David

Subject: RE:

Questions:

1. Wholesalers
 - a. Turns were about 17/year (assuming 21 days of stock)
 - b. Why will turns increase if we increase SKU's from 4 to 7 and then to 14? Shouldn't they go down this year
2. Pharmacies
 - a. I see that average pharmacy stock goes from 2 to 3, but why wouldn't it go up from 2 to 4 or more?
 - b. On average more than double the SKU's (4-7-14-7)

From: Mahony, Edward

Sent: Wednesday, February 20, 2008 7:20 AM

To: Stewart, John H. (US); Gasdia, Russell

Cc: Barnes, Jason; Fogel, David; Long, David

Subject: RE:

Dr Richard is right that the number looks low.

- **OIG confirmed compliance for 2008**

CONFIDENTIAL

PPLPC004000150465

2/19/08 Email from R. Sackler (PPLPC004000150467)

Allegation: Request To Attend District Manager Meeting

Massachusetts AG FAC ¶348:

348. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the day-to-day supervisors of the sales reps. Then, having missed the meeting, he engaged Gasdia again by email. . . . Gasdia told Richard that Purdue had hired 147 new sales reps at the Board's direction. Gasdia told Richard that Purdue instructed the sales reps to focus on converting patients who had never been on opioids or patients taking "low dose Vicodin, Percocet, or tramadol" — all patients for whom Purdue's opioids posed an increase in risk.

told the Sacklers that they had received another 88 calls to Purdue's compliance hotline, but not

ue's opioid sales were hundreds of
as that doctors were not

nted at the Board meeting read:

The 10mg and 20mg tablet
enough to offset the higher
ange in prescriptions by strength.
staff reported to the Sacklers that
persons to maintain demand. For
rdue would order its sales reps to

o increase sales. Richard Sackler

a District Managers who were the

he meeting, he engaged Gasdia

new sales reps at the Board's

reps to focus on converting

dose Vicodin, Percocet, or

increase in risk.³⁴⁸

ed Massachusetts doctors to

times in 2011.

2011 Email: Managers Focused On Proper Patient Selection

The managers all indicated that proper patient selection is key.

- o Some physicians think of Duragesic when we present Butrans
- o The Butrans doses available are not considered to be “equianalgesic” to the available doses of Duragesic. Therefore, a patient who requires Duragesic has pain that is “beyond” Butrans and if they convert a patient from Duragesic to Butrans there is a risk on “failure” on Butrans. This has occurred in some areas, but the representatives are improving in their ability to focus the physicians on more appropriate patients (low dose Vicodin, Percocet, or tramadol, as well as opioid naive who now require an opioid analgesic)

- Butrans, not OxyContin
- OIG confirmed compliance for 2011

istent with recent market research conducted at the American Academy of
agement conference (John forwarded you a presentation on this research
review)
stives are improving their ability to focus the physicians on managed care
are Butrans is available and we are also increasing our messaging on the
wings Program to reduce the patient's out-of-pocket costs until we can
approved formulary status for Butrans
indicated that proper patient selection is key.
icians think of Duragesic when we present Butrans
s doses available are not considered to be “equianalgesic” to the available
Duragesic. Therefore, a patient who requires Duragesic has pain that is
Butrans and if they convert a patient from Duragesic to Butrans there is a
failure” on Butrans. This has occurred in some areas, but the representatives
ving in their ability to focus the physicians on more appropriate patients
Vicodin, Percocet, or tramadol, as well as opioid naive who now require an
algesic)
felt that we can improve in our call focus and frequency on high-potential
ing that where we focus our efforts with greater call frequency, we see a
ber of Rx per M.D. This is not a surprise, but now that we have a few
f call data as well as Rx data, we see a pretty clear correlation. (This will be
next week at the Mid-Year meeting)
sed tactics managers can take to assist representatives with call planning
cian selection for their call lists.
xpanded by 125 new territories during the 4th quarter 2010. With additional
management level, we actually hired approximately 147 new
to the Sales Force between October 2010 and March 2011.
ers all see that the newer representatives are not having the same level of
our veteran representatives.
ile some of the newer representatives are doing well, most of the newer
representatives are behind our more experienced representatives in
performance.
is not a surprise as relationships need to be developed to be effective at
filling. Also, many of the representatives we hire do not have a pain
management background, since there are only a few companies who are in
this market.
• All the manager's were confident that with our training focus for these new
representatives we will see improvement. They also felt that as we progress
into the second half of 2011 they will increase effectiveness as they build
more relationships with their physicians.
We have some representatives who are underperforming and the managers all indicated the
value of a program we initiated called the “Performance Enhancement Plan”.
o This is designed to focus the manager's efforts on representatives who are not
performing to expectations. It is not probation. Instead it is designed to improve
performance before a representative is performing so poorly they need to be placed
onto probation.
o The program focuses on selling skills, call activity focus, product knowledge and any

CONFIDENTIAL

PPLPC012000329609

6/16/11 Email from R. Gasdia (PPLPC012000329609)

Pre-2007 Released Marketing Allegations About Richard Sackler

Allegation: Misperceptions Of OxyContin

Massachusetts AG FAC ¶176:

176. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined — and recorded in secret internal correspondence — that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. In fact, OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth could reduce OxyContin sales.

- There is no such “direct[ion]” in the cited document
- Doctors knew from the label that this was not true

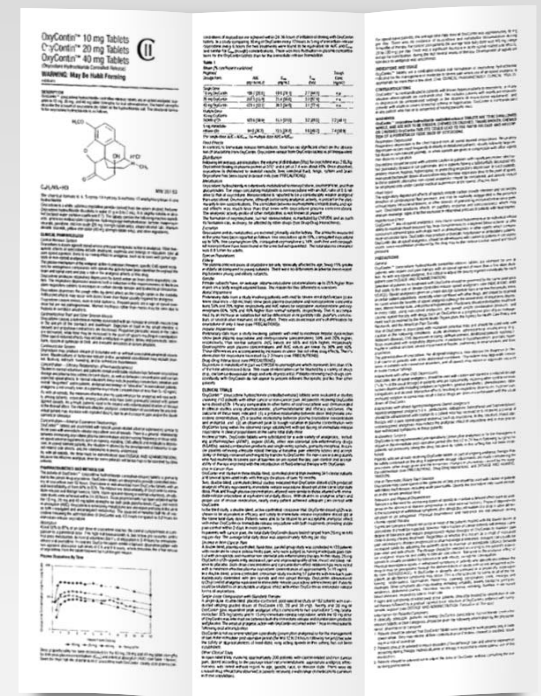
ko warned: “I don’t believe we have a sufficiently strong
al or no abuse liability.” To the contrary, Kaiko wrote,
ll among the most abused opioids in the U.S.” Kaiko
d, ... it is highly likely that it will eventually be
substantially would it improve your sales?”⁶³
a party, Richard Sackler spoke as the Senior Vice
ed the audience to imagine a series of natural disasters: an
cane, and a blizzard. He said: “the launch of OxyContin
of prescriptions that will bury the competition. The
ense, and white....”⁶⁴ Over the next twenty years, the
e. They created a manmade disaster. Their blizzard of
and parents and grandparents across Massachusetts, and
Sacklers were behind Purdue’s decision to deceive
Sackler, Kathe Sackler, and other Purdue executives
ternal correspondence — that doctors had the crucial
aker than morphine which led them to prescribe
substitute for Tylenol.⁶⁵ In fact, OxyContin is more

⁶³ 1997-02-02 email from Richard Sackler, PDD1701345999.
⁶⁴ 1997-03-02 email from Richard Sackler, PDD1701345999.
⁶⁵ PKY180280951.

⁶⁶ 1997-06-12 email from Richard Sackler, PDD8801141848 (Staff reported: “Since oxycodone is perceived as being a ‘weaker’ opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain. Physicians are positioning this product where Percocet, hydrocodone, and Tylenol with Codeine have been traditionally used. Since the non-cancer pain market is much greater than the cancer pain market, it is important that we allow this product to be positioned where it currently is in the physician’s mind.” Richard Sackler replied: “I think you have this issue well in hand. If there are developments, please let me know.”); 1997-05-28 email from Richard Sackler PDD1508224773; 1997-04-23 email from Richard Sackler, PDD1701801141.

Label Has Always Equated the Abuse Potential of OxyContin & Morphine

- “OxyContin is a mu-agonist opioid **with an abuse liability similar to morphine** and is a Schedule II controlled substance” (Original 1995 Label)
- “OxyContin is an opioid agonist and a Schedule II controlled substance **with an abuse liability similar to morphine**” (2001, 2005, 2007 Labels)
- “OxyContin contains oxycodone, a Schedule II controlled substance with a **high potential for abuse similar to other opioids including ... morphine**” (2015 Label)
- “OxyContin contains oxycodone, a substance with a **high potential for abuse similar to other opioids including ... morphine**” (2018 Label)



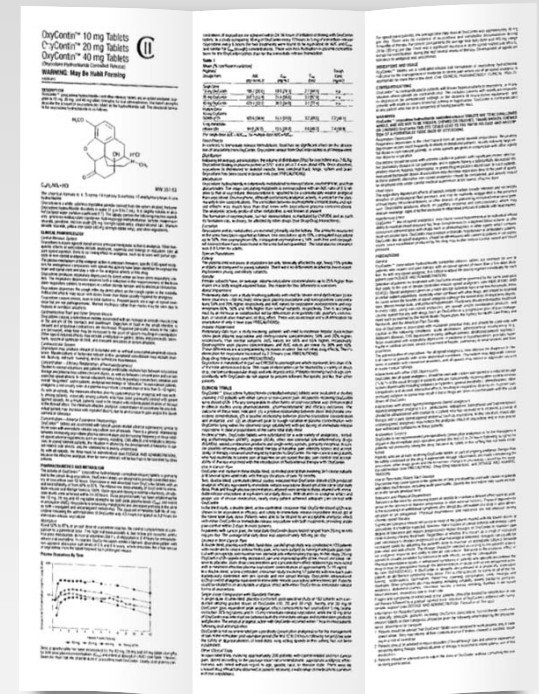
Label Showed OxyContin Is Twice As Strong As Morphine

Table 3

*Multiplication Factors for Converting the Daily Dose of Prior Opioids to the Daily Dose of Oral Oxycodone**
(Mg/Day Prior Opioid x Factor=Mg/Day Oral Oxycodone)

	Oral Prior Opioid	Parenteral Prior Opioid
Oxycodone	1	—
Codeine	0.15	—
Fentanyl TTS	SEE BELOW	SEE BELOW
Hydrocodone	0.9	—
Hydromorphone	4	20
Levorphanol	7.5	15
Meperidine	0.1	0.4
Methadone	1.5	3
Morphine	0.5	3

*To be used only for conversion to oral oxycodone. For patients receiving high-dose parenteral opioids, a more conservative conversion is warranted. For example, for high-dose parenteral morphine, use 1.5 instead of 3 as a multiplication factor. In all cases, supplemental analgesia (see below) should be made available in the form of immediate-release oral oxycodone or another suitable short acting analgesic.



1995 OxyContin Label (PDD150170001)

Employees' Misstatements Admitted, Settled and Released In 2007

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

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

UNITED STATES OF AMERICA

Dkt. No. _____

PURDUE FREDERICK COMPANY, INC.)
Purdue Frederick Company)

AGREED STATEMENT OF FACTS

Introduction

The PURDUE FREDERICK COMPANY, INC. (referred to in this Agreed Statement of Facts as "Purdue Frederick Company"), doing business as The Purdue Frederick Company, was a New Jersey corporation created in 1892 and was purchased by its parent, Purdue Frederick Company, Inc. ("Purdue Frederick"), at all times relevant to this Agreed Statement of Facts, PURDUE and other entities were engaged in the pharmaceutical business throughout the United States.

Purdue Frederick developed and originally marketed OxyContin Tablets ("OxyContin"), an opioid analgesic, to be taken every twelve hours. OxyContin is a controlled-release formulation of the controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive Officer in 2003.

Attachment B to Plea Agreement
United States v. The Purdue Frederick Co., Inc. Page 1 of 16

Case 1:07-cr-00029-JPJ Document 5-2 Filed 05/10/07 Page 1 of 19 Pageid#: 12

Agreed Statement of Facts 129

Allegation: February 2001 Reaction To Reports of Death

Massachusetts AG FAC ¶182:

182. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state. The Sacklers knew that the reports underestimated the destruction. Richard Sackler wrote to Purdue executives: “This is not too bad. It could have been far worse.”

promotional videos with that same false claim:

“There’s no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don’t wear out, they go on working, they do not have serious medical side effects.”⁷³

We were directed to lie. Why mince words about it?

g. They saw that potential for billions of dollars and

re warned that a reporter was “sniffing about the

family put the threat on the agenda for the next Board

. They planned a response that “deflects attention away

Sackler received a plea for help from a Purdue sales

a community meeting at a local high school, organized

by mothers whose children overdosed on OxyContin and died. “Statements were made that

OxyContin sales were at the expense of dead children and the only difference between heroin

and OxyContin is that you can get OxyContin from a doctor.”⁷⁷

182. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state.⁷⁸ The Sacklers knew that the reports underestimated the destruction. Richard

⁷³ “I Got My Life Back” video, transcript, PDD9521403504.

⁷⁴ 2017-10-16, Christopher Glazek, “The Secretive Family Making Billions From The Opioid Crisis,” *Esquire* Magazine (quoting Purdue sales representative Shelby Sherman).

⁷⁵ 2000-11-30 email from Michael Friedman, PDD1706196247.

⁷⁶ 2000-12-01 email from Mortimer D. Sackler, PDD1706196246. Defendant Mortimer Sackler’s father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

⁷⁷ 2001-01-26 email from Joseph Coggins, #171855.1.

⁷⁸ 2001-02-08 email from Mortimer Sackler, PDD8801151727.

Cited Email Reacts To Lengthy *New York Times* Article

- The allegation distorts the email
- Negative *New York Times* article expected
- Not as negative as expected
- It included the response of Purdue's medical director

From: Sackler, Dr Richard

Sent: Thursday, February 08, 2001 9:59 PM
To: Hogen, Robin; Haddox, Dr. J. David; mx; hru
Cc: pdg; eda; edm
Subject: FW: NYTimes.com Article: Cancer Painkillers Are Being Abused

This is not too bad. It could have been far worse.
Thanks for all the support.

Richard S. Sackler, M.D.
President, Purdue Pharma, L.P.
Laptop 2000 machine
One Stamford Forum
Stamford, CT 06901
Telephone
Internet
Intranet Located in Connecticut

2/8/01 Email from R. Sackler
(PPLPC045000004037)

-----Original Message-----
From: msackler@me.net

Allegation: January 2001 Time Magazine Article

Massachusetts AG FAC ¶185:

185. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain – who far outnumber the drug addicts abusing our product."

Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."⁷⁹ The next week, on February 14, a mother wrote a letter to Purdue:⁸⁰

"My son was only 28 years old when he died from Oxycontin on New Year's Day. We all miss him very much, his wife especially on Valentine's Day. Why would a company make a product that strong (80 and 160 mg) when they know they will kill young people? My son had a bad back and could have taken Motrin but codin, then Oxycontin then Oxycontin

ability issue here. Any suggestions?"⁸¹

d Sackler wrote down his solution to the overwhelming and stigmatize people who become addicted to opioids. We have to hammer on the abusers in every way possible.

They are reckless criminals."⁸² Richard followed that millions from selling addictive drugs, and blame the became addicted. By their misconduct, the Sacklers in every way possible. And the stigma they used as a

's February 14 letter, the Sacklers achieved a long-term. *Time* reported that "OxyContin's sales have hit \$1 same article noted that "OxyContin has been a factor in medical examiners are still counting."⁸³

lished an article about OxyContin deaths in New d Sackler they were concerned. Richard responded with

9801151727.

⁷⁹ 2001-02-14 email from James Heins, #3072810.1.

⁸⁰ 2001-02-01 email from Richard Sackler, PDD8801133516.

⁸¹ 2001-03-05 article in *New York Times*, PDD9316101737.

One-Page Memo Discussing January 2001 Time Magazine Article

Dear Colleagues,

Some of you have expressed concern about an article in this week's *Time* magazine, "The Potent Perils of a Miracle Drug," which unfortunately emphasizes the abuse and diversion rather than the therapeutic qualities of our leading product, OxyContin®.

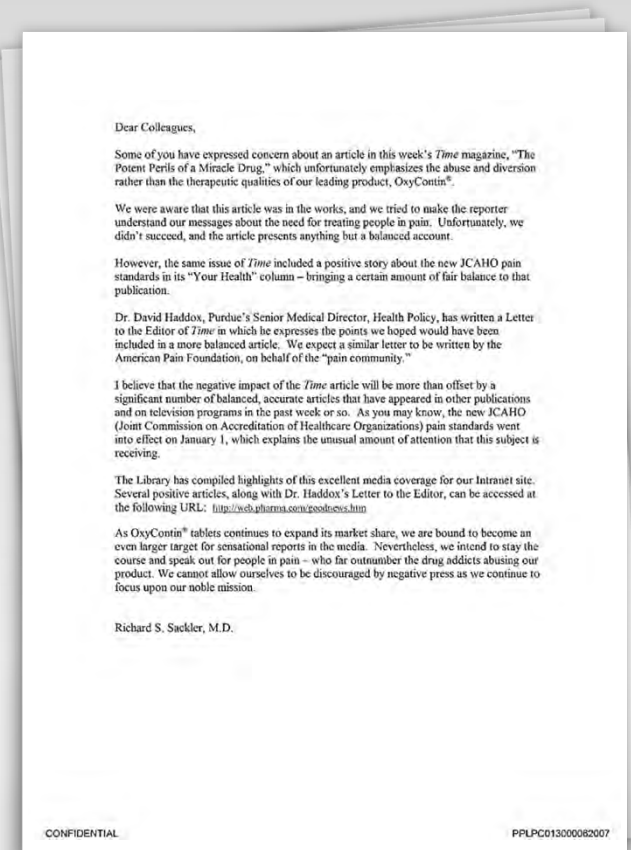
We were aware that this article was in the works, and we tried to make the reporter understand our messages about the need for treating people in pain. Unfortunately, we didn't succeed, and the article presents anything but a balanced account.

However, the same issue of *Time* included a positive story about the new JCAHO pain standards in its "Your Health" column - bringing a certain amount of fair balance to that publication. ...

As OxyContin® tablets continues to expand its market share, we are bound to become an even larger target for sensational reports in the media. Nevertheless, **we intend to stay the course and speak out for people in pain - who far outnumber the drug addicts abusing our product.** We cannot allow ourselves to be discouraged by negative press as we continue to focus upon our noble mission.

Richard S. Sackler, M.D.

- No suggestion "deaths were the fault of 'the drug addicts'"



1/9/01 Letter from R. Sackler (PPLPC013000062006)

Allegation: The Blizzard Of 1996

Massachusetts AG FAC ¶175:

175. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said: “the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white...” Over the next twenty years, the Sacklers made Richard’s boast come true. They created a manmade disaster. Their blizzard of dangerous prescriptions buried children and parents and grandparents across Massachusetts, and the burials continue.

OxyContin without strict controls. Kaiko warned: “I don’t believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability.” To the contrary, Kaiko wrote,

“... among the most abused opioids in the U.S.” Kaiko

d, ... it is highly likely that it will eventually be substantially would it improve your sales?”⁶³

a party, Richard Sackler spoke as the Senior Vice

and the audience to imagine a series of natural disasters: an

cane, and a blizzard. He said: “the launch of OxyContin

of prescriptions that will bury the competition. The

ense, and white...”⁶⁴ Over the next twenty years, the

ie. They created a manmade disaster. Their blizzard of

and parents and grandparents across Massachusetts, and

Sacklers were behind Purdue’s decision to deceive

Sackler, Kathie Sackler, and other Purdue executives

ternal correspondence — that doctors had the crucial

aker than morphine, which led them to prescribe

substitute for Tylenol.⁶⁵ In fact, OxyContin is more

701345999.
D1701345999.

28801141848 (Staff reported: “Since oxycodone is perceived as pushed in OxyContin being used much earlier for non-cancer pain, tercoet, hydrocodone, and Tylenol with Codeine have been market is much greater than the cancer pain market, it is important that currently is in the physician’s mind.” Richard Sackler replied: “I here developments, please let me know.”); 1997-05-28 email from

Richard Sackler PDD1508224773; 1997-04-23 email from Richard Sackler, PDD1701801141.

56

MA AG FAC ¶175

Cited Document: The Blizzard Of 1996

OXYCONTIN™: THE MOST SIGNIFICANT LAUNCH IN PURDUE HISTORY!

For millennia, humans knew that great changes in the fortunes of civilizations and enterprises are heralded by cataclysms in geology and weather.

Eclipses, earthquakes, volcanoes, hurricanes, and blizzards have each preceded such changes, and each upheaval has had its significance and meaning.

Soothsayers and wise men, shamans and high priestesses, each have a claim on the capacity to interpret such phenomena for the rest of us and advise us about how we should now align ourselves for the coming of the New Age.

The Blizzard of '96, coming less than four years before the change of the millennium, is without doubt an omen of change.

This unexpected surge of snow, this untimely tempest threw a wrench into the flawless planning that Jim, Ron, and dozens of others had made to bring us all together here on Sunday evening. Unfortunately Michael, Paul, Robert and I were not with you on Sunday, nor

the truth, which is, that we were on a final and unexpected mission to enhance the launch of OXYCONTIN Tablets.

Michael and I were late (and Paul and Robert are missing) not because transportation was snarled and airports were closed. We apologize for the disinformation spread here by Jim, Ron, Mark, and others, but they were acting on Michael's orders.

We were high in the Himalayas, deep in Tibet, to learn from the Wise One everything possible about the meaning of this intemperate interruption of our plans and what we should be doing to take advantage of the launch of OXYCONTIN Tablets. It was Paul who first said that it was imprudent to depend upon our own powers of prognostication. "Let's go where the knowledge is," suggested Paul. We all wanted to be sure that we were bringing you the most authoritative information about the significance of the Blizzard of '96. "We need an expert," said Paul conclusively.

vermin, and that they borrow your watch to tell you the time."

"There is an alternative to McKinsey," said Robert Reder. "I know a Wise One in the mountains of Tibet."

I ventured, "Well, there is a chance, because Michael loves mountains, snow and skiing. Paul, Robert,



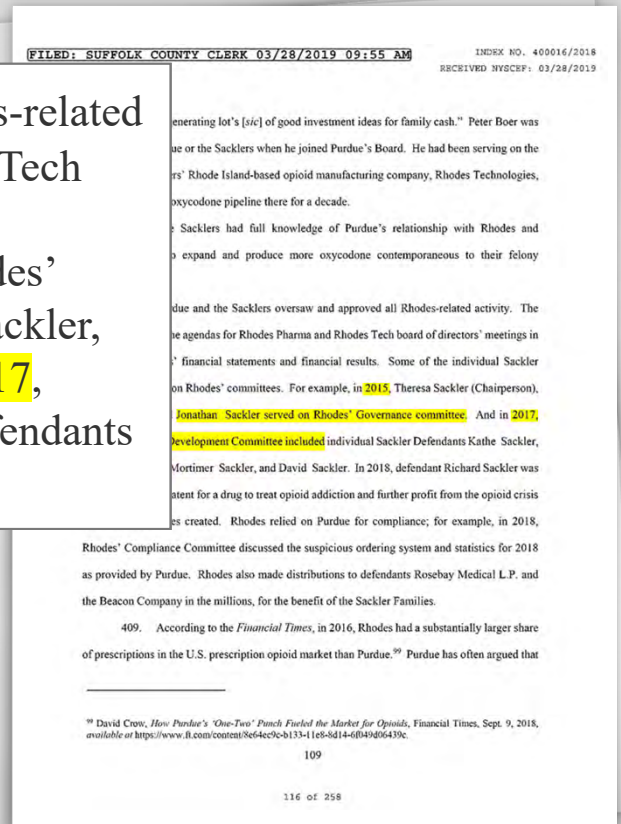
Marketing Allegations About Jonathan Sackler

Allegation: Rhodes Board Committees

New York AG FAC ¶408:

408. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler.

- Jonathan Sackler never served as a Rhodes director or on any Rhodes committee
- Irrelevant to deceptive marketing claims



Allegation: Exploring Possibility Of Using PET Scans To Identify Abusers

New York AG FAC ¶374:

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

- 2008 email, no “exploration”
- OIG confirmed compliance for 2008

FILED: SUFFOLK COUNTY CLERK 03/28/2019 09:55 AM
HYCERF DOC. NO. 17

INDEX NO. 400016/2018
RECEIVED HYCERF: 03/28/2019

i. The Sacklers Intentionally Blamed Individuals Instead of Purdue to Address The Risk Its Opioid Products Posed

Jonathan Sackler dictated Purdue's strategy for responding to the
opioid crisis. In an email, Jonathan Sackler wrote to Richard Sackler: "we have to hammer on the
culprits and the problem. They are reckless criminals."
Jonathan Sackler was glorified as some sort of populist victim."

Jonathan Sackler was discussing whether people dependent on opioids "want to be
something that will totally revise your belief that addicts don't
deserve sympathy. They get themselves addicted over and over again."
Jonathan Sackler stated that addicts are criminals, and they engage in it with full, criminal
intent. He further wrote: "This vilification is

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

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

100

107 of 258

NY AG FAC ¶374

Allegation: Knowledge Of Opioid Risks

Massachusetts AG FAC ¶226:

226. The Sacklers also knew and intended that the sales reps would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths." He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when "high doses of an opioid are used for long periods of time."

225. Purdue managers determined that two sales reps hired in the 2008 expansion

prescriptions in Massachusetts that they were among
ny rewarded them with bonuses and all-expense-paid trips
examples to motivate other reps to sell more opioids.¹²⁷
w and intended that the sales reps would push higher doses
th, Richard Sackler directed Purdue management to
y strength, giving higher measures to higher strengths."¹²⁸
ckler on the instruction. The Sacklers knew higher doses
k as the 1990s, Jonathan and Kathe Sackler knew that
"high doses of an opioid are used for long periods of

he Sacklers voted to pay former CEO and criminal convict
was one of several multi-million-dollar payments to the
r loyalty and protect the Sackler family.
working on a crush-proof reformulation of OxyContin to
The Sacklers learned that another company was planning
e-proof opioids are safer for patients.¹³² Mortimer Sackler
r studies to find out whether reformulated OxyContin was
s of patients. He wrote to Richard Sackler: "Purdue should

be leading the charge on this type of research and should be generating the research to support

¹²⁷ 2018-02-18 deposition of Catherine Yates Sypek pg. 120; 2018-03-01 deposition of Timothy Quinn pg. 99.

¹²⁸ 2008-03-13 email from Richard Sackler, PPLPC012000170948-949.

¹²⁹ 1997-03-12 memo from John Stewart, PDD1701785443.

¹³⁰ 2008-02-14 Board minutes, PKY183212622.

¹³¹ 2007-10-26 Sales & Marketing presentation, pg. 2, PPLPC012000159022.

¹³² 2008-02-07 email from Robert Kaiko, PPLPC013000244844.

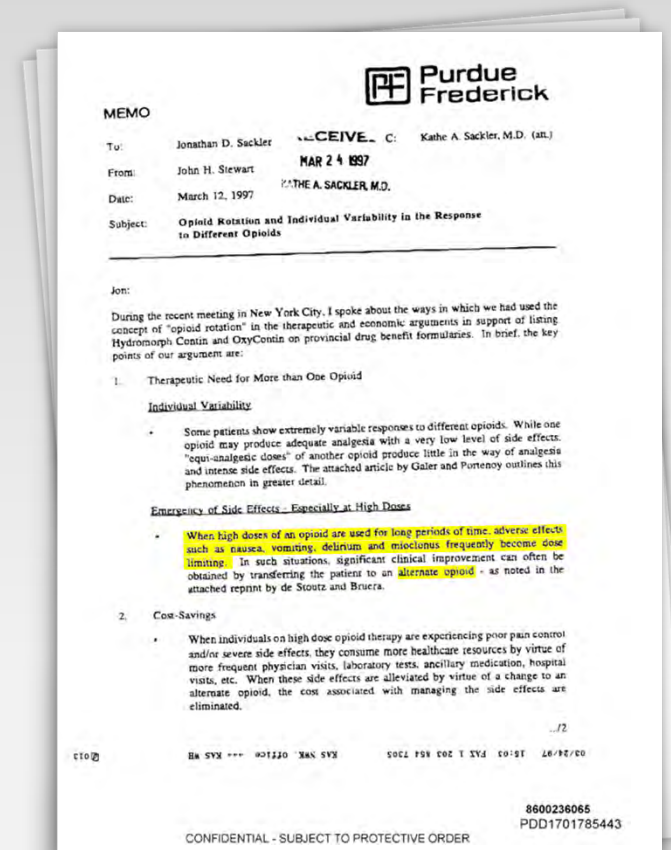
Irrelevant 1997 Memo Discusses Need For Alternate Opioid Analgesics

To: Jonathan D. Sackler
From: John H. Stewart
Date: March 12, 1997

1. Therapeutic Need for More than One Opioid

Emergency of Side Effects – Especially at High Doses

- When high doses of an opioid are used for long periods of time, adverse effects such as nausea, vomiting, delirium and mioclonus frequently become dose limiting. In such situation, significant clinical improvement can often be obtained by transferring the patient to an alternate opioid – as noted in the attached reprint by de Stoutz and Bruera.



3/12/97 Memo from J. Stewart (PDD1701785443)

Allegation: Pushing Staff About Sales

Massachusetts AG FAC ¶234:

234. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales. Staff told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, “in spite of all the pressures.” Kathe demanded that staff identify the “pressures” and provide “quantification of their negative impact on projected sales.”

“John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.”¹⁴⁵

232. Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids and get more pills in each prescription. That same Saturday night,

her set of instructions, directing him to identify tactics for on an adjusted basis (adjusted for strength and average number of next day, Gasdia was writing up plans for how adding sales reps, moting more intermediate doses of OxyContin could help increase

er followed through on his weekend threat that he would have the two days later, Richard circulated his own sales analysis to the to “put this high in the Board agenda,” and proposed that he and edo of the annual plan as well as the 5-year plan for Purdue’s

me, Jonathan, Kathe, and Mortimer Sackler were also pushing staff

three Sacklers that they would use opioid savings cards to meet the tin scripts at the same level in 2008 as in 2007, “in spite of all the

pressures.”¹⁴⁹ Kathe demanded that staff identify the “pressures” and provide “quantification of their negative impact on projected sales.”¹⁵⁰

¹⁴⁵ 2008-03-08 email from Russell Gasdia, PPLPC012000174127.

¹⁴⁶ 2008-03-08 email from Richard Sackler, PPLPC012000175157.

¹⁴⁷ 2008-03-09 email from Russell Gasdia, PPLPC012000174161.

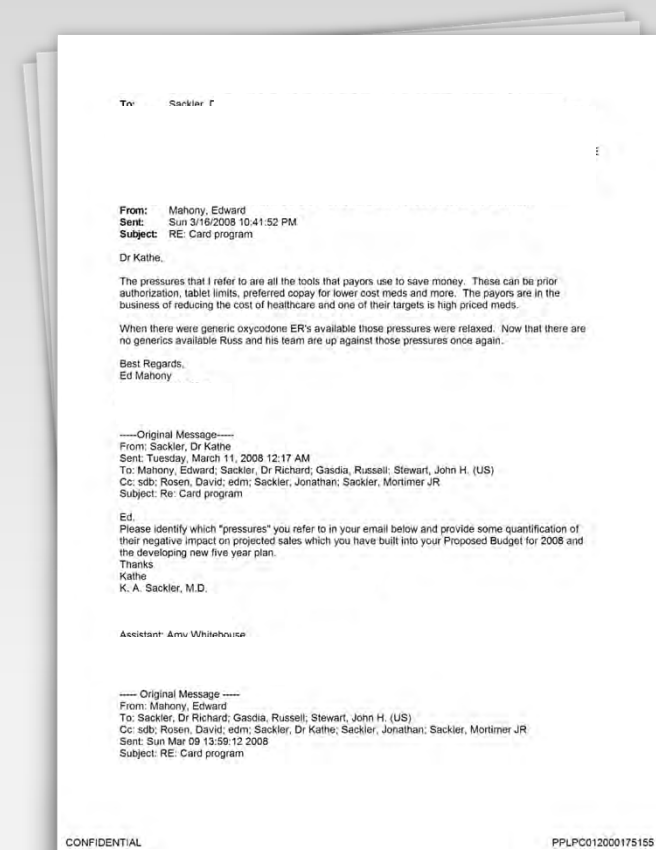
¹⁴⁸ 2008-03-10 email from Richard Sackler, PPLPC023000164605.

¹⁴⁹ 2008-03-09 email from Edward Mabony, PPLPC012000175155-156.

¹⁵⁰ 2008-03-11 email from Kathe Sackler, PPLPC012000175155.

Irrelevant 2008 Email Contains No Communication From Jonathan Sackler

- He is cc'd on an information request
- Sales, not marketing
- OIG confirmed compliance for 2008



3/9/08 Email from E. Mahony (PPLPC012000175155)

Allegation: “Starting To Look Ugly”

Massachusetts AG FAC ¶344:

344. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. He wrote to John Stewart: “this is starting to look ugly. Let’s talk.” Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

even went to pharmacies to ask Massachusetts pharmacists to encourage doctors to prescribe opioids for the elderly.

343. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids.³⁴¹ In Massachusetts, sales reps recorded in their notes that they

opioids more than a thousand times in 2011. Massachusetts
s to commit to prescribe opioids without disclosing

ot satisfied that these tactics would be enough to boost
is starting to look ugly. Let’s talk.”³⁴² Stewart and the

response and set up a meeting with Jonathan for the

reported to the Sacklers that Purdue had hired 47 more
orders. Staff told the Sacklers that Purdue employed 639
visited prescribers 173,647 times.³⁴⁴ More than 3,800 of

those visits were in Massachusetts.³⁴⁵

346. Meanwhile, the Sacklers voted to pay \$10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue’s marketing of OxyContin.³⁴⁶ The Sacklers were on notice that Purdue’s unfair and deceptive marketing raised serious concerns. Staff also

³⁴¹ 2011-05-25 email from Russell Gaudin, PPLPC012000326017.

³⁴² 2011-05-25 email from Jonathan Sackler, PPLPC012000326194.

³⁴³ 2011-05-25 email from John Stewart, PPLPC012000326193.

³⁴⁴ 2011-05-02 Board report, pgs. 5, 6, 36, PPLPC012000322430, -431, -461. Staff told the Sacklers that the sales rep visits compared to a target for the quarter of 168,210 visits; and that reps visited 6.66 prescribers per day, on average, compared to a target of 7.0.

³⁴⁵ Exhibit 1.

³⁴⁶ 2011-05-20 Board minutes, PKY183212910.

Irrelevant 2011 Email Concerns Butrans Sales

From: Gasida, Russell

Subject: Butrans Weekly Report for the week ending May 13, 2011

Colleagues

While we experienced a **small increase** (29) from the previous week, based on total Rx's, we gained market share and reached 1.07%, the highest level since launch. Also, we are seeing increases in utilization of the 10mcg/hr and 20mcg/hr strengths.

From: Sackler, Jonathan

Sent: Wednesday, May 25, 2011 1:09 PM

To: Stewart, John H. (US)

Subject: FW: Butrans Weekly Report for the week ending May 13, 2011

John, this is **starting to look ugly**. Let's talk.

- Butrans, not OxyContin
- Sales, not marketing
- OIG confirmed compliance for 2011

to stimulate sales growth. In association with their meeting, a lot of analyses have been
ed – and I'll ask Russ to pull together the salient points along with the feedback and action
om the RIM Meeting – and set a time to get together and discuss.

Sackler, Jonathan
Wednesday, May 25, 2011 1:09 PM
Stewart, John H. (US)
FW: Butrans Weekly Report for the week ending May 13, 2011

this is starting to look ugly. Let's talk.

Sackler
user Boulevard

From: Gasida, Russell
Sent: Wednesday, May 25, 2011 8:37 AM
To: Sackler, Dr Richard; Sackler, Mortimer D.A.; Sackler, Dr Raymond R; Sackler, Dr Kathie; Sackler,
Jonathan; Sackler, Theresa; Pickett, Cecil; Boer, Peter; Levant, Judy; Baker, Stuart D.; Stewart, John
H. (US)
Cc: Mahony, Edward; Dolan, James; Landau, Dr. Craig; Long, David; Lundie, David; Stiles, Gary;
Melin, William; Weinstein, Bert; Abrams, Robin; Silbert, Richard W; Strassburger, Philip; Haddox, Dr.
J. David; Must, Alan
Subject: Butrans Weekly Report for the week ending May 13, 2011

Colleagues

While we experienced a **small increase** (29) from the previous week, based on total Rx's, we gained
market share and reached 1.07%, the highest level since launch. Also, we are seeing increases in
utilization of the 10mcg/hr and 20mcg/hr strengths.

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

- Improving physician "targeting" to ensure representatives are calling on the highest potential
physicians
- Increasing call frequency on a select "super core" of physicians. We are seeing a direct
correlation between call activity and results. The results indicate it is taking more calls than
expected to generate a first prescription (Buprenorphine is "new" to many physicians, the 7-
day transdermal system is a "new" concept and identifying a patient who's managed care
plan covers them are all contributing factors to a longer selling cycle)
- Improving selling skill effectiveness to:

CONFIDENTIAL

PPLPC012000326194

5/25/01 Email from J. Sackler (PPLPC012000326193)

Allegation: Study Changes In Market Share

Massachusetts AG FAC ¶358:

358. A few days later, sales and marketing staff scrambled to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to “capture more cost sensitive patients.” Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

356. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales rep. When he returned, Richard argued to the Vice President of Sales that a legally-required warning about Purdue's opioids wasn't needed. He asserted that the warning “implies a danger of untoward reactions and hazards that simply aren't there.” Richard insisted there should be “less threatening” words to describe Purdue opioids.³⁶⁵

voted to pay their family \$200,000,000.³⁶⁶ and marketing staff scrambled to prepare responses to Sackler asked about launching a generic version of OxyContin to see if Purdue could identify more patients.” Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

staff were organizing more ways for Richard Sackler to proposed to Richard:

acts with representatives, you may want to if the upcoming conventions where we will the ones listed below, we will have a OxyContin & Butrans. In addition, we are programs for Butrans and OxyContin in the er.”

the opportunity to be on the convention is presentations being provided by our wide range of interactions over the course we can arrange for one-on-one meetings with are attending, many of them are approved conversations regarding the market, perceptions around Butrans

³⁶⁵ 2011-07-20 email from Richard Sackler, PPLPC00100091102.

³⁶⁶ 2011-06-24 Board minutes, PKY183212924-925.

³⁶⁷ 2011-06-28 email from Edward Mahony, PPLPC012000331343; attachment PPLPC012000331345.

Irrelevant 2011 Request For Information Unrelated To Marketing

Overall S&P for 2011

OxyContin – Russ Gasdia

4. Jon asked for market share change over time for opioid medicines over time --- by strength.

- **OIG confirmed compliance for 2011**

Overall S&P for 2011

Marketing Report – Russ Gasdia

1. What is the data that supports our belief that the generic Oxy business that existed in 2010 has not converted to brand Oxy?
 - a. A sub-question to the above – where has the generic Oxy business gone (i.e. which competitive products), and also where has the lost Oxy brand business gone?
2. Mortimer Jr. asked if we should launch an OxyContin AG to capture more cost sensitive patients.

ONU

For 1 Day R&D Meeting – Gary Stiles

1. Questions on the commercial value proposition - seeking a constipation claim may be a serious barrier to adoption-use bowel dysfunction. Dr. Richard - "brilliantly designed program for the wrong goal" basically, can you sell this product? Does it solve a bigger issue than constipation? What specific clinical studies would have to be successful to have a saleable Targin claim that reduces pain and improves quality of life e.g. bowel dysfunction.
2. Are we testing a PCO-like formulation in ONU?
3. Jon - Will the oxy/naloxone have any effect on respiratory depression?

CONFIDENTIAL

PPLPC012000331345

6/28/11 Email from E. Mahony w/attachment (PPLPC012000331345)

Allegation: Pressing For Sales Updates

Massachusetts AG FAC ¶366:

366. In January 2012, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler jumped into the weeds with the sales staff, this time about advertising. Richard noticed that online ads appeared indiscriminately on webpages with content associated with the ad — regardless of whether the association was positive or negative. Staff assured Richard that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids, and would not appear with articles “about how useless or damaging or dangerous is our product that we are trying to promote.”

paid their family \$551,000,000.³⁷⁸

♦ ♦ 2012 ♦ ♦ ♦

Jonathan Sackler started the year pressing Sales VP Russell

A few days later, Richard Sackler jumped into the weeds with the sales staff, this time about advertising. Richard noticed that online ads appeared indiscriminately on webpages with content associated with the ad — regardless of whether the association was positive or negative. Staff assured Richard that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids, and would not appear with articles “about how useless or damaging or dangerous is our product that we are trying to promote.”³⁸¹

Staff told the Sacklers that Purdue employed 632 sales reps and, as of 2011, had visited 165,994 times.³⁸² More than 3,600 of those visits were

satisfied with the sales effort. In February, staff reported a decrease in sales rep visits to the Sacklers. Staff asked the Sacklers to be patient, because reps were attending to the company's mandatory National Sales Meeting

119328.
PLPC012000358983.
PLPC012000361065-066.
PLPC012000361064.
C012000362250, -291. Staff told the Sacklers that the sales rep visits were 7.03 prescriptions per day, on average,

123

MA AG FAC ¶366

Irrelevant 2012 Request For Resumption Of Butrans Sales Update

From: Sackler, Jonathan
Sent: Monday, January 09, 2012 04:55 PM
To: Gasdia, Russell
Subject: Butrans

Russ, are you going to resume a weekly (bi-weekly?) update on sales?

- Butrans, not OxyContin
- Sales, not marketing
- OIG confirmed compliance for 2012

na.com]

ermesso, I dropped the ball last week. I'll have a
012, I'm going to move to bi-weekly for Butrans

(bi-weekly?) update on sales?

Stamford, CT. 06901

tel: (203) 588-7200 fax: (203) 588-6500 jsackler@pharma.com

Executive Assistant: Alicia Laing

tel: (203) 588-7202 fax: (203) 588-6500 alicia.laing@pharma.com

1/9/12 Email from J. Sackler (PPLPC012000358983)

Allegation: Studied News Reports

Massachusetts AG FAC ¶429:

429. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.

428. In December, staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales reps visited the most susceptible prolific prescribers.⁴⁹⁹

429. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis

staff told Jonathan Sackler about the same concern. Jonathan and asked staff to assure him that journalists covering the Sacklers.⁵⁰¹

❖ ❖ 2014 ❖ ❖

staff reported to the Sacklers on how Purdue's program for compared to recent agreements between other drug companies had agreed that sales reps should not be paid prescriptions, but Purdue still paid reps for generating the public the money they spent to influence continuing. Other companies had adopted "claw-back" policies so as they earned from misconduct, but Purdue had not. The resolutions each quarter certifying their oversight of the, but the Sacklers did not.⁵⁰²

⁴⁹⁹ 2013-12-04 email from David Rosen, PPLPC012000454676.

⁵⁰⁰ 2014-01-03 email from Burt Rosen, PPLPC020000748356 ("I spoke to Richard just before the year end and raised concerns over our internal documents.")

⁵⁰¹ 2014-01-02 email from Jonathan Sackler, PPLPC020000748356.

⁵⁰² 2014-01-16 quarterly compliance report to the Board, PPLP00410797.

Irrelevant 2014 Observation About Lack Of Press Focus On IR Oxycodone

From: Sackler, Jonathan
Sent: Thursday, January 02, 2014 5:14 PM
To: Walsh, Kathy
Subject: RE: Search Results: Oxycodone IR follow up

Yes, it was helpful. My takeaway: no apparent focus on makers of IR oxycodone, and no apparent interest in the distribution chain EXCEPT in the case of FL pain clinics ("pill mills"). Is that what you see?

Jon Sackler

From: Walsh, Kathy
Sent: Friday, January 03, 2014 11:22 AM
To: Sackler, Jonathan
Subject: RE: Search Results: Oxycodone IR follow up

Agreed, so far no focus on the manufacturers of IR oxycodone and only rare mentions of the immediate release version of the drug in media reports.

- Nothing to do with the family or marketing

1/2/14 Emails w/ J. Sackler (PPLPC020000748356)

CONFIDENTIAL

PPLPC020000748356

Allegation: Request For Briefing On Public Health Initiatives

Massachusetts AG FAC ¶468:

468. In December, staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff was calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.

proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through "disproportionate focus on key customers." They told the Sacklers that sales reps would also target prescribers with the lowest levels of training, physician's assistants and nurse practitioners, because they were "the only growing segment" in the opioid market.⁵⁶⁵ Purdue executives expected that, each quarter, the sales reps would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.⁵⁶⁶

Staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication for each drug. Richard Sackler sought details on how staff was calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.⁵⁶⁷ In December, the Sacklers were invited to a "Beneficiaries Meeting" where staff briefed the Sackler family members about the company's efforts to sell

⁵⁶⁵ 2015-11 budget for 2016, slides 24, 26, 49, PPLPC011000069975, -69977, -70000.

⁵⁶⁶ 2015-11-03 email from Zach Perlman, Executive Committee materials, slide 36, PPLPC011000065030.

⁵⁶⁷ 2015-12-09 email from Zach Perlman, PPLPC011000073228 attaching Executive Committee presentation, slides 12-13, PPLPC011000073230.

⁵⁶⁸ 2015-10-28 email from Stuart Baker, PPLPC011000063897; see also November 2013 Beneficiaries Meeting, PPLP004410528.

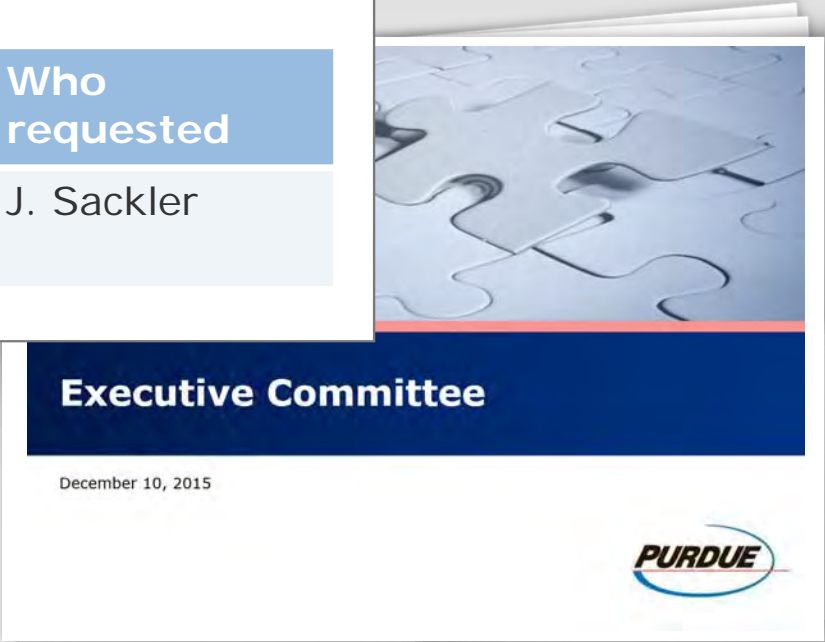
2015 Request For Briefing On Market Impact Of CDC Guidelines

Budget action items (2/5)

December followup

Request	Who requested
Follow up briefing on OxyContin market impact of CDC guidelines	J. Sackler

- Purdue distributed the CDC Guidelines to more than 150,000 health care providers



Allegation: Proposed A New Opioid

Massachusetts AG FAC ¶492:

492. In November, Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board.⁶⁰³ At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps to 302 reps. They knew sales reps would continue to promote opioids in Massachusetts.

Commissioner: "the goal should have been to sell the least dose of the drug to the smallest number of patients." The reporter concluded: "Purdue set out to do exactly the opposite."⁶⁰¹

492. In November, Jonathan Sackler suggested that Purdue launch yet another opioid.⁶⁰² Staff promised to present a plan for additional opioids at the next meeting of the Board.⁶⁰³ At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps

to 302 reps. They knew sales reps would continue to promote opioids in Massachusetts. Staff promised to present a plan for additional opioids at the next meeting of the Board.⁶⁰³ At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps to 302 reps. They knew sales reps would continue to promote opioids in Massachusetts.



planned sales rep territories for 2018

⁶⁰¹ 2017-10-23 email from Robert Josephson, PPLPC016000318910.
⁶⁰² 2017-11-21 email from Jonathan Sackler, PPLPC016000321334.
⁶⁰³ 2017-11-21 email from Craig Landau, PPLPC016000321333.
⁶⁰⁴ 2017-11 Board budget, slides 47, 51, PPLPC016000323215.

Irrelevant Question: Should Purdue Consider Abuse-Deterrent Morphine?

Do you think we should consider an ANDA filing for AD CR morphine?

- Jon

- Never pursued
- Irrelevant to deceptive marketing claims

We'll be presenting a consolidated ADF strategy to the board on Thursday, Nov 30th. This will certainly be part of it.

Craig Landau, MD
President & CEO

ation errors.

er, Jonathan

Per our prior conversation:

"To date, the U.S. Food and Drug Administration has approved 10 opioid drugs with these properties. But their uptake has been slow among doctors who are treating patients in pain. The reason for their more limited use is likely multifold. We know there can be a learning curve that comes with new technologies. Some prescribers may not be aware of the existence of these drugs, or may be uncertain of when to prescribe the abuse-deterrent versions. But we also know a significant barrier to use can be price. Because these new formulations are currently only available as brand-name products, they're inherently more expensive than the numerous non-abuse deterrent formulations that are also available in generic formulations."

"But to transition this market more quickly to the ADFs, and consider permanently withdrawing the older formulations that lack abuse-deterrent features in the event these products were judged to be less safe? there are a number of factors we must consider. One of the factors that the FDA would consider relates to generic access. We must have the potential to improve access to the newer formulations, for appropriately selected and monitored patients, through the introduction of generic competitors."

<https://www.fda.gov/News/Events/Newsroom/PressAnnouncements/ucm586117.htm>

Do you think we should consider an ANDA filing for AD CR morphine?

CONFIDENTIAL

PPLPC016000321334

11/21/17 Email from J. Sackler (PPLPC016000321334)

No Allegations About Beverly Sackler

Marketing Allegations About David Sackler

Allegation: Rhodes Board Committees

New York AG FAC ¶408:

408. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler.

- David Sackler was never a Rhodes director and never served on a Rhodes Committee
- Irrelevant to deceptive marketing claims

INDEX NO. 400016/2018
RECEIVED NYCCEF: 03/28/2019
COUNTY CLERK 03/28/2019 09:55 AM

generating lot's [sic] of good investment ideas for family cash." Peter Boer was
ue or the Sacklers when he joined Purdue's Board. He had been serving on the
rs' Rhode Island-based opioid manufacturing company, Rhodes Technologies,
oxycodone pipeline there for a decade.

Sacklers had full knowledge of Purdue's relationship with Rhodes and
o expand and produce more oxycodone contemporaneous to their felony

due and the Sacklers oversaw and approved all Rhodes-related activity. The
e agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in
financial statements and financial results. Some of the individual Sackler
on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson),
Jonathan Sackler served on Rhodes' Governance committee. And in 2017,

Development Committee included individual Sackler Defendants Kathe Sackler,
Mortimer Sackler, and David Sackler. In 2018, defendant Richard Sackler was
patent for a drug to treat opioid addiction and further profit from the opioid crisis

the Sackler Families created. Rhodes relied on Purdue for compliance; for example, in 2018,
Rhodes' Compliance Committee discussed the suspicious ordering system and statistics for 2018
as provided by Purdue. Rhodes also made distributions to defendants Rosebay Medical L.P. and
the Beacon Company in the millions, for the benefit of the Sackler Families.

409. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share
of prescriptions in the U.S. prescription opioid market than Purdue.⁹⁹ Purdue has often argued that

⁹⁹ David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, *Financial Times*, Sept. 9, 2018,
available at <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6049d06439c>.

Allegation: Received A Memo Regarding “Strategy”

Massachusetts AG FAC ¶440:

440. That same month, Richard and Jonathan’s father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue’s strategy, including specifically putting patients on high doses of opioids for long periods of time. The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum dose limit or a maximum duration of use. Raymond asked David, Jonathan, and Richard to talk with him about the report.

Purdue.”⁵²⁰ Richard Sackler replied immediately to agree that the development in Massachusetts was good news.⁵²¹

440. That same month, Richard and Jonathan’s father, Raymond Sackler, sent David,

confidential memo about Purdue’s strategy, including
uses of opioids for long periods of time. The memo
argued that patients should not be given high doses of
opioids for long periods of time, but Purdue had defeated
it or a maximum duration of use. Raymond asked David,
about the report.⁵²²
removed Russell Gasdia as Vice President of Sales and
placement to sell more opioids faster.⁵²³ Gasdia warned his
sales operation intensely — “there are times this becomes
sure enough, Richard told Gasdia’s replacement that he
he could increase opioid sales: “it is very late in the day to
which was not making as much money as Richard
caution Richard that it was “a little early” to be attacking
t Purdue only two weeks.⁵²⁶

PC019000926225. The bill encouraged use of OxyContin by
from being dispensed if an abuse-deterrent formulation is available.
PLPC019000926225.

⁵²⁰ 2014-05-05 email from Raymond Sackler, PWG000412141; 2014-05-04 attached memo from Burt Rosen, PWG000412143.
⁵²¹ 2014-06-10 email from Richard Sackler, PPLPC012000483200.
⁵²² 2014-06-10 email from Russell Gasdia, PPLPC012000483223.
⁵²³ 2014-06-10 email from Richard Sackler, PPLPC012000483235.
⁵²⁴ 2014-06-10 email from Mark Tunney, PPLPC012000483235.

Irrelevant History Of The Abuse-Deterrent Formula

From: Timney, Mark
Sent: Monday, May 05, 2014 7:45 AM
To: Sackler, Dr Raymond R

Dr. Raymond,

As discussed, please find a brief history and update regarding the support being received on ADF.

From: <Sackler>, Raymond Sackler
Date: Monday, May 5, 2014 at 3:23 PM
To: "Sackler, Jonathan" , "Richard S. Sackler"
David Sackler
Subject: FW: Request for Summary for Dr. Raymond

Dear Richard, Jon and David,
I wanted to share the following with you. We should discuss it when you have time available.

ments are being requested from. In any case, nice job constructing it!!!

Richard
4:49 PM

Redacted-Privilege

is encouraging and suggests that the momentum is favorable to our reasing the safety of some of the strong opioids.* I don't see any allenge its perspective and frame other than the Zohydro decision explained, in my view, and clearly was unexpected.
to predict this outcome suggests to me that there may be a factor or ve don't understand and that (if known and factored into the ht have lead to a less satisfactory recitation. If this is the case, and that there are factors that we don't know or understand, we may yet e surprises.

Raymond Sackler
May 5, 2014 at 3:23 PM

h and David,
the following with you. We should discuss it when you have time available.

kler, M.D.

age-----
ark
May 05, 2014 7:45 AM

re: osackler;cc:raymond R
Cc: Rosen, Burt; Must, Alan
Subject: FW: Request for Summary for Dr. Raymond

Produced by Purdue Pharma L.P. pursuant to Subpoenas in accordance with Purdue Pharma Work Group Letter dated November 7, 2016
Subject to District of Columbia Confidentiality Agreement dated February 16, 2017, and Confidentiality Agreements Entered with Purdue Pharma Work Group States

PWG000412141
Confidential Treatment Requested

5/5/14 Email from Raymond Sackler (PWG000412141)

Board Members Did Not Personally Participate In Marketing

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

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

N.Y. Bus. Corp. Law §717