In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 3: Diversion

April 26, 2021



Claimants' Allegation: Purdue's Diversion Efforts Were Insufficient

NY AG FAC 1853:

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

NY AG FAC 1874:

NY AG FAC ¶853

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

NY AG FAC ¶874

No allegation the Directors personally participated in Purdue's anti-diversion activities — and they did not

The Directors Responsibly Monitored But Did Not Personally Participate in Purdue's Anti-Diversion Efforts

- Directors monitored but did not personally participate in Purdue's anti-diversion activities — they had no role in deciding which prescribers to place in Region Zero
- The Board monitored anti-diversion activities based on information from management, including that:
 - Purdue was <u>vigorously implementing</u> its Abuse Deterrence & Detection (ADD)
 Program, specifically including Region Zero
 - Sales reps were <u>trained</u> in the ADD Program and Region Zero requirements
 - Management <u>monitored</u> the ADD Program
 - The ADD Program was working to stop diversion
 - Multiple Departments were working to stop diversion and ensure compliance with DEA requirements

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

N.Y. Bus. Corp. Law §717

DOJ's Allegation: Family Directors Should Have Known of Diversion

DOJ alleges in Addendum A to the Sackler Settlement Agreement:

- "3. Although the Named Sacklers <u>knew that the legitimate market for Purdue's</u> <u>opioids had contracted</u>, the Named Sacklers <u>nevertheless requested that Purdue executives recapture lost sales</u> and increase Purdue's share of the opioid market."
- "4. As a result of these requests, from at least 2013-2018, <u>Purdue developed an aggressive marketing program</u> [Evolve 2 Excellence (or E2E), conceived by McKinsey & Co.] that focused on detailing over 100,000 doctors and nurse practitioners each year, <u>including thousands of prescribers that the Named Sacklers knew or should have known were prescribing opioids that were not for a medically accepted indication; were unsafe, ineffective, and <u>medically unnecessary</u>; and that were <u>diverted</u> for uses that lacked a legitimate medical purpose."</u>

DOJ/Sackler Settlement Agreement, Addendum A, ¶¶3-4

DOJ's Allegations Are Demonstrably Untrue

- The Board was advised there was a huge, multibillion-dollar legitimate market for Purdue to pursue
- The Board was continuously advised by management that Purdue was operating in compliance with law — and for 5 years this was confirmed by the OIG of HHS
- The Board's focus on increasing sales on the understanding it was being done in compliance with law — was perfectly appropriate
- The Board relied on McKinsey's marketing advice, which McKinsey said simply brought "best industry practices" to Purdue
- The resulting marketing program, E2E, targeted the legitimate market for Purdue's opioids and emphasized OxyContin's abuse-deterrent properties

Annual Prescriptions and Dollars in Various Segments of the Analgesic Market

(IMS MAT August 2012)

	Dollars	% Change	TRxs	% Change	
Non-Opioid/Non- NSAID	\$3.9 Billion	7.6%	50.6 million	8.8%	
Extended- Release Opioids	\$5.3 Billion	-2.8%	26.2 million	-0.1%	
Immediate- Release SEOs	\$1.4 Billion	-11.6%	23.8 million	10.8%	
Combination Opioids	\$1.5 Billion	5.5%	189.9 million	-2.5%	

2012

Total market: \$12.1B

Purdue's sales: \$2.8B



Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

Extended-Release Opioid Competitive Landscape

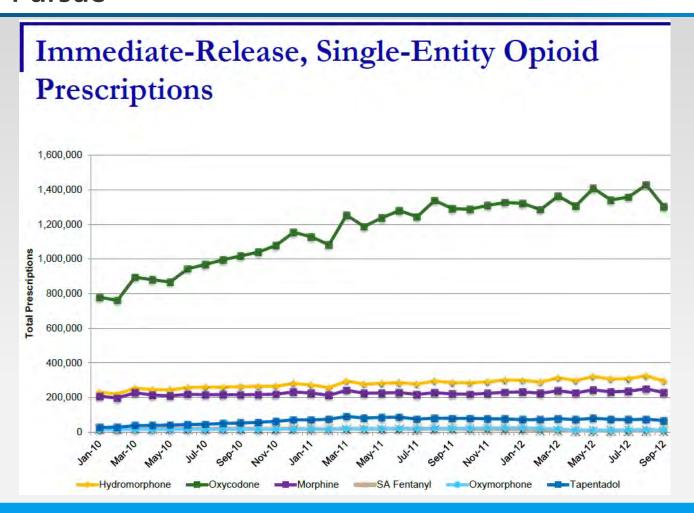
Brand Name	Chemical Name	Company	Brand	Generio
Avinza®	Morphine sulfate extended-release capsules	Pfizer	V	
Butrans®	Buprenorphine transdermal system	Purdue	√	
Exalgo®	Hydromorphone hydrochloride extended-release tablets	Mallinckrodt	√	
Embeda®*	Morphine sulfate and naltrexone extended-release capsules	Pfizer	V	
Duragesic®	Fentanyl transdermal system	Janssen	V	1
Kadian®	Morphine sulfate extended-release capsules	Actavis	V	V
MS Contin®	Morphine sulfate controlled-release tablets	Purdue	V	V
Nucynta® ER	Tapentadol extended-release oral tablets	Janssen	1	
Opana® ER	Oxymorphone hydrochloride extended-release tablets	Endo	√	√**
OxyContin®	Oxycodone hydrochloride controlled-release tablets	Purdue	√	
Dolophine®	Methadone hydrochloride tablets	Roxane	V	V

2012

Extend-Release Opioids: \$5.3 billion market



Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)

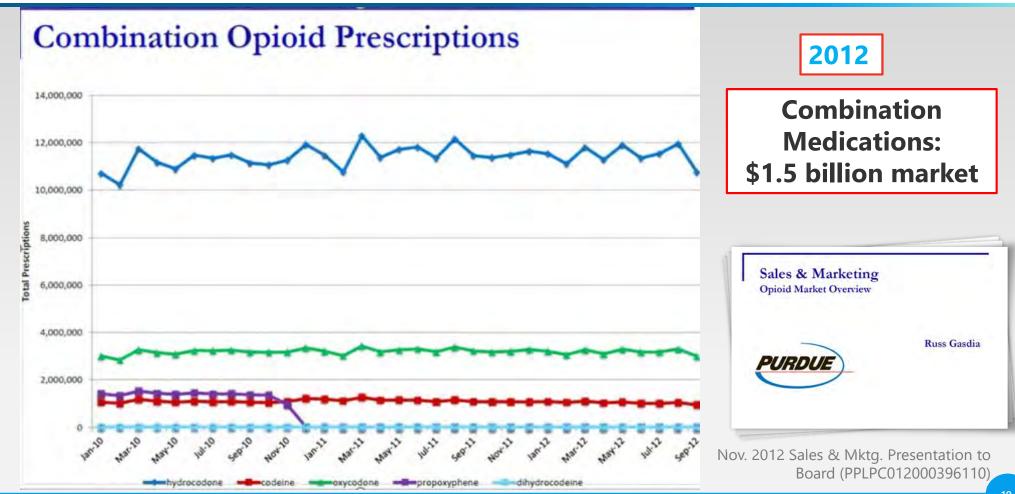


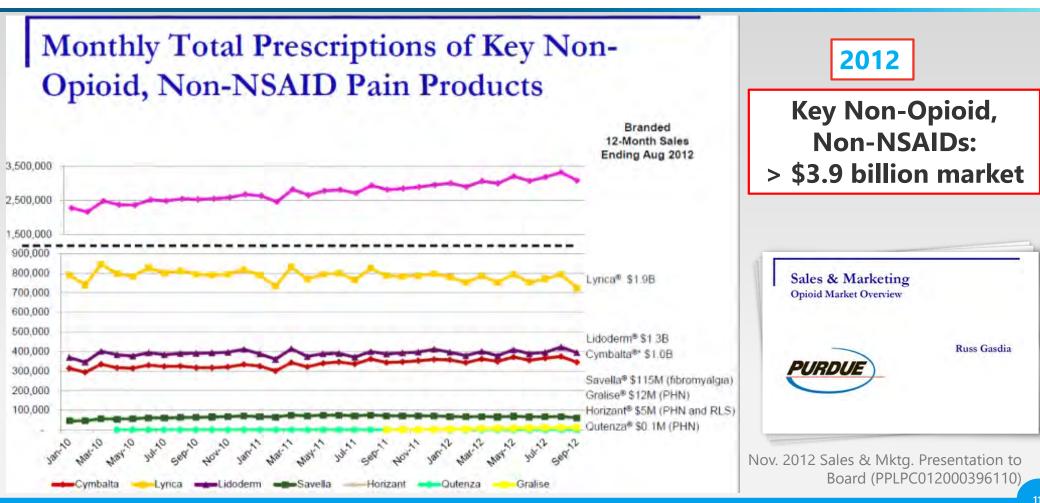
2012

Immediate-Release
Opioids:
\$1.4 billion market

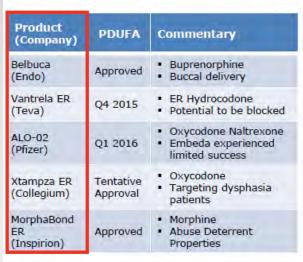


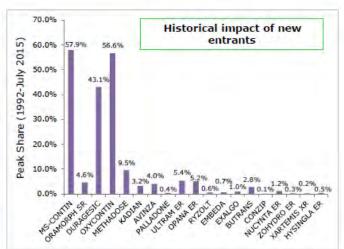
Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)





More EROs are expected to enter the market in 2016





Impact of new entrants:

- Projected peak share 0.9% to 2.2%
- Peak sales \$60MM to \$150MM
- Impact on portfolio is \$32MM

PURDUE

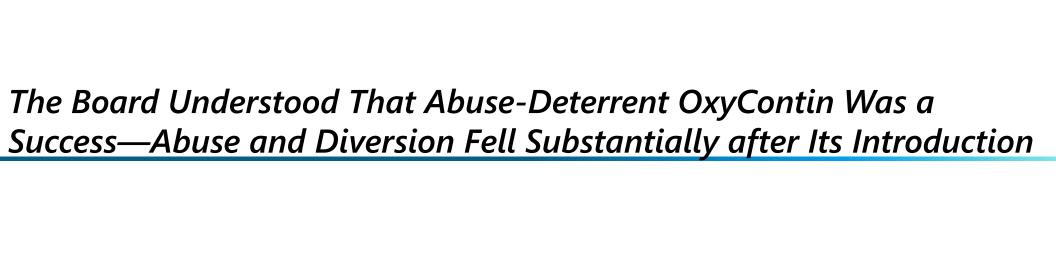
CONFIDENTIAL

42

New EROs Continued to be Introduced



Nov. 30, 2015 Budget Presentation to Board (PPLPC063000003207)



DOJ alleges:

- "Purdue's profits declined in 2010 after the introduction of its Reformulated OxyContin.... The Named Sacklers and Purdue executives tracked Purdue's lost sales closely and regularly scrutinized sales reports and related data. They attributed the majority of the decline to two trends: (i) individuals abusing opioids moving from OxyContin to opioids that were easier to abuse ... and (ii) increased scrutiny of prescribers, pharmacists, and other actors in the opioid distribution chain." (DOJ/Sackler Settlement Agreement, Addendum A 12)
- The Board considered it a great success that abuse and diversion fell after the introduction of the abuse-deterrent formulation ("ADF") of OxyContin
- The Board had authorized over \$1 billion in anti-abuse initiatives, including the ADF

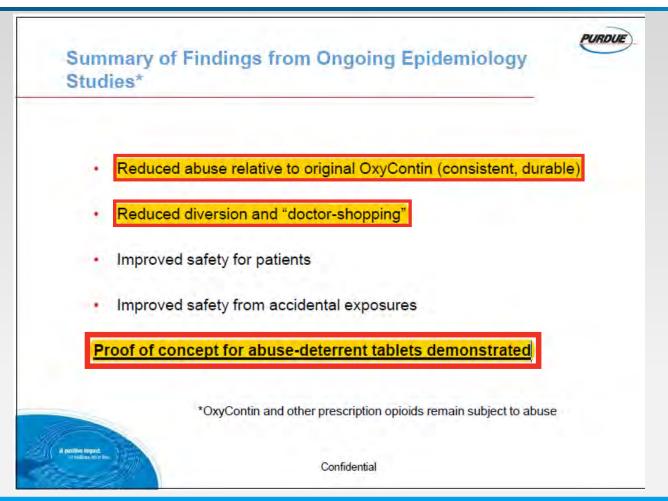
Positive Impact of AD OxyContin

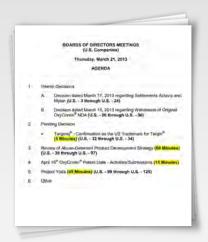
- □ Positive Media Coverage of Abuse-Deterrent Formulations
- Meaningful Reduction in Abuse Especially Parenteral
- □ Fewer Pharmacy Thefts Reported by Law Enforcement
- Positive Reputation and Relationships with FDA and DEA
- Opportunity to link AD Formulations with Broader Anti-Abuse Initiatives
- Opportunity to Build on Expertise with ADFs





PPLP004409860 (July 25, 2013 Presentation to Board)





PPLPC044000041968 (Mar. 21, 2013 Presentation to Board)

Summary from Ongoing ORF Epidemiology Studies

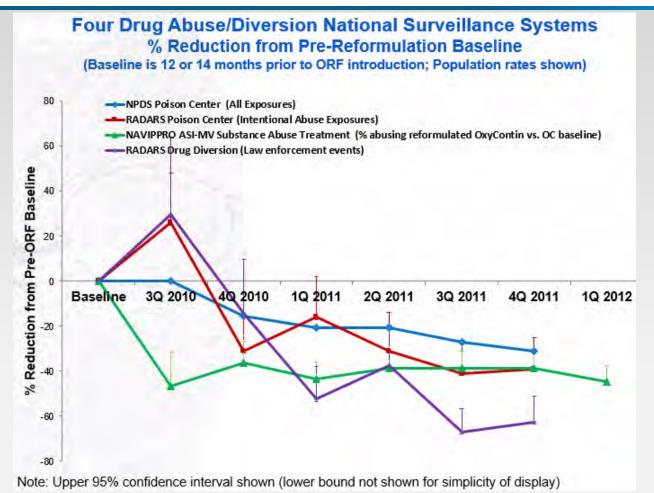
Evidence supports:

- Reduced abuse
 - Consistent trend across studies
 - Effect is durable and/or improving
 - Injecting > Snorting > Oral
- Reduced diversion and "doctor-shopping"
- Improved safety for patients
 - Reduced therapeutic error exposures in poison centers
- Improved safety from accidental exposures
 - Reduced unintentional general exposures
- No change or increasing abuse of comparator opioids
- Proof of concept for physicochemical abuse-deterrence

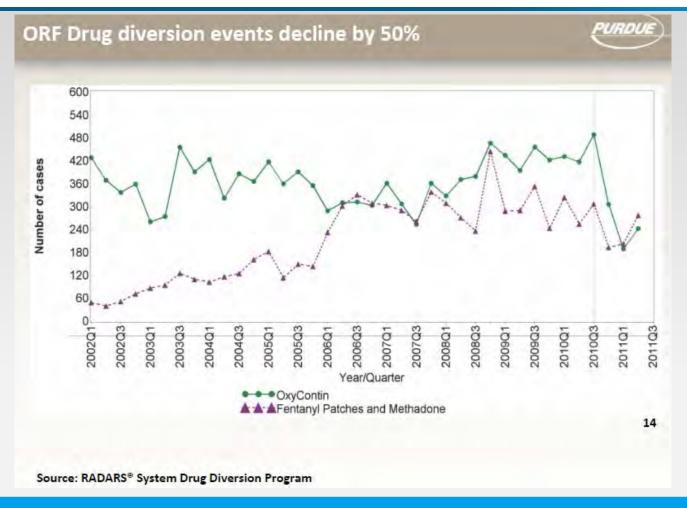


* Validates ADF strategy

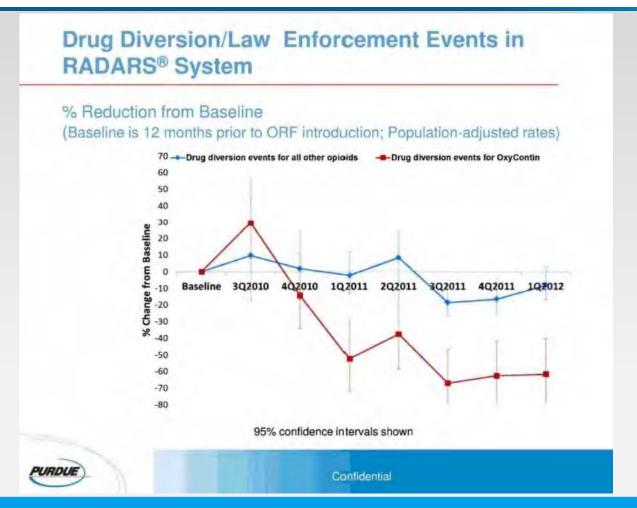
PPLP004409195 (Nov. 3, 2012 Purdue Presentation to Beneficiaries)

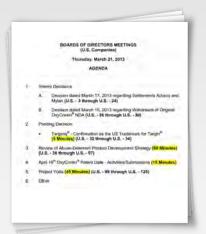


June 18, 2012 Presentation to Board (PPLPC057000011188)

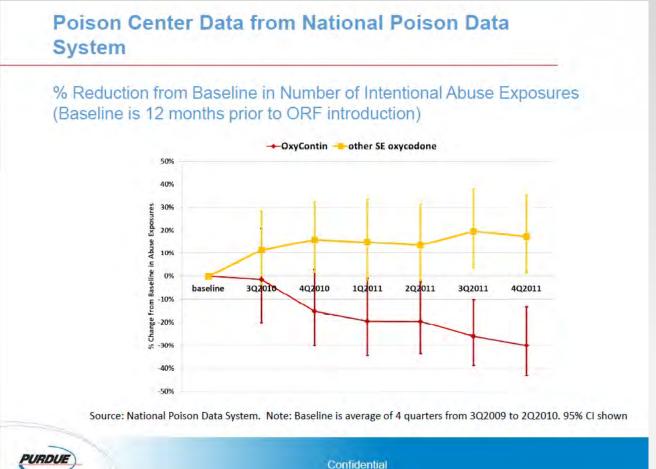


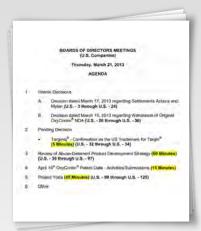
Attachment to Exec. Comm. Notes Sent to Board on Oct. 25, 2011 (PURDUE-COR-00032185)



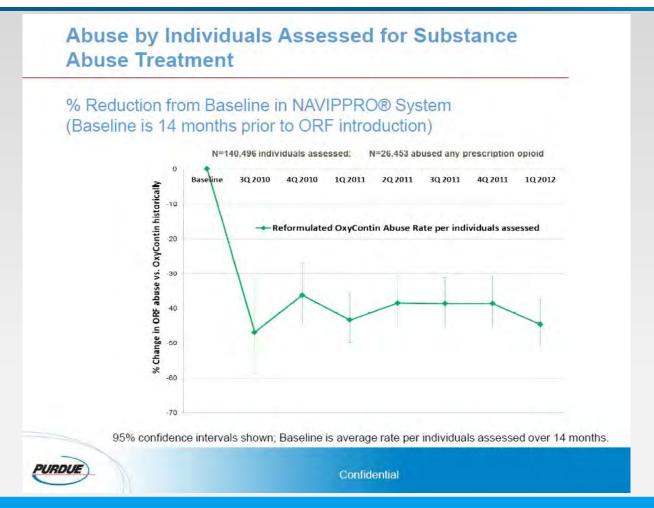


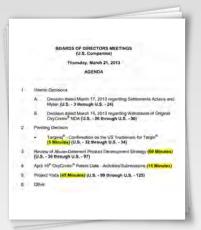
PPLPC044000041964 (Mar. 21, 2013 Presentation to Board)





PPLPC044000041962 (Mar. 21, 2013 Presentation to Board)

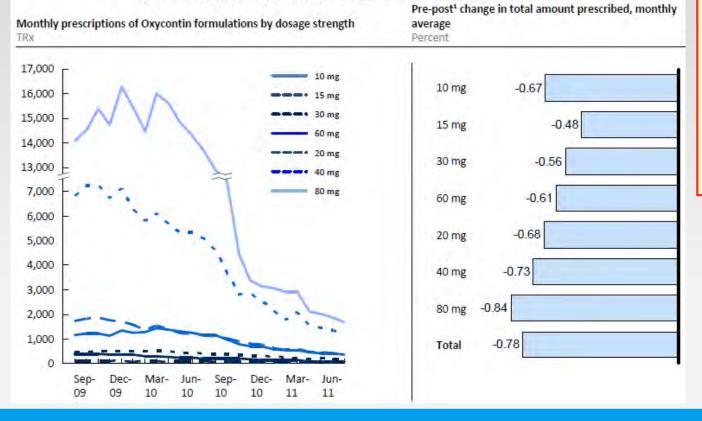




PPLPC044000041961 (Mar. 21, 2013 Presentation to Board)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Prescriptions by Region Zero Prescribers Fell Substantially

Among Region 0 prescribers the volume decreased for all formulations

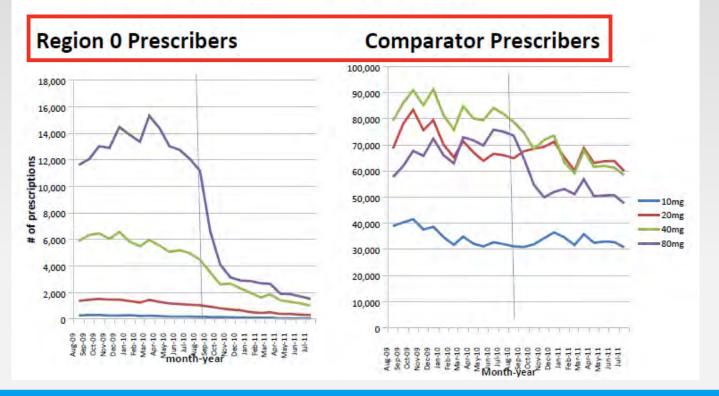


- Region Zero was a list of suspicious prescribers identified through Purdue's Abuse Diversion & Detection (ADD) Program
- Purdue sales reps did not call on Region Zero prescribers, but Purdue could not prevent them from prescribing OxyContin

Attachment to Exec. Comm. Notes Sent to Board Oct. 25, 2011 (PPLPC042000024694)

The Board Understood That Abuse-Deterrent OxyContin Was a Success — Prescriptions by Region Zero Prescribers Fell Substantially

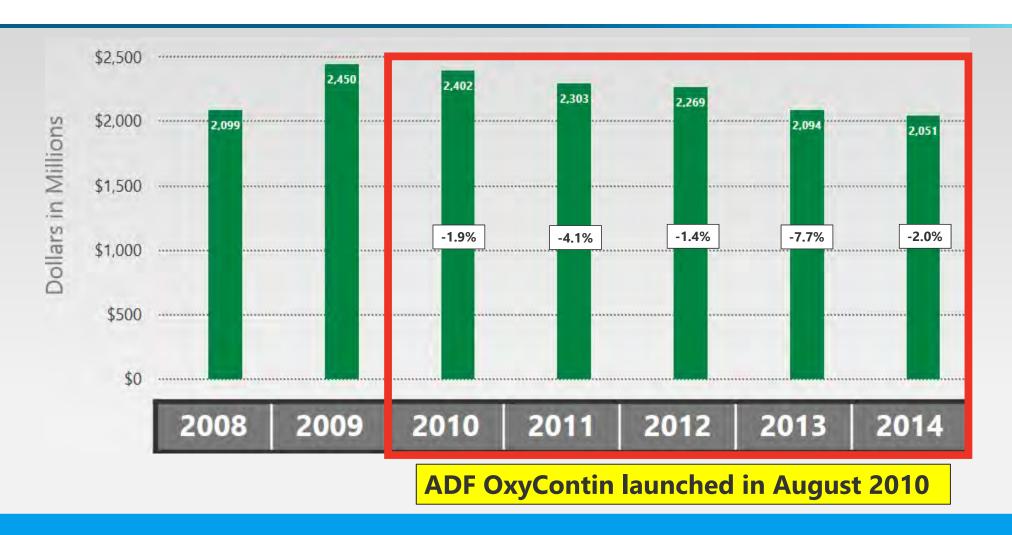
Number of prescriptions per month by OxyContin strength



Attachment to Exec. Comm. Notes Sent to Board Oct. 25, 2011 (PPLPC042000024694)

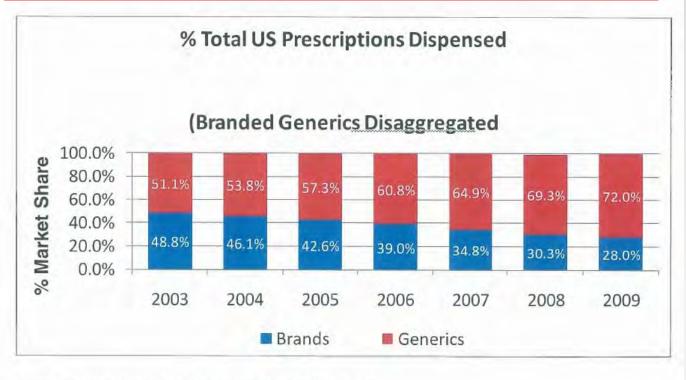
- Purdue sales began to decline in 2010 for multiple reasons and that prompted focus on sales
- The Board was advised that the Company's marketing campaign E2E was
 designed to encourage HCPs to identify and convert to OxyContin appropriate
 patients not currently on OxyContin
- As sales fell, the Board dramatically increased Purdue's cash on hand to ensure the vitality of the Company

The Decline in Purdue Sales Began in 2010 and Was Gradual



- The overall share of generic prescriptions was rising
- New, competing long-acting opioids were entering the market
- New entrants were targeting OxyContin
- The total market share held by branded extended-release opioids ("EROs") like OxyContin was falling

Overall Generic Share of Rx's is Increasing



Source: IMS "Perspective on the US Pharmaceutical Market A New Reality"

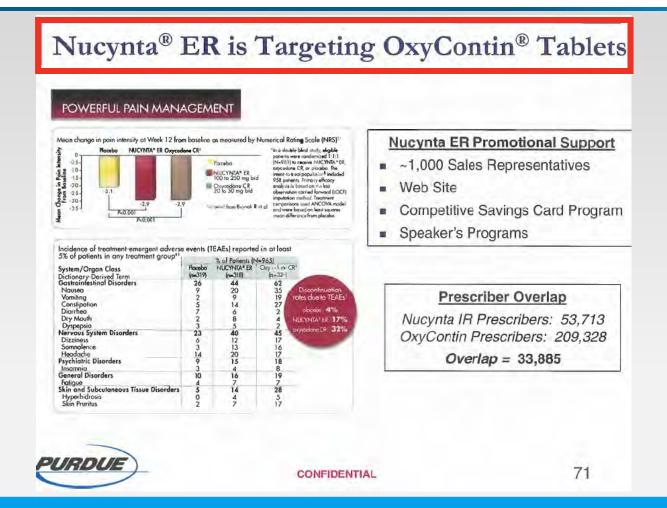
Nov. 2010 Full Budget Presentation (PPLP004404901)

Potential Market Factors - External

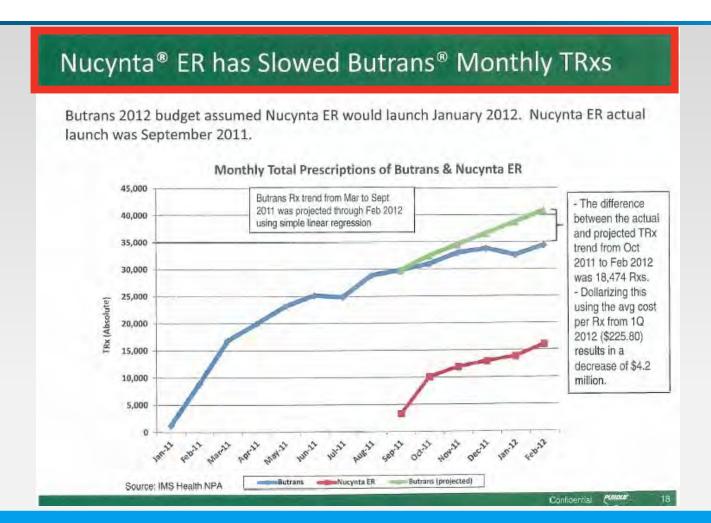
- New long-acting, single-entity opioid entrants (i.e., Nucynta[®] ER, Remoxy[®]) threaten TRx market share and diminish share of voice
- Managed care coverage is strong but ongoing challenges exist



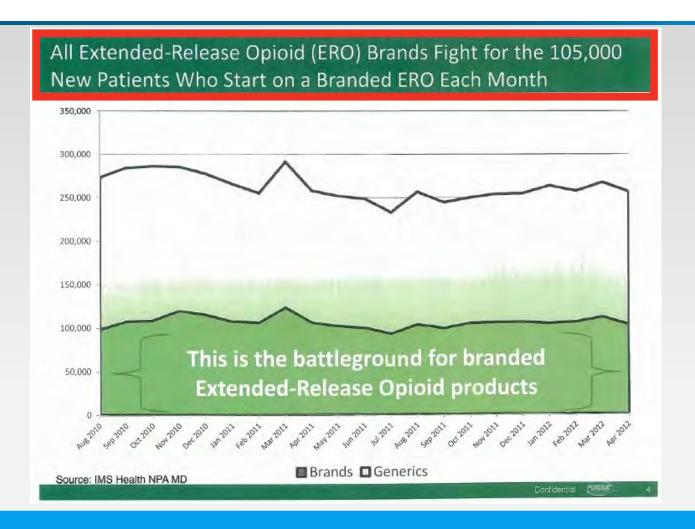
Nov. 2010 Sales & Marketing Presentation (PPLP004404901)



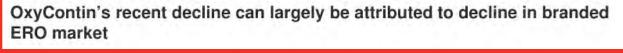
Oct. 2011 Full Budget
Presentation at
PPLPUCC003392177

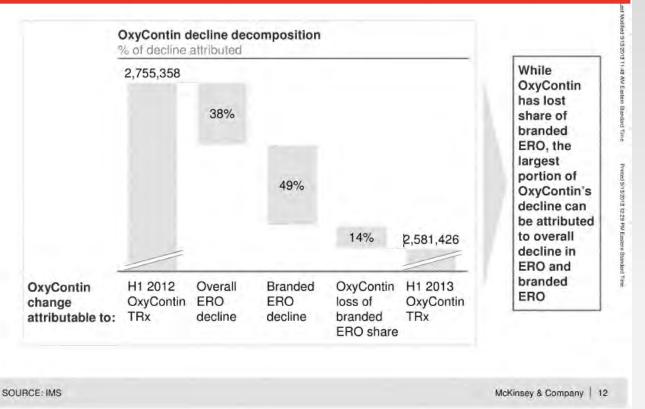


June 2012 Full Budget Presentation



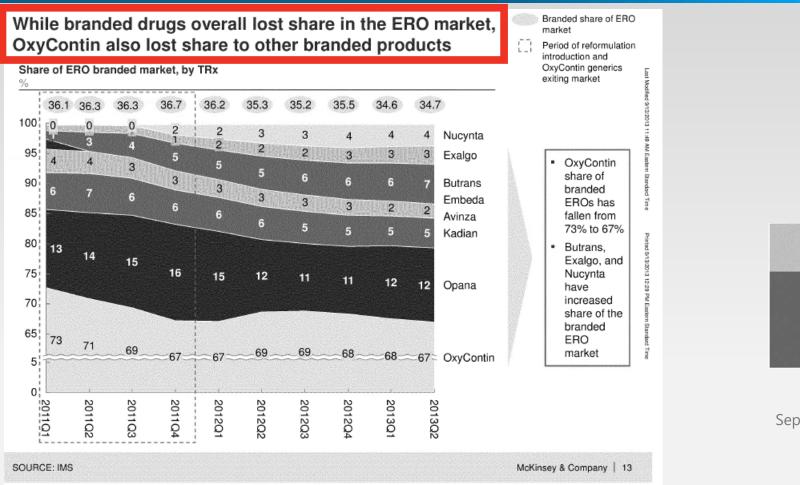
June 2012 Full Budget Presentation (PPLPUCC001174050 at slide 4)







Sept. 13, 2013 McKinsey Deck PURDUE-COR-00016506





Sept. 13, 2013 McKinsey Deck PURDUE-COR-00016507

Events Potentially Impacting the Extended Release Opioid Market

Competitive

- Increased Genericization: Opana® ER, Exalgo®, Generic OER Agreements
- Re-launch of Embeda®
- Approval/Launch of Targiniq
- Approval/Launch of Zohydro
- Approval/Launch of ER oxycodone/APAP

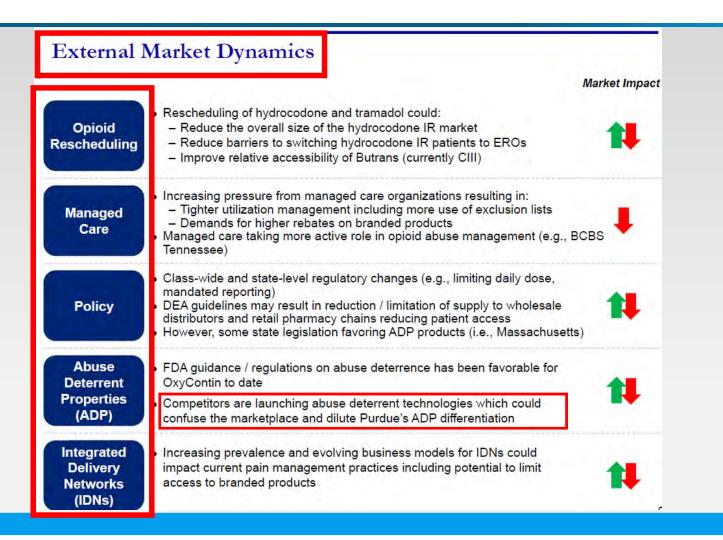
Nov. 2013 Year End Budget Book (PPLP004409973)

Events Potentially Impacting the Extended Release Opioid Market

- □ Legislation + Market Events
 - Affordable Care Act
 - State legislation, such as in WA
 - Support for abuse deterrent formulations (e.g., STOPP Act)
 - Restrictions on APAP doses beginning in Jan 2014
 - Hydrocodone combinations to schedule II
 - e-prescribing for Schedule II products
 - DEA pressure on physicians and pharmacies
 - Other pressures (e.g. PROP)

Nov. 2013 Year End Budget Book (PPLP004409973)

The Board Understood There Were Multiple Reasons for the Sales Decline

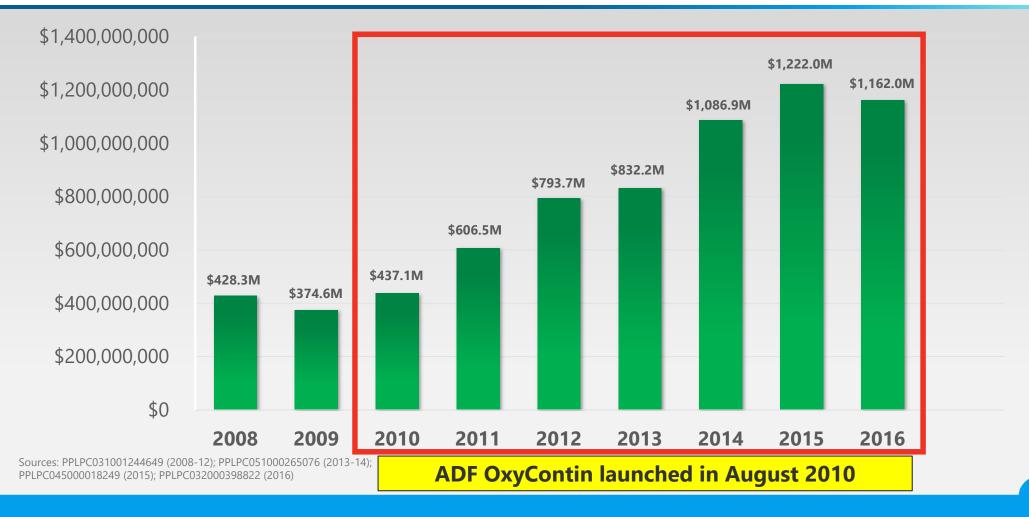


OxyContin®
2014 Budget Proposal

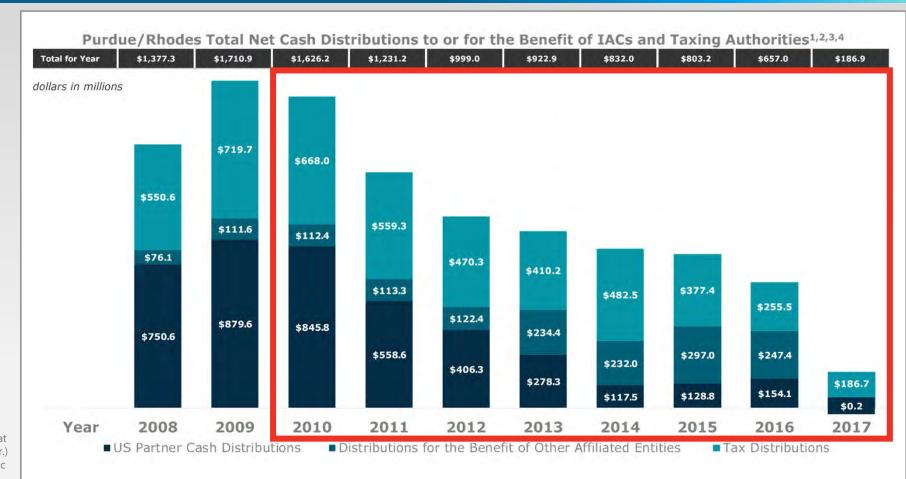
Ron Cadet

OxyContin 2014 Budget Proposal (PPLP004409973)

The Board Responded By Leaving Enormous Amounts Of Cash in Purdue After Distributions To Ensure The Company's Vitality



The Board Cut Distributions As It Left More and More Cash in Purdue



AlixPartners Cash Transfers of Value Report (12/16/2019) at Slide 11 (SDNY (Bankr.) No. 19-23649-rdd Doc 654-1)



The Board Understood That McKinsey Brought Industry Best Practices to Purdue

July 18, 2013 McKinsey Report to Board:

These ideas are primarily about implementing industry best practices in execution. These best practices can be adapted for Purdue and rolled out quickly. These include: higher call productivity, fully delivery of OxyContin P1s, higher reach of decile 6-10 prescribers, greater adherence to call lists, and field training on how to appropriately engage medical.

Industry best practice targets physicians based on a composite value incorporating TRx and NBRx, as well as access and other behavioral indicators.

Best practice field force optimization requires a significant holistic approach ... with robust analysis of many factors....

CONFIDENTIAL

Memorandum to John Stewart Russ Gasdia

From McKinsey & Company

July 18, 2013

Identifying granular growth opportunities for OxyContin: First Board update

In June, Purdue engaged McKinsey to conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities.

While our work is only partially complete, we believe there is significant opportunity to improve OxyContin performance despite strong opioid marketplace trends that may be shaping a 'new normal'. We are pursuing 20+ distinct opportunities. All require further analysis, some will require testing, but several can be implemented quickly.

This memo provides an interim update that is not comprehensive of all the work done. The memo is divided into four sections:

- 1. Overall analytical approach
- 2. Early findings from diagnostic
- 3. Emerging opportunities
- 4. Next steps

1. Overall analytical approach

We set out to objectively examine OxyContin performance in seven areas —market landscape, commercial resourcing levels, messaging, targeting, field execution, market access, and medical/scientific support. In each area, we are taking an independent, fact-based, and granular approach. For the analyses, we are leveraging existing data, and where needed, we have requested that Purdue purchase new data (e.g., IMS prescribe level milligrand dosing data). In

July 25, 2013 Board Book (PPLP004409781)

The Board Understood That McKinsey Brought Industry Best Practices to Purdue

August 8, 2013 McKinsey Report:

Today Purdue spends as much effort detailing the lesser value prescribers (decile 0-4) as it does on the higher value prescribers (decile 5-10). To put this in perspective, the average prescriber in decile 5-10 writes 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on higher value prescribers.

CONFIDENTIAL

Memorandum to John Stewart Russ Gasdia

From McKinsey & Company

August 8th, 2013

Identifying granular growth opportunities for OxyContin: Addendum to July 18th and August 5th updates

This addendum highlights two additional findings since our July 18th and August 5th updates and specific actions we believe Purdue should take to begin to increase sales.

1. Prescriber Targeting

Our refined analyses confirm significant opportunity to improve sales through better targeting. We believe the upside is >\$100 million in annual sales.

Today Purdue spends as much effort detailing the lesser value prescribers (decile 0-4) as it does on the higher value prescribers (decile 5-10). To put this in perspective, the average prescriber in decile 5-10 wither s15 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 30% of effort on higher value prescribers. (Exhibit 1)

The Board Understood That McKinsey and E2E Stressed OxyContin's Abuse-Deterrent Properties

Work Streams/Issue Teams

Training and Communications

- Prepare for full implementation at the 2014 National Sales Meeting
- Conduct ongoing internal communications regarding the transformative changes and associated benefits
- Identify, write-up and communicate supporting analytics from the "internal pilots" and other sources

Messaging

- OxyContin[®] sales and marketing messaging/positioning
- Payer "pull through" improvements
- Messaging about abuse-deterrent formulations/properties
- Liaise with R&D and Corporate Affairs to develop information in support of messaging efforts.

Alternative promotion strategies

Call centers, video detailing, relationship marketing, and other approaches to "np-see" and "low-see" prescribers

Pharmacy/Trade

- Alternative distribution methods, if the current shortages don't show clear signs of resolution
- Communication of pharmacy policy changes and their potential impact
- Active liaison with wholesalers and chain pharmacies

OxyContin Growth Opportunities Action Plan

September 12th, 2013

Sept. 12, 2013 Presentation to Board (PPLPC063000002005)

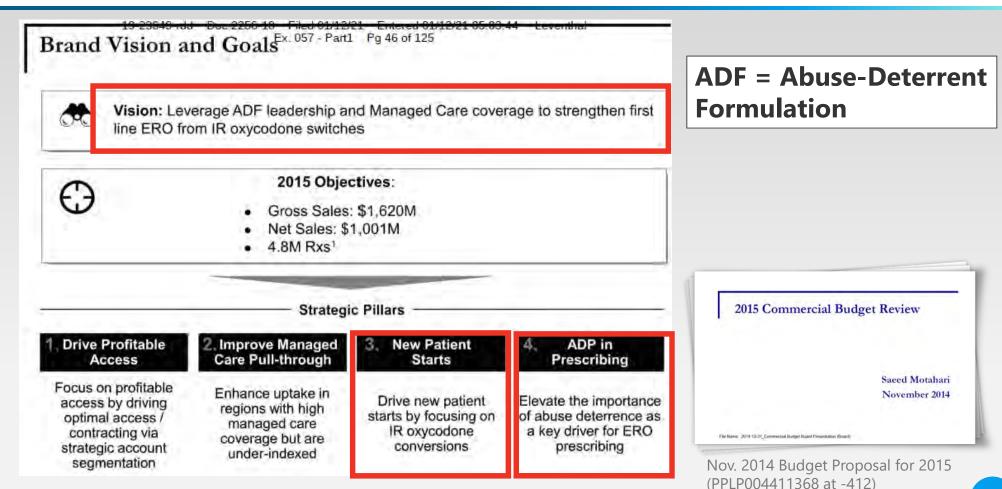
The Board Understood That McKinsey and E2E Stressed OxyContin's Abuse-Deterrent Properties

2015 Brand Strategy and Forecast

- OxyContin remains the dominant branded ERO; however, the regulatory, payer and competitive landscape will put increasing pressure on OxyContin
- Four strategies will drive OxyContin success:
 - Drive profitable access
 - Improve Managed Care Pull-through
 - Increase oxycodone IR conversions
 - Elevate the importance of abuse deterrence
- The current forecast projects a 2015 gross sales of \$1,620M and net sales of \$1,001M (-29% & -36% lower than 2014 LE respectively)
 - Decline driven by settlements (\$313M), share decline (\$153M) in part due to Hysingla ER, higher rebate rates (\$102M) and change in strength and tab mix (\$99M), but offset in part by 6% price increase of \$109M
 - The product contribution has improved by \$118M vs. 10 Year Plan despite shifting of AGs
- 2015 S&P budget of \$92.8M (-14% vs 2014 LE)
 - Marketing \$21.3M (-1.5% vs 2014 LE)
 - Sales Force \$86.1 (-17% vs 2014 LE)



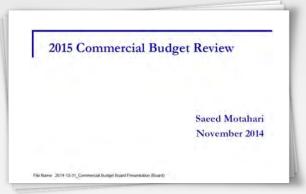
Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -408)



68% of IR oxycodone conversions go to other ERO molecules: Opportunity to increase IR oxycodone to OxyContin® conversion rate

SWITCHED FROM/ADDED TO PRODUCT	OXYCODONE PLAIN, OXYCODONE COMBOS	
Switched To/Added On Product	Sum of MAT TRxs Mar2014	% of Total
OXYCONTIN*	266,970	32.0%
GENERIC 2X/DAY MORPHINE	225,771	27.1%
TRANS. FENTANYL	174,057	20.9%
METHADONE	61,323	7.4%
OPANA ER/GENERICS	52,057	6.2%
BUTRANS*	23,850	2.9%
EXALGO*	13,398	1.6%
NUCYNTA ER*	10,466	1.3%
KADIAN*	3,870	0.5%
AVINZA*	1,891	0.2%
ZOHYDRO ER*	168	0.0%
TOTAL BRANDED PRODUCTS*	320,613	38.5%
TOTAL ALL PRODUCTS	833,821	100.0%

Each 0.1% increase in the IR oxycodone to ERO conversion rate equals \$350k in gross sales



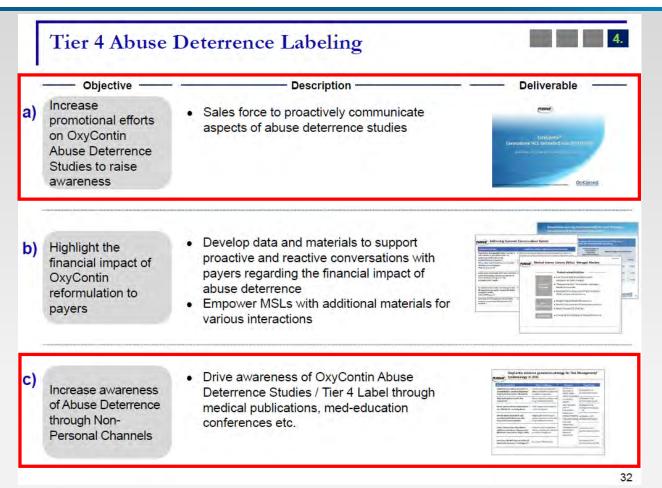
Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -409)

2015 Brand Strategy and Forecast

- OxyContin remains the dominant branded ERO; however, the regulatory, payer and competitive landscape will put increasing pressure on OxyContin
- Four strategies will drive OxyContin success:
 - Drive profitable access
 - Improve Managed Care Pull-through
 - Increase oxycodone IR conversions
 - Elevate the importance of abuse deterrence
- The current forecast projects a 2015 gross sales of \$1,620M and net sales of \$1,001M (-29% & -36% lower than 2014 LE respectively)
 - Decline driven by settlements (\$313M), share decline (\$153M) in part due to Hysingla ER, higher rebate rates (\$102M) and change in strength and tab mix (\$99M), but offset in part by 6% price increase of \$109M
 - The product contribution has improved by \$118M vs. 10 Year Plan despite shifting of AGs
- 2015 S&P budget of \$92.8M (-14% vs 2014 LE)
 - Marketing \$21.3M (-1.5% vs 2014 LE)
 - Sales Force \$86.1 (-17% vs 2014 LE)



Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -408)





Nov. 2014 Budget Presentation to Board (PPLP004411383)

OxyContin Strategic Pillars and Objectives

1. Drive Profitable Access

- a) Rebate based on data-driven, profitable levels
- b) Streamline contracting processes
- c) Customize value propositions based on segment needs
- d) Identify and engage key healthcare stakeholders & influencers

2. Improve Managed Care Pull-through

- a) Enhance pullthrough efforts via close team collaboration of field sales and account management teams
- b) Target pull-through
 "identify / prioritize"
 efforts in territories
 that are underindexed vs. national
 average in spite of
 favorable managed
 care coverage

3. New Patient Starts

- Target molecule to molecule switch from IR oxycodone to OxyContin
- b) Target HCPs with high NBRx share and a high oxycodone to non-OxyContin switch rate
- c) Educate payers on the benefits of maintaining a patient on same ERO molecule to minimize access barriers

4. ADP in Prescribing

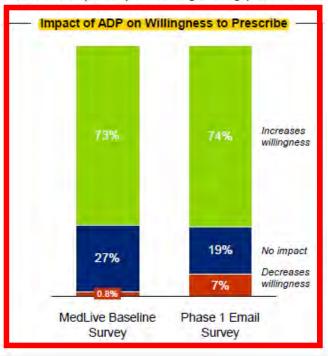
- a) Leverage Tier 4
 labeling in appropriate promotions
- b) Highlight the financial impact of OxyContin reformulation to payers
- c) Equip sales force to effectively communicate OxyContin Abuse Deterrence clinical information
- d) Increase promotional efforts on OxyContin Abuse Deterrence Studies to raise awareness

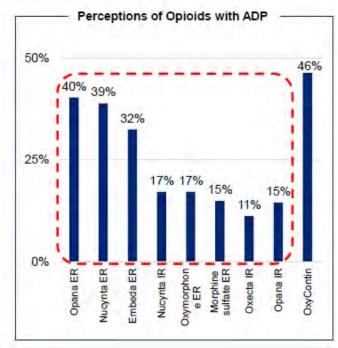


Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -413)

Opportunity to further differentiate OxyContin® versus other EROs and educate on ADPs

Although ~3/4 of physicians indicate an increased willingness to prescribe opioids that have ADPs, misperceptions regarding pain medications and ADFs are common





ADP = Abuse- Deterrent Properties



Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -410)

Notes from 10/30/13 Board Meeting

From: Mallin, William Sent: Wednesday, October 30, 2013 8:19 AM To: Stewart, John H. (US); Mahony, Edward Cc: Mallin, William

Subject: Board Notes & Actions - Day One Raw Notes

Gents:

Raw notes from the meeting day one. We can review for the meaningful actions once today is completed.

Purdue U.S. Budget Presentation October 29th & 30th, 2013

Notes & Actions



"not just push to obtain scripts"

 Must focus on sales force incentives (behaviors) not just push to obtain scripts – integrate this across the entire culture not just sales – language, attitude, etc – do well by doing good (Dr K/Judy)

"do well by doing good"

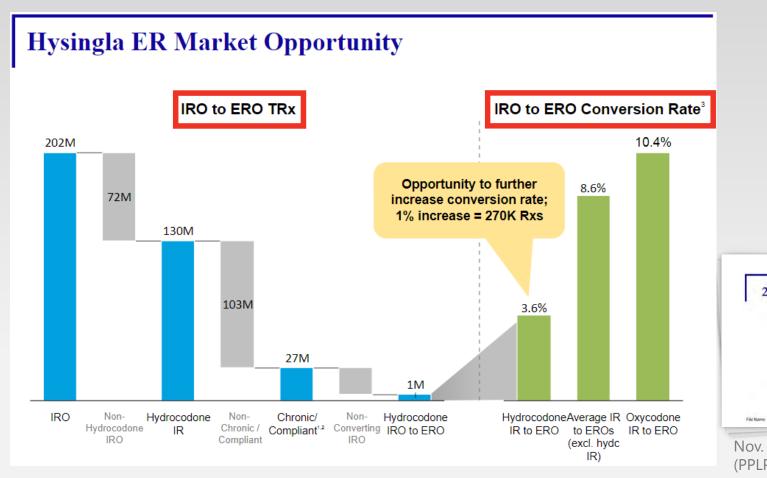
"be driven to be of high value to patients and physicians"

2.3 In regard to the E2E Project, the following comments/questions were raised:

i. In terms of incentives, the salesforce (and indeed the entire organization) should be driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products.

"not simply to increase prescriptions for Purdue products"

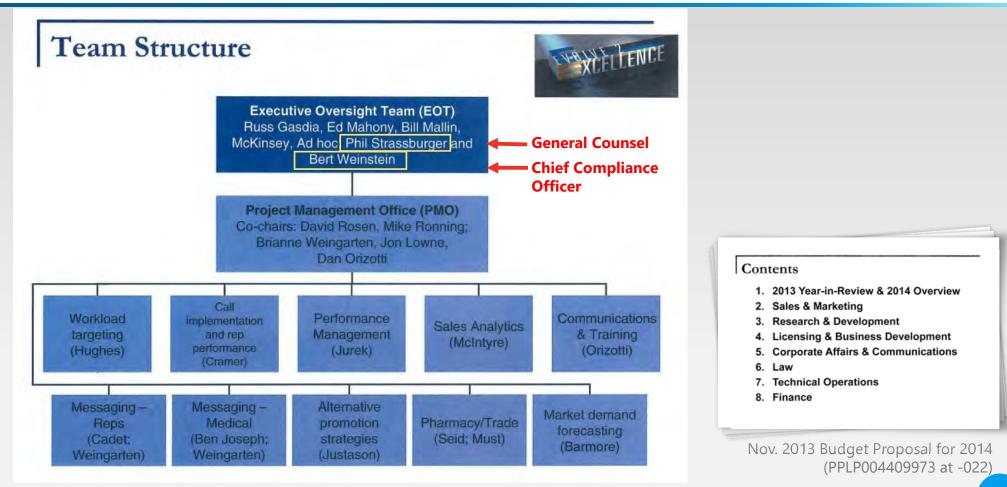






Nov. 2014 Budget Proposal for 2015 (PPLP004411368 at -444)

The Board Understood That Compliance Was Built into the Oversight of E2E



DOJ's Allegations Against the Family Depend Entirely on McKinsey/E2E — And Discard All of the States' Marketing Claims

- In Purdue's Addendum A, DOJ alleges that Purdue engaged in marketing misconduct from 2010-2018 (Purdue Addendum A ¶¶4, 9, 25, 40-41, 45)
- But in Sackler Addendum A, DOJ limits its allegations against the former Directors to the period <u>2013</u>-2018 (Sackler Addendum A ¶¶4, 5, 23)
- Significance:
 - 1. DOJ recognizes that the Board was entitled to rely on assurances from the OIG of HHS that Purdue was operating in compliance with the CIA from 2007-12
 - DOJ's allegations against the former Directors depend entirely on McKinsey/E2E
 and are disproved by the evidence discussed above
 - 3. DOJ rejected all of the States' prepetition claims of deceptive marketing because McKinsey/E2E are not alleged to have involved deception

DOJ Falsely Alleges That A "Titration Up Marketing Campaign" Was Presented to the Board

DOJ alleges:

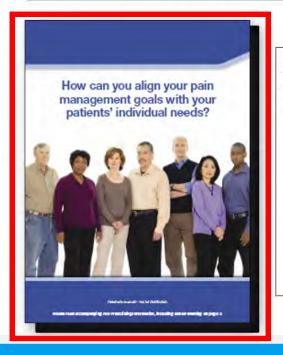
"113. At the November 2013 meeting concerning Purdue's 2014 budget, a Purdue executive discussed with the Board the company's plans to 'refine the message' of the company's titration up marketing campaign and specifically referenced the 'Individualize the Dose' campaign, a Conversion & Titration Guide, and the S.T.A.R.T. principles to 'highlight important elements of titration throughout the course of treatment." (DOJ/Sackler Settlement Agreement, Addendum A, ¶113)

- No "Titration Up Marketing Campaign" was ever presented to the Board
- DOJ's allegations distort the "Individualize the Dose" campaign, the "Conversion & Titration Guide" and "S.T.A.R.T." principles
- The Board was told titration was to go up or down as appropriate for the patent

No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Refining Our Message

Evolution of the "Individualize the Dose" Campaign



Campaign/ Message Refresh:

- Refreshed creative
- Refine promotional messages
 - Initiation/ Conversion
 - Titration
 - Managed Care Access/ Pull Through
 - Abuse Deterrent Formulation
 - Purdue's heritage in Pain Management

From the cited Nov. 2013 budget presentation to the Board

Contents

- 1. 2013 Year-in-Review & 2014 Overview
- 2. Sales & Marketing
- 3. Research & Development
- 4. Licensing & Business Development
- 5. Corporate Affairs & Communications
- 6. Law
- 7. Technical Operations
- 8. Finance

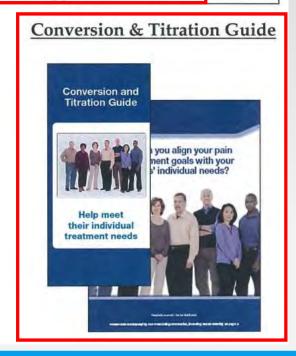
Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -059)

No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Improving New Patient Starts

Help HCPs identify appropriate patients for OxyContin® and how to initiate therapy





From the cited Nov. 2013 budget presentation to the Board

Contents

- 1. 2013 Year-in-Review & 2014 Overview
- 2. Sales & Marketing
- 3. Research & Development
- 4. Licensing & Business Development
- 5. Corporate Affairs & Communications
- 6. Law
- 7. Technical Operations
- 8. Finance

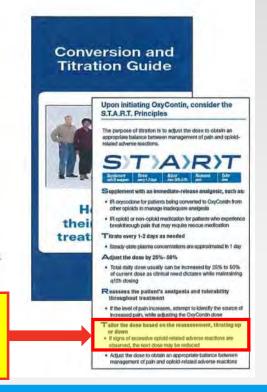
Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -060)

No "Titration Up Marketing Campaign" Was Ever Presented to the Board

Encouraging Appropriate Titration of OxyContin®

START Principles:

- The objective of the S.T.A.R.T.
 Principles is to provide a suggested framework and talking points for the appropriate initiation and titration of OxyContin.
- Collectively, they are intended to highlight important elements of titration throughout the course of treatment.
- "Tailor the dose based on the reassessment, titrating up or down
- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced"



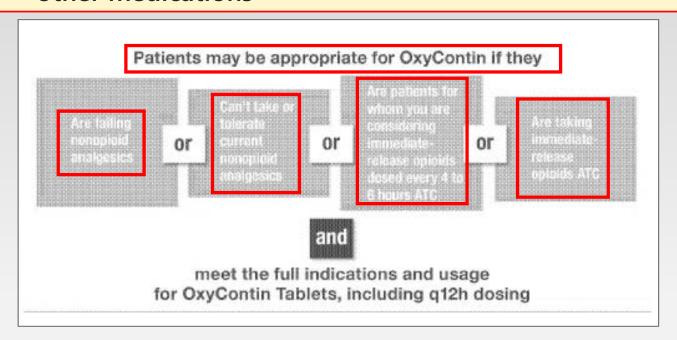
From the cited Nov. 2013 budget presentation to the Board

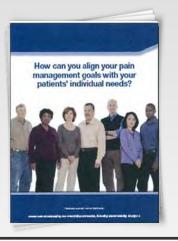
OxyContin®
2014 Budget Proposal

Ron Cadet

Nov. 2013 Budget Proposal for 2014 (PPLP004409973 at -063)

"Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications





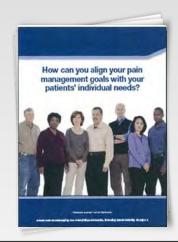
Individualize the Dose Brochure

PAZ000046439 at -442

"Initiation Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

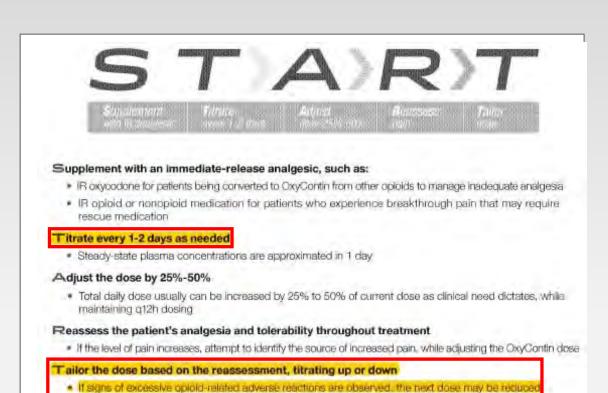
To convert from other opioids to OxyContin

- Determine a patient's estimated 24-hour oxygodone requirement
- Refer to published potency data in clinical practice guidelines published by authorities in the field of pain medicine, but such ratios are approximations and there is substantial interpatient variation
- It is safer to under estimate a patient's 24-hour oral oxycodone requirement and provide rescue medication (e.g., immediate-release oxycodone) than to overestimate
- Begin with half of the estimated daily oxycodone requirement as the initial daily OxyContin estimate, then divide into two doses taken 12 hours apart
- Managé inadéquaté analgesia by supplementation with immediate-reléasé oxycodone



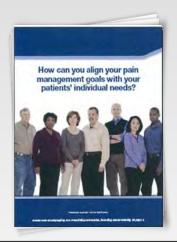
Individualize the Dose Brochure

PA7000046439 at -446



· Adjust the dose to obtain an appropriate balance between management of pain and opioid-related

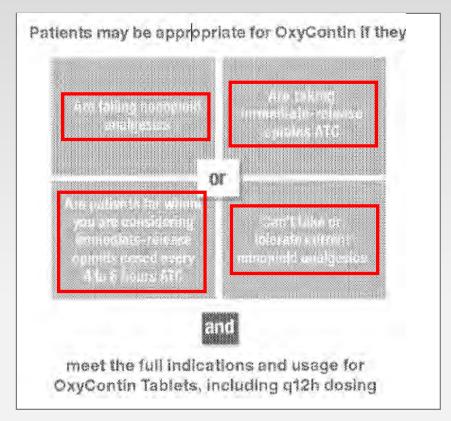
adverse reactions



Individualize the Dose Brochure

PAZ000046439 at -448

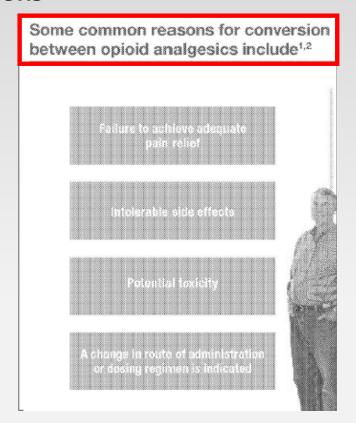
"Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications





Conversion & Titration Guide PAK000971874, at -879

"Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications





Conversion & Titration Guide PAK000971874, at -881

"Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

"When initiating OxyContin as the first opioid analgesic in patients taking nonopioid analgesics who require ATC [around-the-clock] therapy, OxyContin 10 mg q12h is a reasonable starting dose"

10 mg is the lowest dose of OxyContin on the market



Conversion & Titration Guide

PAK000971874 at -883

"Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

To convert from other opioids to OxyContin

 Determine a patient's estimated 24hour oxycodone requirement

**

- It is safer to underestimate a patient's 24-hour oral oxycodone requirement and provide rescue medication (e.g., immediate-release oxycodone) than to overestimate
- Begin with half the estimate daily oxycodone requirement as the initial daily dose

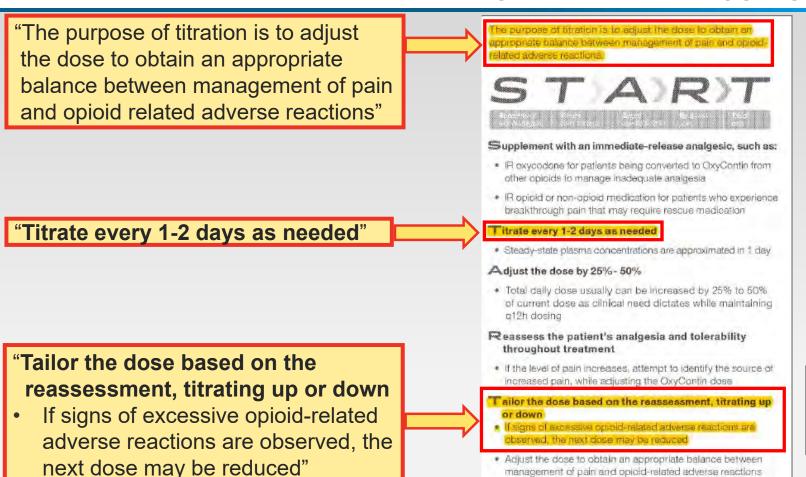
To convert from other oral oxycodone formulations to OxyContin, consider the following

- Determine the patient's total daily oral oxycodone dose
- Administer one-half of the patient's total daily oral oxycodone dose as OxyContin q12h



Conversion & Titration Guide
PAK000971874 at -884. -885

management of pain and opicid-related adverse reactions





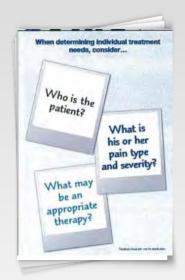
Conversion & **Titration Guide**

PAK000971874 at -891

"Initiation/Conversion" — Purdue sought to convert appropriate patients from other medications

Patients may be appropriate for OxyContin if they

- Are failing nonopioid analgesics or
- Can't take or tolerate current nonopioid analgesics or
- Are patients for whom you are considering immediate-release opioids dosed every 4 to 6 hours ATC [around the clock] or
- Are taking immediate-release opioids ATC and
- Meet the full indications and usage for OxyContin Tablets, including q12h dosing



Patient Profiles

PAK000971389 at -391

 "Initiation/Conversion" — For newly-converted patients, Purdue recommended low initial doses, and then titrating up or down as appropriate

Sam should be started on the lowest appropriate dose and titrated as clinical need dictates

- Monitor closely for respiratory depression, especially within the first 12-72 hours of initiating therapy with OxyContin
- Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions while maintaining an every-twelve-hour dosing regimen



Patient Profiles

PAK000971389 at -392



The Board Was Advised That Purdue Was Vigorously Implementing Its ADD Program, Including Region Zero

Region Zero was the name of Purdue's Do-Not-Call list

Region 0 prescribers

- Prescribers identified through Purdue's Abuse and Diversion Detection (ADD) program
 - designed to ensure that the company does not promote Purdue's products in circumstances where there is a concern about potential abuse or diversion related activities
- Government entities knew about the Region Zero program and required that Purdue keep it in place

Changes in Prescribing Patterns
Following Introduction of
Reformulated OxyContin: A Window
into Diversion?

Purdue Presentation Sent to Board Oct. 25, 2011 (PPLPC042000024694)

Region Zero Used Objective Criteria To Identify Suspicious Prescribers

	 "Excessive number of patients for the practice type" 		
2002	– "Atypical pattern of prescribing techniques or locations"		
	"Information that a healthcare professional or patients are diverting medication"		
	- "A prescriber writing a large number of prescriptions for patients who receive prescriptions and pay with cash"		
	 "Sudden unexplained change in prescribing or dispensing patterns" 		
	 "Allegations that patients from a given practice have overdosed on medications" 		
2002	 "Allegations that prescriber, dispenser, staff or patient has or is actively abusing medications" 		
	 "Unlicensed individual is signing prescriptions or dispensing medications" 		
	 "Large number of patients who travel hundreds of miles for their prescriptions without rational explanation" 		
	- "Reports of frequent early requests for new prescriptions made long before the initial prescription would normally be completed"		
	 "Credible allegations that a healthcare professional is under active investigation related to abuse or diversion by any law enforcement or regulatory authority" 		
2003	 "A healthcare professional who moves his or her practice from one state to another on more than one occasion within a 		
	couple of years" (PDD1503493410)		
2007	 "A Prescriber with an atypical patient population from that customarily observed in such an office based on this location and 		
	other attendant circumstances" (PPLP00342999)		
2015	 "A Prescriber lacks understanding about the risks associated with prescribing opioids" "Facts that suggest that the Prescriber's patients are seeking opioids for misuse and abuse, including but not limited to facts that a Prescriber has failed to comply with his or her state's prescription monitoring program" (PPLP004035073) 		

The Board Understood That Government Entities Required Purdue To Keep Region Zero In Place And Approved Purdue's Implementation Of It

- Purdue was required to keep the Region Zero program in place for 10 years by the 2007 consent judgments (e.g., Kentucky Consent Judgment ¶13)
- New York separately required Purdue to maintain Region Zero in 2015 (AOD)
- An auditor approved by the New York Attorney General ("NYAG"") reviewed and endorsed Purdue's implementation of Region Zero in 3 Annual Reports (2016 2018)
- Purdue sent Annual Reports about Region Zero to the Ohio AG as designee of all Consent Judgment States
- On request, Purdue provided government officials with information about prescribers on its Region Zero list

E.g., 10/10/13 Purdue Letter to Tenn. AG; 5/18/09 Purdue Letter to VA AG

Purdue Was Required To Keep the ADD Program and Region Zero In Place For 10 Years By 2007 Consent Judgments

Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees or its contract or third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history, to the extent such history is available and relevant, and shall take such further steps as may be appropriate based, on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.

ispensing controlled substances. Upon identification of on involving a Health Care Professional with whom Purdue or third-party sales representatives, including Medical Liaisons, tuct an internal inquiry which will include but not be limited to a 2 Professional's prescribing history, to the extent such history is id shall take such further steps as may be appropriate based on es, which may include ceasing to promote Purdue products to 2 Professional, providing further education to the Health Care priate use of opioids, or providing notice of such potential abuse to medical, regulatory or law enforcement authorities. Purdue's ction shall expire ten (10) years following the Effective Date of onths from the date on which the last of Purdue's patents tres, whichever is earlier, but in no event shall be earlier than 3 the Effective Date of this Judgment.

all implement and maintain a training and education program ontin Abuse and Diversion Detection Program, and shall require d contract or third-party sales representatives, including Medical acticing Health Care Professionals in person or by telephone for

ter than thirty (30) business days after the Effective Date of this Judgment. Further

type; e) a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medications with cash; f) multiple allegations that

0

OxyContin to complete the training and education program no

Purdue Annually Reported About Region Zero For 3 Years, But Was Required Not To Name Any Specific HCP In The Annual Reports

(e) beginning one (1) year after the Effective Date of this Judgment, for a period of three (3) years, produce and provide on an annual basis to the Attorney General on the anniversary of the Effective Date of this Consent Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports, the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and

procedures which are designed to begin training currently employed Covered Persons on at, and about how to comply with this Judgment;

Attorney General (per the Notice below), no later than one lays after the Effective Date of this Judgment, a written adgment, a written affirmation setting forth Purdue's raph;

of three (3) years from the Effective Date of this Judgment, ang all Covered Persons of the requirements of Paragraphs 2

it,

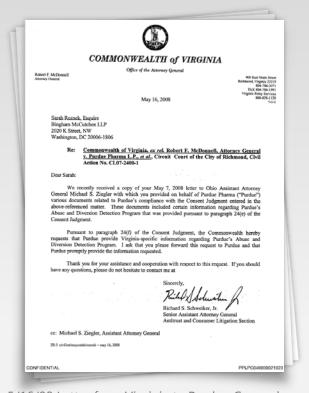
ne (1) year after the Effective Date of this Judgment, for a roduce and provide an an annual basis to the Attorney General ffective Date of this Consent Judgment a report containing Abuse and Diversion Detection Program including, but not number of reports, the number of investigations, and a Juding the number of "Do Not Call" determinations, but shall ay specific Health Care Professionals; and a request, the Attorney General may obtain state-specific subsection (c). In addition, Purdue agrees to accept service of

to the extent necessary for compliance with this Judgment, no later the

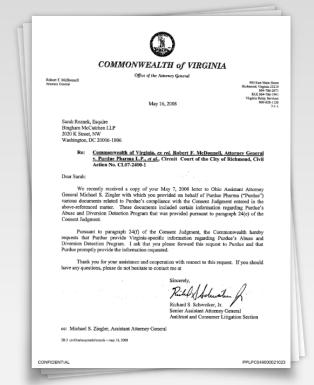
AGs Could Request State-Specific Information And Purdue Was Required To Provide It

24. Purdue shall: to the extent necessary for compliance with this Judgment, no later than ninety (90) days after the Effective Date of this Judgment, institute compliance ied to begin training currently employed Covered Persons on ent, and about how to comply with this Judgment; (f) upon written request, the Attorney General may obtain state-specific e Altorney General (per the Notice below), no later than one days after the Effective Date of this Judgment, a written information as described in subsection (e). In addition, Purdue agrees to accept service of a civil investigative demand or similar process by the Attorney General udgment, a written affirmation setting forth Purdue' requesting the names of any specific Health Care Professionals described in of three (3) years from the Effective Date of this Judament, subsection (e). The Attorney General in receipt of such information shall not disclose ing all Covered Persons of the requirements of Paragraphs 2 it except as provided by law. one (1) year after the Effective Date of this Judgment, for a roduce and provide on an annual basis to the Attorney General Effective Date of this Consent Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports, the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and ed in subsection (e). In addition, Purdue agrees to accept service of

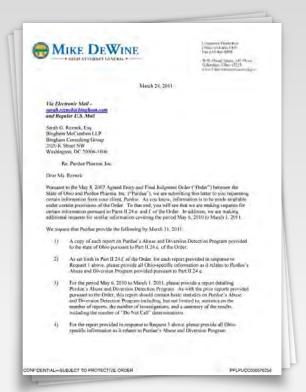
Purdue Provided AGs State-Specific Information On Request Per Consent Judgments



5/16/08 Letter from Virginia to Purdue Counsel (PPLPC049000021023)



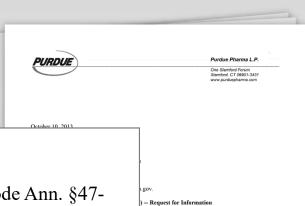
5/13/10 Letter from Virginia to Purdue Counsel (PPLPD004671883)



3/24/11 Letter from Ohio to Purdue Counsel (PPLPUCC500578254)

Purdue Provided AGs State-Specific Information On Request Per Consent **Judgments**

In October 2013, Purdue sent the Tennessee AG's Office a list of 75 Tennessee HCPs on its "Do Not Call" list.



Dear Ms. Peacock:

I am writing in response to the Request for Information Issued Pursuant to Tenn. Code Ann. §47-18-101 et seq. dated October 8, 2013 (the "Request") which seeks documents and information from Purdue relating to Tennessee-based Health Care Professionals ("HCPs") about whom Purdue has made "Do Not Call" determinations since May 8, 2007. These determinations are made as part of Purdue's Abuse and Diversion Detection program ("ADD Program"). In response to the Request, enclosed please find a spreadsheet that provides identifying information for 75 HCPs, including first and last name, city, state, zip code and recommendation.

"Request") which seeks documents and based Health Care Professionals ("HCPs") about nations since May 8, 2007. These determinations ion Detection program ("ADD Program"). In spreadsheet that provides identifying informa state, zip code and recommendation. Please be ial, and we request that you treat this information der your regulatory authority any questions regarding the enclosed

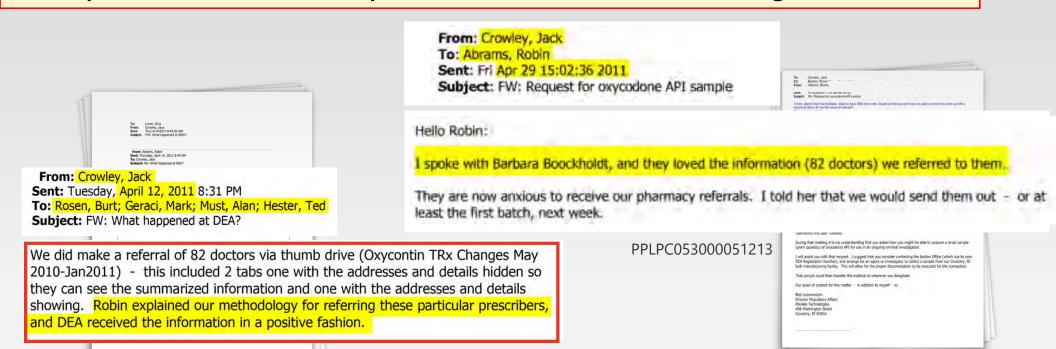
PPLPC049000079234

Dedicated to Physician and Patient

w/ Encl

Purdue Referred HCPs to the DEA

- Between 2002 and 2018, Purdue referred 222 HCPs to the DEA
- In April 2011, alone, Purdue provided DEA the names of 82 Region Zero HCPs

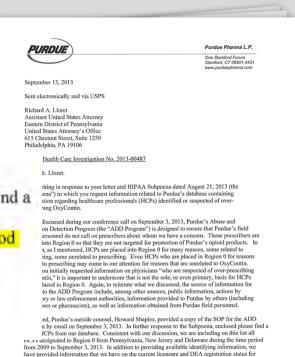


PPLPUCC9007416689

Purdue Provided Region Zero Information to the U.S. Attorney for the Eastern District of Pennsylvania

In 2013, Purdue sent the names of Region Zero HCPs in Pennsylvania, New Jersey, and Delaware to the U.S. Attorney for the Eastern District of Pennsylvania

As agreed, Purdue's outside counsel, Howard Shapiro, provided a copy of the SOP for the ADD Program by email on September 3, 2013. In further response to the Subpoena, enclosed please find a list of HCPs from our database. Consistent with our discussion, we are including on this list all HCPs designated to Region 0 from Pennsylvania, New Jersey and Delaware during the time period from 2009 to September 3, 2013. In addition to providing available identifying information, we have provided information that we have on the current licensure and DEA registration status for these individuals and the type of healthcare professional license that they hold (MD, PA, DO).



PPLPC049000079240

these individuals and the type of healthcare professional license that they hold (MD, PA, DO).

Dedicated to Physician and Patient

PPLPC049000079240

Purdue Provided Region Zero Information to the U.S. Senate Caucus on International Narcotics Control

As previously explained, Purdue provides information related to its Abuse and Diversion Detection Program ("ADD program") and Region 0 list to law enforcement and regulatory authorities upon request. That includes members of the Federation of State Medical Boards that have requested information pursuant to the Caucus' January 13, 2014 letter to them. In exchanges with your staff, Purdue has volunteered to provide the Caucus with blinded information that it will be providing to law enforcement and regulatory authorities where that information supplements what Purdue has already provided to the Caucus. Purdue provided you with that supplemental information for the State of California on January 7, 2014, and with this letter is providing blinded information that has been provided to law enforcement and regulatory authorities in Alabama, New York, New Jersey, Pennsylvania, and Delaware. This chart combines responses that Purdue has furnished to the following authorities: Office of the Attorney General, State of New Jersey, United States Attorney for the Eastern District of Pennsylvania,

King & Spalding LLP 1700 Pennsylvania Ave, NW Suite 200 King & Spalding Washington, D.C. 20006-4707 Theodore M. Hester March 12, 2014 BY HAND The Hon. Dianne Feinstein, Chair The Hon. Charles Grassley, Co-Chairman Senate Caucus on International Narcotics The Hon. Charles Schumer The Hon. Tom Udall I am providing a further written response on behalf of Purdue Pharma L.P. to your letter of November 8, 2013. This response supplements the November 13, 2013 meeting between your staffs and representatives of Purdue Pharma: Ms. Robin Abrams, Vice President, Associate General Counsel, Mr. Burt Rosen, Vice President, Federal Government Affairs, and myself; Purdue's prior written responses dated November 22, 2013, and January 7, 2014; and the Region 0 list of 2,630 providers that I provided to your staffs on February 12, 2014. As previously explained, Purdue provides information related to its Abuse and Diversion Detection Program ("ADD program") and Region 0 list to law enforcement and regulatory authorities upon request. That includes members of the Federation of State Medical Boards that have requested information pursuant to the Caucus' January 13, 2014 letter to them. In exchanges with your staff, Purdue has volunteered to provide the Caucus with blinded information that it will be providing to law enforcement and regulatory authorities where that information supplements what Purdue has already provided to the Caucus. Purdue provided you with that supplemental information for the State of California on January 7, 2014, and with this letter is providing blinded information that has been provided to law enforcement and regulatory authorities in Alabama, New York, New Jersey, Pennsylvania, and Delaware. This charcombines responses that Purdue has furnished to the following authorities: Office of the Attorney General, State of New Jersey, United States Attorney for the Eastern District of Pennsylvania,

PPLPC049000103061

Purdue Provided Region Zero Information To 25 Agencies 17 States

State	Agencies	State	Agencies
2000	Nevada State Board of Medical Examiners (April 27, 2013), (August 11, 2015)	Wyoming	Wyoming Board of Medicine (February 26, 2014)
Nevada	Nevada State Board of Pharmacy (September 3, 2013) Nevada State Board of Osteopathic Medicine (September 25, 2013)	Georgia	Georgia Composite Medical Board (February 27, 2014)
	Medical Board of California (September 11, 2013), (September 25, 2013) Dental Board of California (September 12, 2013)	West Virginia	West Virginia Board of Medicine (February 27, 2014) West Virginia Board of Osteopathic Medicine (February 27, 2014)
California	Board of Registered Nursing of California (September 25, 2013) Osteopathic Medical Board of California (September 25, 2013)	Arizona	AZ Board of Osteopathic Examiners in Medicine and Surgery (February 28, 2014)
	Physician Assistant Board of California (September 26, 2013) Board of Podiatric Medicine of California (September 26, 2013)	Pennsylvania	Pennsylvania Department of State, Bureau of Professional and Occupational Affairs (February 28, 2014)
Tennessee	Office of Tennessee Attorney General (October 15, 2013)	Kansas	Kansas State Board of Healing Arts (March 4, 2014)
New Jersey	Office of the Attorney General (November 8, 2013)	North Dakota	ND State Board of Medical Examiners (March 7, 2014)
Illinois	Illinois Department of Financial and Professional Regulation (February 12, 2014)	Alabama	Alabama State Board of Medical Examiners (March 11, 2014)
Virginia	Virginia Department of Health Professions (February 19, 2014)	Alabama	Alabama State board of Medical Examiners (Match 11, 2014)
Wisconsin	Wisconsin Department of Safety and Professional Services (February 25, 2014), (April 28, 2014)	Rhode Island	Board of Medical Licensure & Discipline, State of Rhode Island Department of Health (March 11, 2014)
		Oregon	Oregon Medical Board (May 20, 2014)

PPLPC049000076533; PPLPC049000079271; PPLPC049000079268; PPLPC05100189775; PPLP004437593; PPLP004437542; PPLPC05100018973; PPLPC051000189745; PPLP004438105; PPLP004438118; PPLP004438136; PPLP004438136;

- **DOJ alleges that:** "In or around August 2010, the Named Sacklers, received a Board package that included Region Zero sales data, including the names of Region Zero prescribers" (Addendum A ¶61)
- Nothing in the Board package invited Board input in Region Zero determinations
- The Board package was sent in response to Board questions responsibly monitoring anti-diversion activities ("Do we track IMS scripts for region '0'? What is the rate of 'no call' MD's and if rising, what is the driver?")
- The first part of the Board package was a memo answering the Board's questions and describing the robust steps Purdue was taking to identify suspect prescribers (PPLPC012000283163)
- The second part was a spreadsheet listing Region Zero prescribers giving the Board a snapshot of Region Zero (PPLPC012000283169-70)
- Nothing in the package raised concerns or invited action

Pursider Pitarena
Shareholderen B Guart Marching
Therefore, July 22, 2009
Budderen
Gewelleren Arling Burling har Presentations
Gewelleren Arling Burling har Presentations

1. Consiplance

1. Consiplance
1. Does the first their compresentatives appear to Nove premoted figuils for the treatment of an improperty of "Arling" in sole to broad plan, open and past an experience with premoted and "Arling" in sole to broad plan, open and past an experience with premoted and confidence and the solegon and past an extra sole of confidence and the adaptive "Arring" in the sole of the sol

PLPC012000283163

- **DOJ alleges that:** "Purdue had detailed information (down to the number of prescriptions written, product, and dosage) of Purdue products prescribed by Region Zero doctors and knew that Purdue had been making a considerable profit from these prescriptions." (Addendum A ¶59)
- The Board never saw any of this information apart from the snapshot it received in August 2010
- Purdue could not stop Region Zero doctors from prescribing OxyContin
- The Board was not consulted on Region Zero determinations
- **DOJ admits that:** "After prescribers were referred to ADD, an ADD review team comprised of Purdue employees reviewed information concerning the prescribers to determine whether Purdue should continue to market its opioids to them. <u>The Named Sacklers did not sit on the ADD review team</u>." (Addendum A ¶123)

- **DOJ alleges that** "the Named Sacklers knew, or should have known, that abuse and diversion appeared concentrated among a cohort of high-volume prescribers" (Addendum A ¶71)
- The 2011 presentation that DOJ cites for this:
 - Nowhere suggests that this is a continuing issue
 - Reports that 1900 prescribers have been placed in Region Zero
 - Shows that the abuse-deterrent formulation succeeded in reducing prescriptions by Region Zero prescribers
 - Stresses that the ADD Program is "[d]esigned to ensure that the company does not promote Purdue's products ... where there is a concern about potential abuse or diversion" (Addendum A ¶70; PURDUE-COR-00032186 (emphasis in original))

DOJ alleges:

"126. Purdue sales representatives were trained to report prescribers suspected of abuse and diversion to ADD, and some sales representatives did so. However, many high-volume prescribers, despite having indicia of abuse and diversion, were not reported. Further, even after they were reported to ADD, Purdue continued to detail and generate prescriptions from high volume prescribers that were prescribing opioids that were not for a medically accepted indication; were unsafe, ineffective, and medically unnecessary; and that were often diverted for uses that lacked a legitimate medical purpose. The following are two examples of high-volume prescribers that Purdue detailed during E2E." (Addendum A ¶126)

- There is no evidence that any of this information was ever presented to the Board
- The Directors were not provided data as to specific prescribers that were suggested for review, were under review, or should be under review — or what prescriptions any of them wrote
- DOJ admits the Directors did not sit on the ADD review team that received prescriber-specific information and decided whether to continue to place them in Region Zero (Addendum A ¶123)
- The Directors understood that Purdue conscientiously implemented the ADD Program, and this was confirmed by an auditor approved by the New York Attorney General

NYAG Investigated Purdue from 2013-15, Settled for \$75,000 and Required That Purdue Maintain the ADD Program and Region Zero

WHEREAS, New York laws prohibiting deceptive business practices and false and misleading advertising confer important consumer and public health protections; and WHEREAS, Purdue has cooperated with the OAG's investigation; and WHEREAS, the Attorney General is willing to accept the terms of this Assurance

Law Section 63(15) and to discontinue his investigation; and

A. Maintenance of ADD Program

28. Purdue shall continue to maintain its ADD Program consisting of internal procedures designed to ensure that Purdue's interactions with HCPs that reveal observations or circumstances that suggest potential concerns about abuse, diversion, or inappropriate prescribing of opioid medications generate appropriate review and follow-up. Within ninety (90) business days after the Effective Date of this Assurance, Purdue shall implement the modifications set forth below. The ADD Program shall remain in place for as long as Purdue promotes OxyContin to HCPs through sales representatives.

al has determined that this Assurance is in the public

D AND AGREED, by and between the parties that:

asintain its ADD Program consisting of internal
e's interactions with HCPs that reveal observations or
erns about abuse, diversion, or inappropriate
e appropriate review and follow-up. Within ninety
e of this Assurance, Purdue shall implement the
Program shall remain in place for as long as Purdue
less representatives.

to Purdue sales representatives and medical liaisons
moting Purdue opioid products ("ADD Covered

ve or learn of the situations described in Paragraph

11

An Auditor Approved by NYAG Endorsed Purdue's Implementation of Region Zero in 2016, 2017 and 2018

- Purdue acted "conscientiously and in good faith"
- Its "determinations whether to continue marketing were reasonable"

[T]he Auditor concludes that Purdue is operating the ADD Program in compliance with Section IV.A [which sets for ADD Program requirements]. Set forth below (see Section III.A.2.) is a paragraph-by-paragraph description of the requirements posed by Section IV.A. and the evidence indicating the Company's compliance with those requirements. On a more general level, the evidence reviewed by the Auditor and the Auditor's interactions with its Law Department indicate that the Company is approaching the ADD Program conscientiously and in good faith. While glitches have occurred (see for example discussion below at 4) in the Auditor's view such issues do not result from a lack of commitment to the Program.

As to the second question [the reasonableness of Purdue's determinations regarding whether to continue marketing to HCPs subject to ADD Reports], the Auditor concludes that the Company's determinations whether to continue marketing were reasonable.

The Auditor's work has focused principally on two broad questions: first, whether Purdue is managing its ADD Program in compliance with Section IV.A. of the AOD; and second.

to continue marketing to HCPs subject to

the arrange of the ADD Program of the Section IV.A. and the evidence indicating on a more general level, the evidence on with its Law Department indicate that the nitually and in good faith. While glitches and in good

and in good

issues do not

The Auditor's view such issues do not are context, during the period of review a total Reports the Law Department initially onber included 34 "automatic" placements on HCPs. The Auditor focused most of its a geategory, and found the Law ory indicates an adverse criminal or licensing not called on the doctor during the prior

To continue whether to

 The Board relied on management reports that Purdue was vigorously implementing the ADD Program

ADD Program

- Based on SOP developed in 2002
- Identifies criteria that require field-based personnel to report certain circumstances to Law Department (i.e., aberrant prescribing, long lines of patients, high cash pay patients, out of state patients)
- More than 3200 inquiries conducted since 2002
- If determine sales force shall not promote Purdue products to particular prescriber, put in Region 0
- Approximately 1900 prescribers in Region 0

Changes in Prescribing Patterns
Following Introduction of
Reformulated OxyContin: A Window
into Diversion?

Oct. 25, 2011 Presentation (PPLPC042000024694)

- The Board relied on District Managers' monitoring of sales rep adherence to the ADD Program and management's review of the District Managers' reports
- District Managers personally observed each sales rep's interactions with prescribers several days each year to ensure sales rep compliance with Purdue policies, and reported on:
 - (i) sales reps' knowledge of indicators of diversion set forth in the ADD Program and
 - (ii) sales reps' filing Reports of Concern and ADD Reports

7/30/09 Period 2 IRO Rept. on Systems Engagement at PPLP004433834-38; 9/25/09 2nd Ann. Purdue Rept. to OIG w/exhibits at PDF p. 323 of 627; PPLP03342689, PPLP003430131, PPLP003578717; PPLP004434750-51

District Managers documented their observations in Field Contact Reports (Id.)

Compliance Section of PMP Forms

ompliance to Policies and Procedures		For OIG Demonstration only
Legal Guidelines for Product Promotion	5	For OIG Demonstration only
Healthcare Law Compliance (HCLC) Policies	5	For OIG Demonstration only
Code of Business Ethics	5	For OIG Demonstration only
Indicators of Possible Diversion	5	For OIG Demonstration only
Expense Reporting/Attribution	5	For OIG Demonstration only
Call Reporting	1	For OIG Demonstration only
AE Reporting/Product Complaints	5	For OIG Demonstration only
Reports Of Concern (ROCs)	5	For OIG Demonstration only
Sampling (PDMA)	5	For OIG Demonstration only
Professional Conduct	5	For OIG Demonstration only
Requests for Off-Label Information	5	For OIG Demonstration only
Grants	5	For OIG Demonstration only

Compliance Section of Field Contact Reports



3Q 2010 Quarterly Compliance Report at PPLP004405484



CIA- Sales Promotion Monitoring – 2Q10

Purdue's CIA requires Corporate Compliance to review Field Contact Reports (FCRs) with a compliance category rating of "1," indicating less than 100% compliance with Sales SOPs

- 637 FCRs were prepared during 2Q10
 - 73 FCRs had a Compliance Rating of "1" 18 required Compliance investigation; 17 resulted in discipline
 - 13 representatives recorded call note(s) that: contained language which
 was unclear about indication or proper use of Ryzolt; did not clearly
 show they corrected a Health Care Provider's misconception about
 Ryzolt's Indication; or contained a concerning "Next Call Objective"
 - 1 new representative terminated for multiple violations, including, poor overall performance, failure to perform administrative tasks, and compliance-related activities
 - · 3 representatives in possession of discontinued materials



Management Review of Field Contact Reports
As Reported To The Board

Corporate Compliance Quarterly Report to Board of Directors 2Q10

July 22, 2010

Bert Weinstein

Vice President, Corporate Compliance

PURDUE

2Q 2010 Quarterly Compliance Report at PPLP004404554



 Management regularly reported that Sales Reps and District Managers were trained on the ADD Program

Purdue's National Sales Meeting

- Presentation: "Why should compliance matter to you?"
 Video of 2009 compliance highlights (a version of Jaws for reps)
 Review of CIA history
 - Compliance hot topics: prosecutors looking for jail time, and focused on off-label promotion, and savings card abuse; Federal Sunshine Act
- Scenario-based Workshops "owned" by all the District Managers
 Focused on nine important issues in the field (and a "snowball fight")

· Abuse and Diversion Reporting

- · In-service meals and expenses (2)
- · Off-label promotion
- · Contributions / kickbacks
- · Comparative claims
- Abuse and Diversion Reporting

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

PPLP004403715

Q4 2009 Quarterly Compliance Report at 9 (PPLP004403661)

National Sales Meeting

Well-received compliance workshops for all field personnel:

- Focused on Adverse Event, Product Complaint, Report of Concern and Abuse & Diversion Detection (ADD) Program reporting requirements
- Reviewed AG Agreement obligations (especially "Dear HCP Letter" and "ADD Report" requirements)
- · Reviewed CIA obligations and overall commitment to

Abuse & Diversion Detection (ADD) Program

"ADD Report" requirements

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

PPLP904

4Q 2008 Quarterly Compliance Report at 22 (PPLP004402205)

Sept. 23, 2010 Board Report:

Office of the General Counsel

- Serve as an affiant/deponent in various legal actions
 - Defended our opioid-agonist/sequestered-antagonist patents in deposition
 - · Identified and assisted with retention of expert witnesses
- Invited to consult with Order Monitoring System Committee
 - · Now a member of the committee.
 - Assist with policy development and implementation (eg, the new DEA requirements regarding response to "suspicious orders")
- Collaborating with Robin Abrams and Risk Management & Epidemiology
 - Developing model to attempt identification of suspicious prescribing patterns that warrant further investigation (Polaris/Principled Strategies/Wolters Kluwer)

 The Board was advised that Purdue's Compliance Council reviewed the ADD Program

Major Compliance Oversight Activities

- Compliance Council senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality program
- Reportable Events Committee senior medical, Legal, regulatory and compliance execs meet monthly- review all pending compliance and other matters
- Sales and Marketing Compliance Committee senior Sales and Marketing and Compliance execs meet every six weeks

Sales Discipline Committee – Sales Legal HR and Compliance

Corporate Compliance Quarterly Report to Board of Directors 4Q09

February 4, 2010

 Compliance Council – senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality Program

PPLP004403707

 The Board was advised that Purdue's Risk Management Department was monitoring Diversion Presented The Assessment and Management of Cirroric Pain with an Emphasis or the Appropriate Use of Opinial Analgeric at the Tufts University, Master of Science Program course in Pain in Boston, MA on April 25, 2008. ic meeting in San Juan, Puerto Rico on June 15 Assays in Pain Management presentation at the spioid Risk Management in Boston, MA on June RISK MANAGEMENT & HEALTH POLICY ds for FDA Advisory Committee Meeting fo Submitted manuscript on study assessing the validity of self-reported abuse of OxyContin® t Submitted manager Addiction.

Revised Protocol OTR8001 ("Long-term epidemiology study") in response
Advisory Committee; revisions approved by Protocol Review Committee. Prepared response to FDA Office of Epidemiology and Surveillance's questions at the College on Problems of Drug Dependence Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics Rico on June 15 - 19, 2008: with USA. Authors: Meredith Y. Smith. MPA. 890 Repots of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics to innursamining the acuse and accessor of epoch inagement systems. Authors: J.P. Fitzgerald; M. D. Haddox, DDS, MD. xycorlone HCl Controlled-Release) Tablets, October lline, MS; Melinda A. Philbrook; Meredith Y. reviewed and entered into the Risk Management DataMart for 2nd Quarter 2008. 25 field inquiries conducted in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data for 2nd Quarter 2008. cument for the September 15, 2008 BuTra n of PPLP marketed opioid analgesics taMart for 2nd Quarter 2008. of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data for 2nd Quarter 2008. Healthcare Grants and Giving Review Committee
2Q08 = 144 21

2Q 2008 Board Report at PPLP004367317

The Board was advised that Purdue's Manufacturing & Supply Chain Department was ensuring compliance with DEA requirements

MANUFACTURING & SUPPLY CHAIN

2010.



2Q 2010 Board Report (PPLP004367018)

 The Board was advised that Purdue's Manufacturing, Supply Chain and Pharmaceutical Technology Dept. monitored compliance across all operational areas

MANUFACTURING/SUPPLY CHAIN/PHARMACEUTICAL TECHNOLOGY

Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgradies/improvements (FDA, DA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major product lines. Ensure project milesiones are met and product moves into commercialization. Altain monerational and_management efficiency, continuously improving, and assuring cost

MANUFACTURING/SUPPLY CHAIN/PHARMACEUTICAL TECHNOLOGY

Sustain Compliance across operational areas by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy) without major disruption to supply. Maintain continuous supply of commercial and new products to all customers, on time across the major product lines. Ensure project milestones are met and product moves into commercialization. Attain operational and management efficiency, continuously improving and assuring cost effectiveness.

ufacturing, Supply Chain and Pharmaceutical Technology

nd Supply Chain	Q3 YTD			Full Year		
nd Supply Chain	Actual	Budget	Var	2012 Budget	2011 Actua	
d (MM)	503	419	84	593	629	
OxyContin	356	298	57	409	456	
MS / MSER	139	121	18	163	165	
Oxy APAP	-	-	-	21		
Oxy Export	8	-	8	-	8	
ttles (000)						
Bottles Packed	244	-	244	-	308	
Гime						
Wilson	100.0%	99.0%	1.0%	99.0%	99.85	
Rhodes	99.6%	99.0%	0.6%	99.0%	99.15	
3rd Party	99.0%	99.0%	0.0%	99.0%	99.7 9	
ull						
Wilson	99.7%	99.0%	0.7%	99.0%	99.6	
Rhodes	99.7%	99.0%	0.7%	99.0%	99.99	
3rd Party	99.0%	99.0%	0.0%	99.0%	99.6	
(Months)						
OxyContin	2.2	2.5	(0.3)	2.5	2.6	
BuTrans	3.7	3.0	0.7	3.0	3.3	
	REDAC	TED				

il Technology	Q3 YTD			Full Year	
a rectaiology	Actual	Budget	Var	2012 Budget	2011 Actual
pment Hours	22,911	36,615	(13,704)	40,633	29,784
Production Flours	2.603	5.834	(3.231)	6.474	4.289
Support Hours	20,308	30,781	(10,473)	34,159	25,495
s Manufactured	65	82	(17)	114	89

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

PPLP0043668

Hotline and Other Inquires Q2 2007



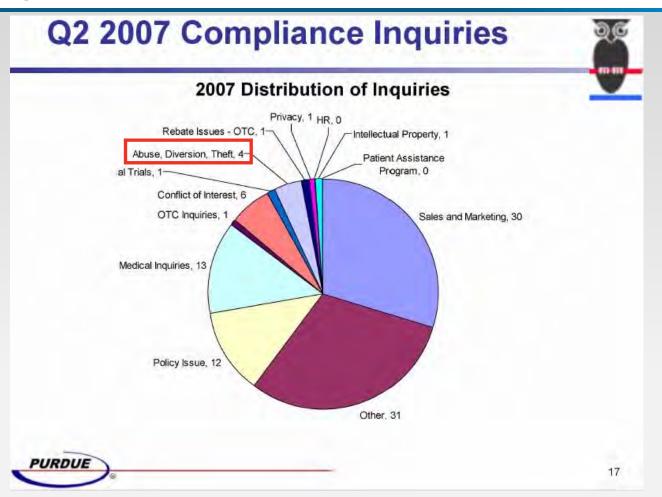
- We handled a total of 101 inquiries in Q2 2007, of which 17 had compliance implications:
 - 3 Policy Matters e.g., expensing gift to MD: insider trading
 - 11 Sales & Marketing Matters e.g., gifts/meals to HCPs; competitor's promotional activities; alleged representative misconduct; AE reporting
 - <u>2 Abuse, Diversion Matters</u> e.g., sales representative reports pursuant to RSOP 1.7.1
 - 1 Other Matter e.g., grant request issues
 - Note: Call Log maintained; available for review



Purdue's CIA and AG Agreement: Status Report

Report to Board of Directors August 6, 2007 Bert Weinstein, VP Corporate Compliance

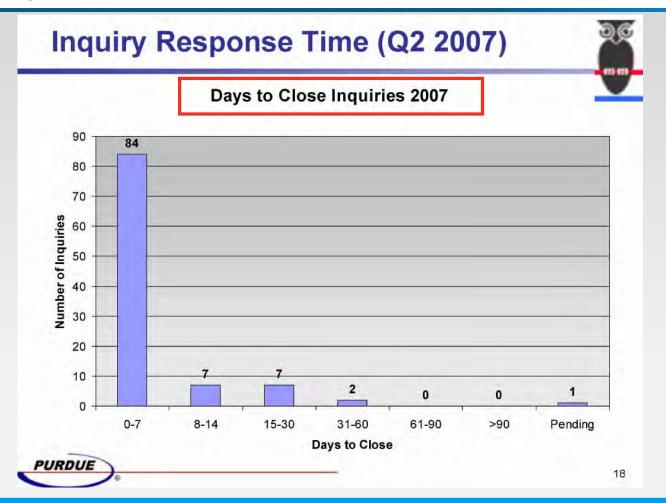
> Aug. 6, 2007 Compliance Report at PLP004399968



Purdue's CIA and AG
Agreement: Status Report

Report to Board of Directors
August 6, 2007
Bert Weinstein,
VP Corporate Compliance

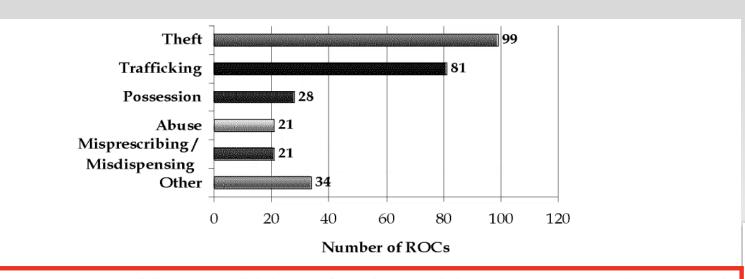
Aug. 6, 2007 Compliance Report at PLP004399970



Purdue's CIA and AG
Agreement: Status Report

Report to Board of Directors
August 6, 2007
Bert Weinstein,
VP Corporate Compliance

Aug. 6, 2007 Compliance Report at PLP004399971

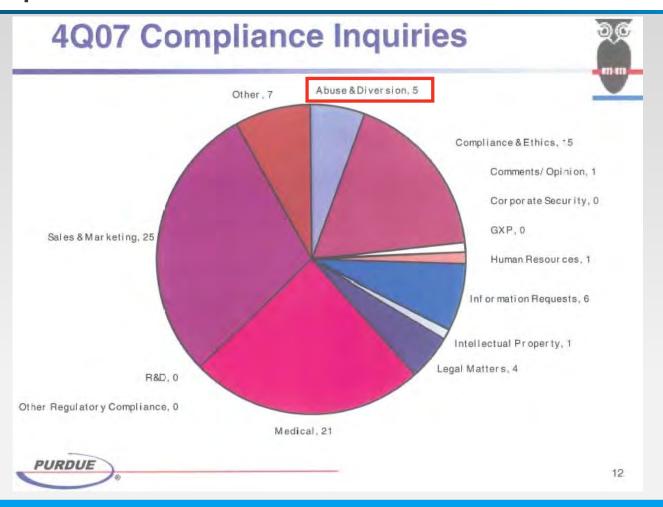


- Figure 1: 284 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics reviewed and entered into the Risk Management DataMart for 3rd Quarter 2007
- 46 field inquiries conducted in response to signals of abuse or diversion of OxyContin[®] as identified via review of ROCs, and RADARS[®] System data

Purdue Quarterly Report to the Board October 15, 2007

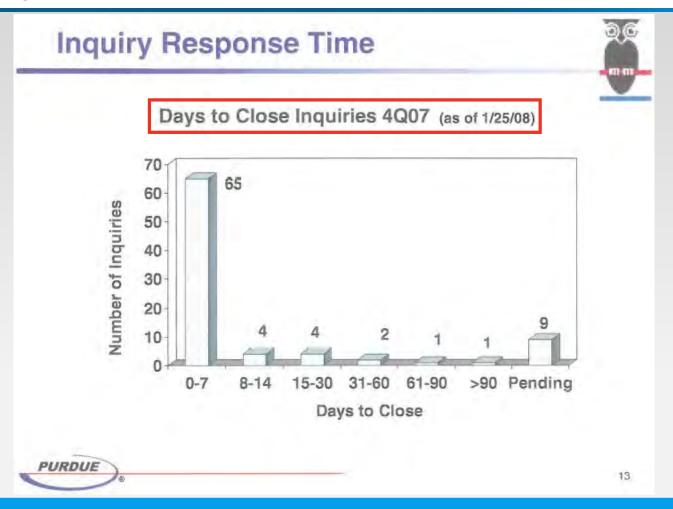
3rd Quarter 2007

3Q 2007 Report to Board at PPLPC012000157437





Report (PPLPC019000195607)



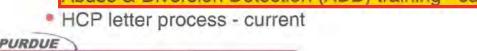


4Q 2007 Quarterly Compliance Report (PPLPC019000195607)

CIA and AG Agreement Status

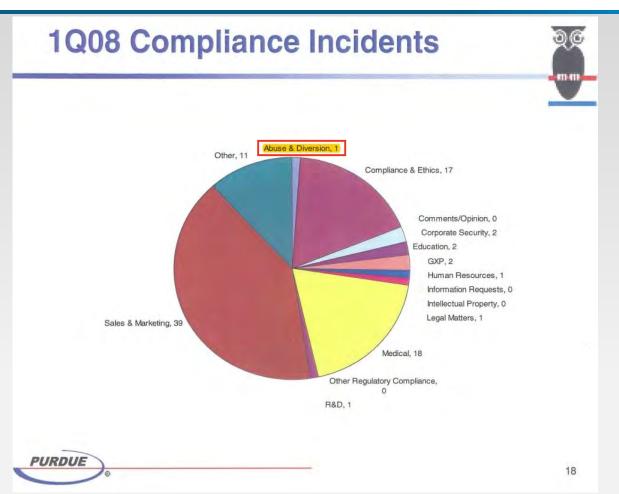


- CIA Implementation Report
 - Submitted to OIG on 11/28/07
 - Questions received 4/7 answered 4/10
 - OIG approval of implementation 5/2
- OIG notice of exclusion of individuals 3/31 letter
 - Purdue responded 4/14 re proposed consulting
 - OIG approval of consulting arrangement 5/5 letter
- IRO Work plan submitted 1/08
- Preparing for IRO review summer
- Annual Report Submission to OIG Due 9/29/08
- Purdue in compliance with AG Agreements
 - Abuse & Diversion Detection (ADD) training current



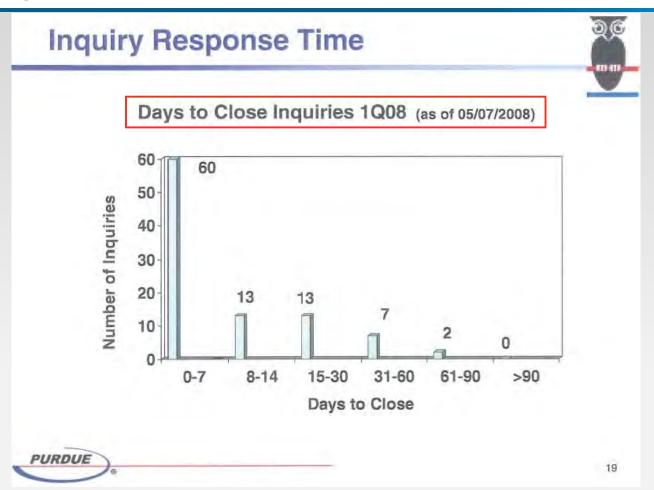


1Q 2008 Quarterly Compliance Report at PPLP004401171





1Q 2008 Quarterly Compliance Report at PPLP004401186





1Q 2008 Quarterly Compliance Report at PPLP004401187

CIA Highlights



All transactions this quarter with OIG / Monitor Keshia Thompson have had successful results. Recap:

- CIA Implementation Report approved by OIG 5/2
- OIG notice of exclusion of individuals 3/31
 - But OIG approved consulting arrangement 5/5
- OIG affirms Par not 'covered' in Rhodes arrangement -6/5

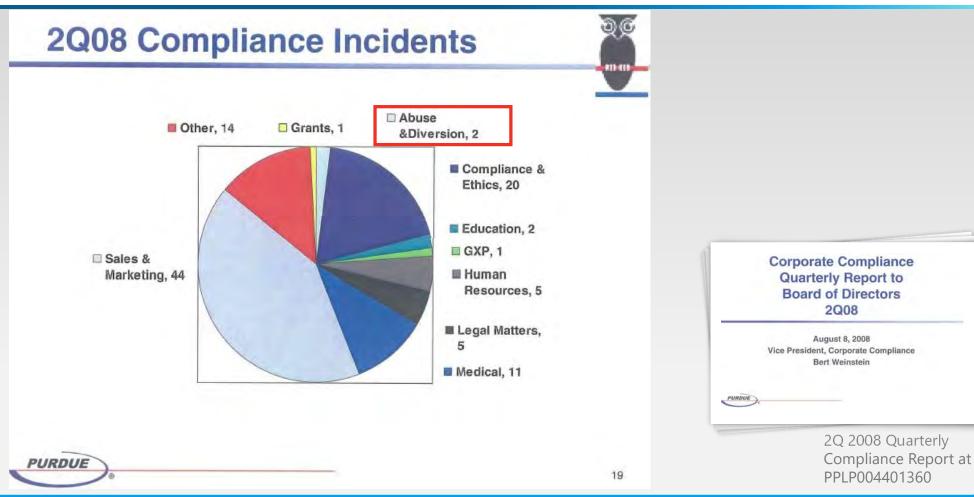
Purdue is also in full compliance with its AG Agreements

- Abuse & Diversion Detection (ADD) training current
- HCP letter process current / monitored monthly via Sales



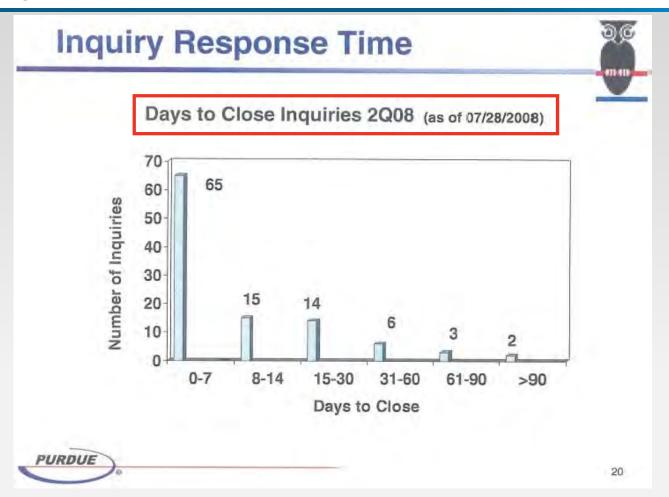
2Q 2008 Quarterly Compliance Report at PPLP004401344

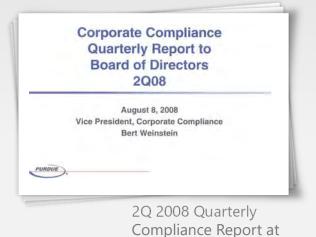
PURDUE



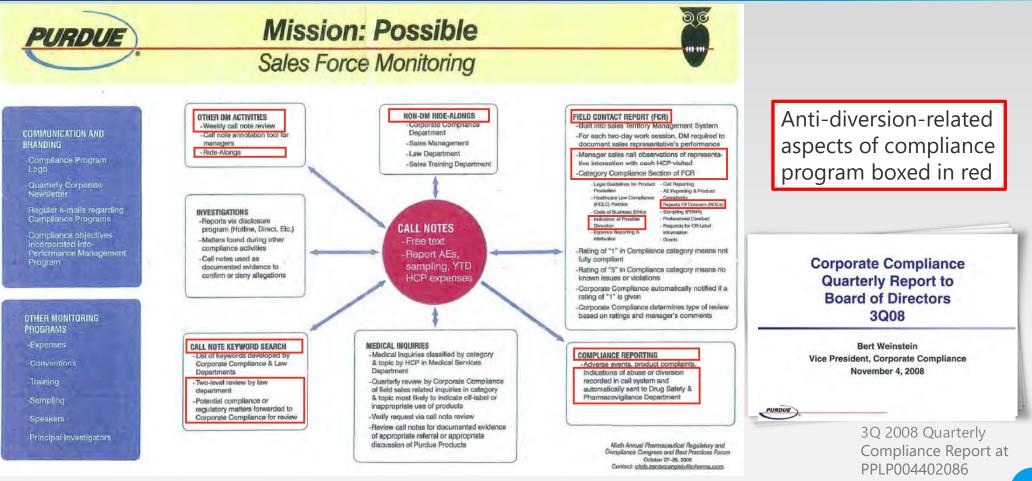


PPLP004401360





PPLP004401361



Purdue CIA Highlights

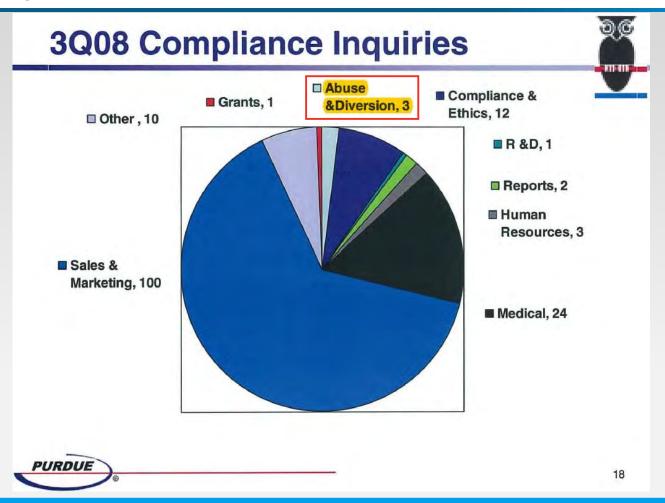


- First Annual Report to OIG submitted 9/25/08, certifies to all CIA requirements, including:
 - Updated policies and procedures
 - Code and other training
 - Disclosure Log information
 - Screening for Excluded Individuals
 - Investigations and Legal Proceedings
 - Material Review Documents
- A copy of the Report (without voluminous attachments) follows these slides
- Purdue is also in full compliance with its AG Agreements
 - Abuse & Diversion Detection (ADD) training current
 - HCP letter process current / monitored monthly via Sales



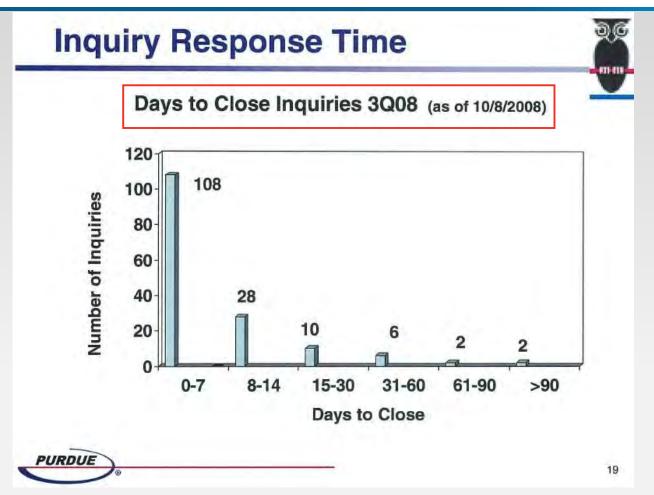
Corporate Compliance
Quarterly Report to
Board of Directors
3Q08

Bert Weinstein
Vice President, Corporate Compliance
November 4, 2008





PPLP004402049





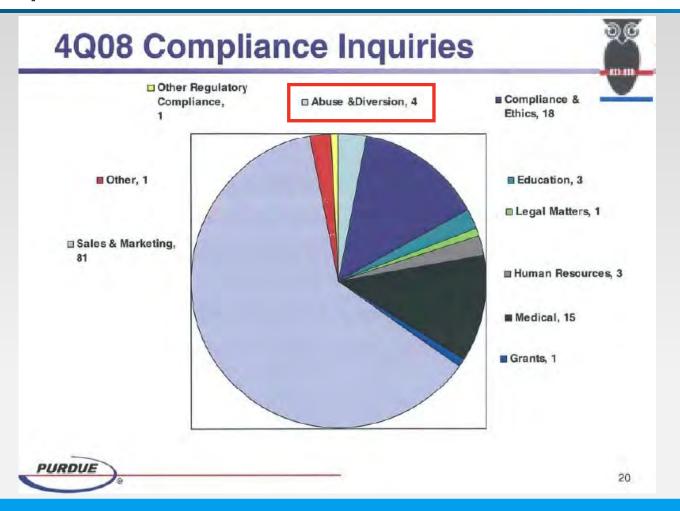
National Sales Meeting



- Focused on Adverse Event, Product Complaint, Report of Concern and Abuse & Diversion Detection (ADD) Program reporting requirements
- Reviewed AG Agreement obligations (especially "Dear HCP Letter" and "ADD Report" requirements)
- Reviewed CIA obligations and overall commitment to compliance with laws, regulations and policies and procedures
- Emphasized appropriate messaging around OxyContin Visual Aid
- · "Be a Compliance Star!" game
 - Exciting and interactive game that tests compliance knowledge
 - Rewarded strong knowledge of compliance concepts
 - Developed in-house

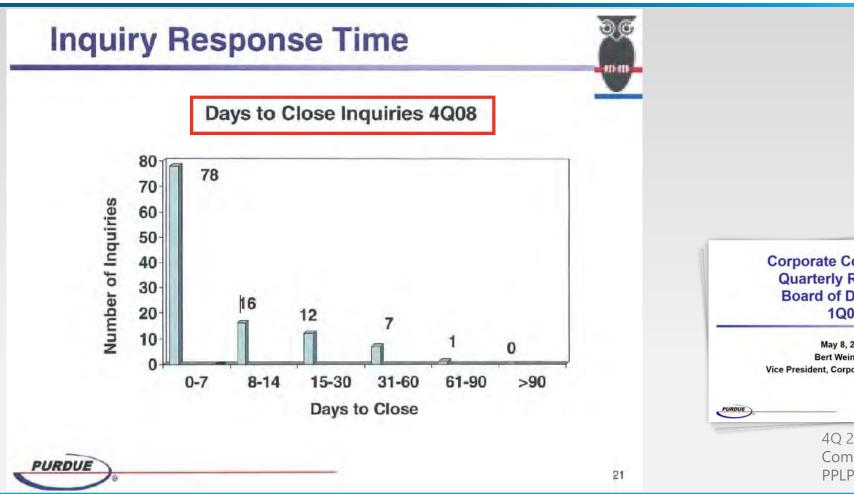




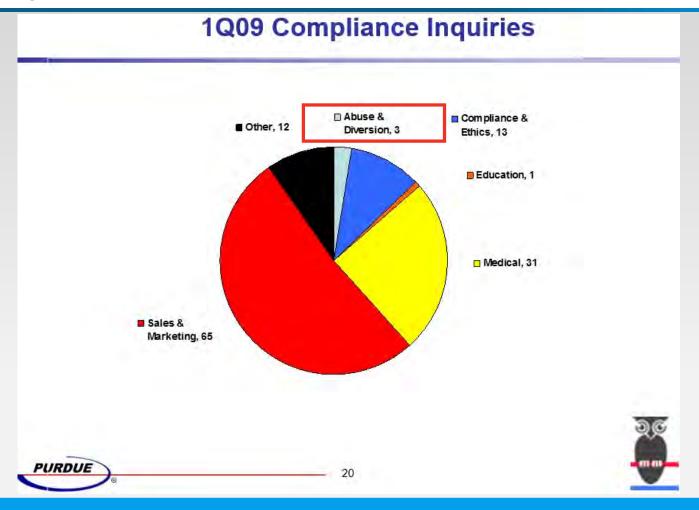




PPLP004402224

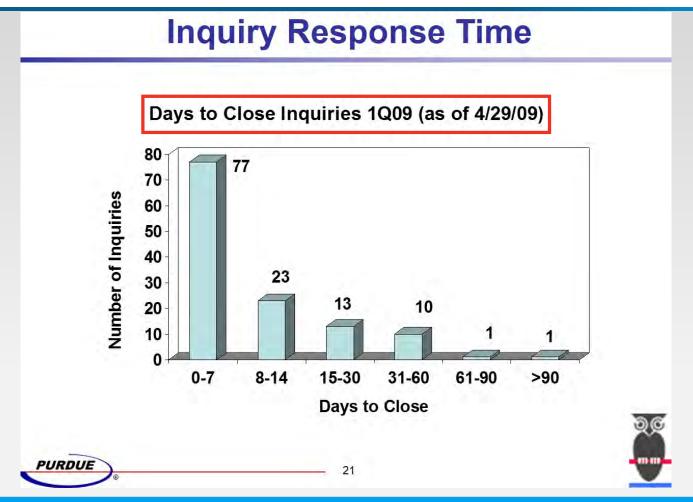


Corporate Compliance Quarterly Report to Board of Directors 1Q09 May 8, 2009 Vice President, Corporate Compliance

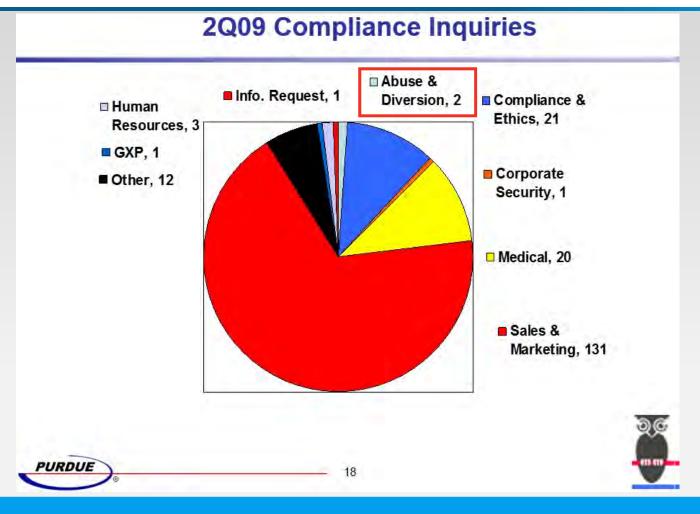


Corporate Compliance
Quarterly Report to
Board of Directors
1Q09

May 8, 2009
Bert Weinstein
Vice President, Corporate Compliance

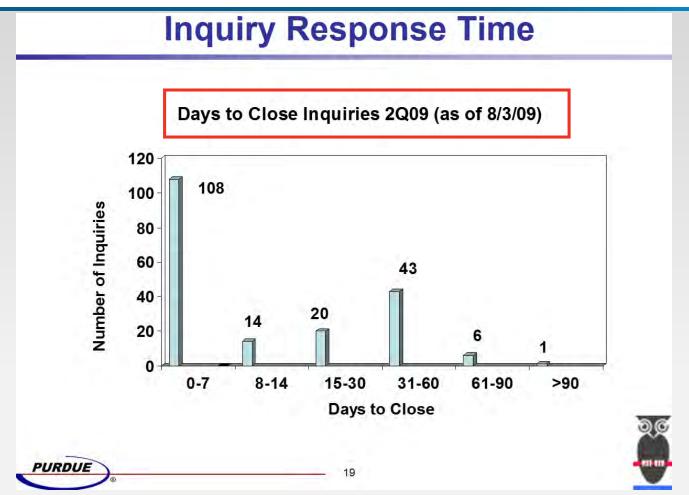






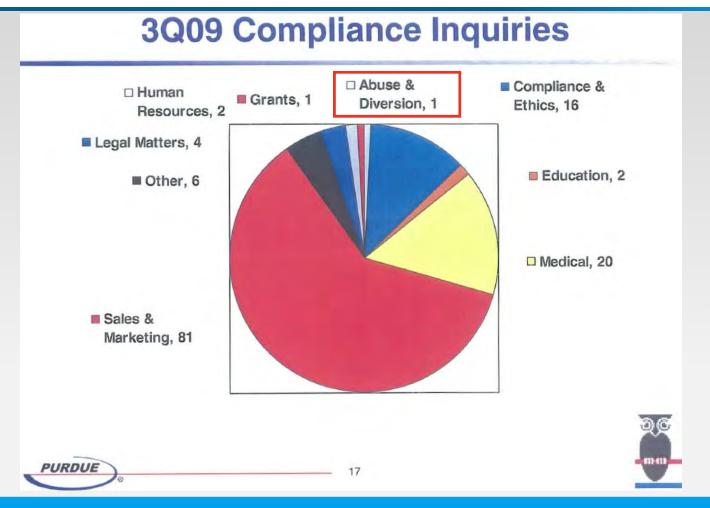


2Q 2009 Quarterly Compliance Report at 18 (PPLPC012000236639)

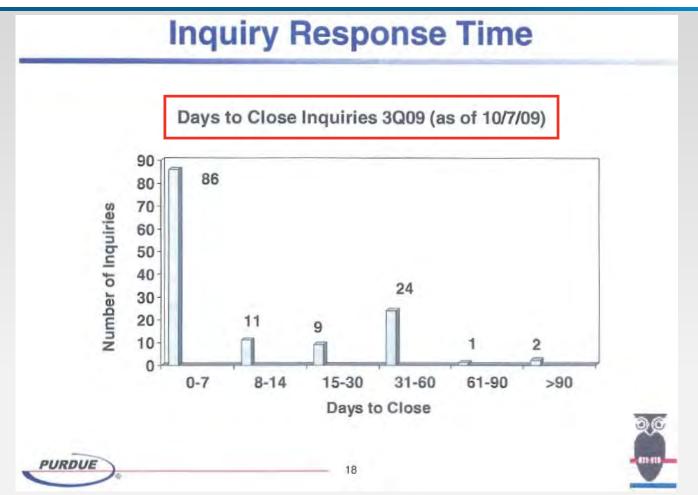




2Q 2009 Quarterly Compliance Report at 18 (PPLPC012000236639)









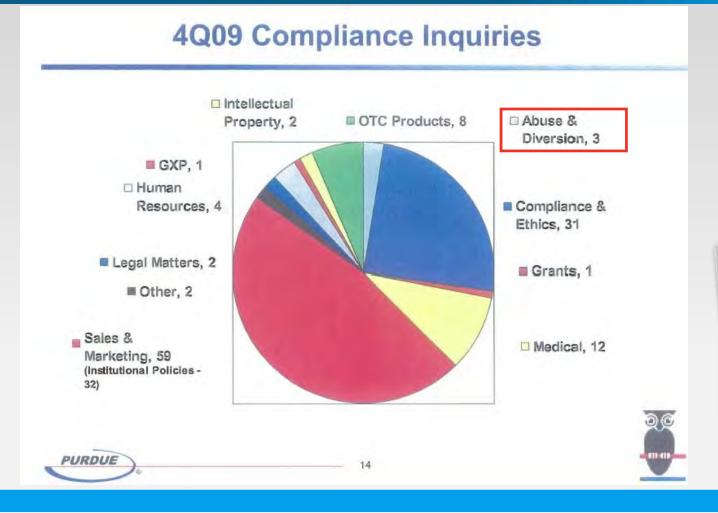
Second Annual Report to OIG

- Purdue's Second Annual Report to the OIG dated 9/25/09 certifies to our compliance with all CIA requirements, including:
 - Updated policies and procedures
 - Code and other CIA training of employees, Board, etc.
 - Disclosure Log information
 - Screening for Excluded Individuals
 - Investigations and Legal Proceedings
 - Material Review Documents
- A copy of the Report (without voluminous attachments) follows these slides – it is FYI only
- Purdue is also in full compliance with its AG Agreements
 - Abuse & Diversion Detection (ADD) training current
 - HCP letter process current, monitored quarterly

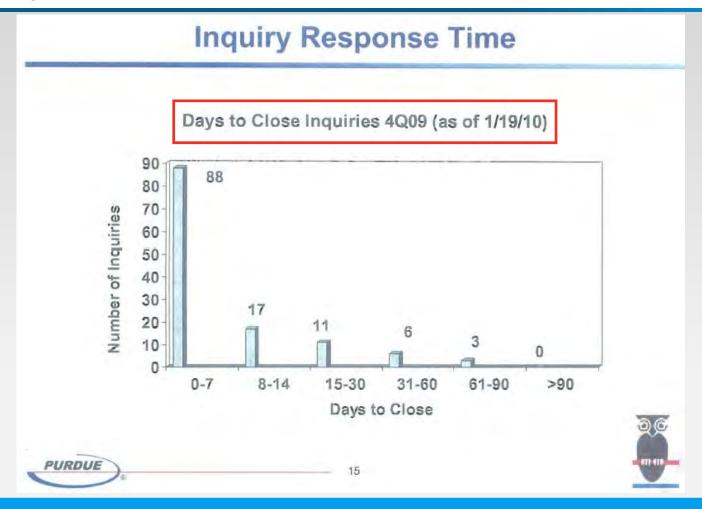














Purdue's National Sales Meeting

- Presentation: "Why should compliance matter to you?"
 - Video of 2009 compliance highlights (a version of Jaws for reps)
 - Review of CIA history
 - Compliance hot topics: prosecutors looking for jail time, and focused on off-label promotion, and savings card abuse; Federal Sunshine Act
- Scenario-based Workshops "owned" by all the District Managers
 - Focused on nine important issues in the field (and a "snowball fight")
 - Abuse and Diversion Reporting
 - In-service meals and expenses (2)
 - Off-label promotion
 - Contributions / kickbacks
 - Comparative claims
 - · Use of discontinued materials
 - · Call notes
 - Savings cards





February 4, 2010

Bert Weinstein

Vice President, Corporate Compliance

10 2009 Quarte



Major Compliance Oversight Activities

- Compliance Council senior execs with responsibility for CIA and compliance oversight meet quarterly, review audits and investigations; recently conducted review of Abuse and Diversion Detection Program and Quality program
- Reportable Events Committee senior medical, Legal, regulatory and compliance execs meet monthly- review all pending compliance and other matters
- Sales and Marketing Compliance Committee senior Sales and Marketing and Compliance execs meet every six weeks
- Sales Discipline Committee Sales, Legal, HR and Compliance meet weekly to discuss open matters and decide discipline
- R&D compliance Compliance Manager focusing on this area





February 4, 2010

Bert Weinstein

Vice President, Corporate Compliance



Supply Chain Security Program 2009 Accomplishments

- Losses in Transit 0
 - (Purdue to Customers/Wholesalers)
- Supply Chain Loss
 - McKesson Memphis, Tennessee
 - OxyContin left outside a secured area over the weekend
 - Crime Stopper Reward \$10,000
 - No arrest made to date
 - Follow-up with McKesson with appropriate recommendations for improvement
- US Government Supply Chain Security Compliance Programs
 - US Customs Trade Partnership against Terrorism (C-TPAT)
 - U.S. Transportation Security Administration (TSA) –
 "Certified Cargo Screening Program" (CCSP)
- Pharmaceutical Cargo Security Coalition (PCSC)
 - Value of goods recovered \$76,000,000 in 2009 vs.
 \$16,000,000 in 2008

Brand Protection / Investigations Program

2009 Accomplishments

- Counterfeiting
 - Internet Monitoring
 - Law Enforcement Assistance
 - . RFID
 - · Chemical Lab & Analysis
- Diversion (all Products)
 - Doctor Shopping / False Rx
- · Product Complaints/Tampering
 - e.g. "Skittles"
- Bottle Tracking
 - Approvals in 6 states (Washington, Oregon, New Mexico, Ohio, Georgia, Florida)
 - Deployed 29 stores State of Washington
 - 6 Individuals Arrested (Washington)

Physical Security Program 2009 Accomplishments

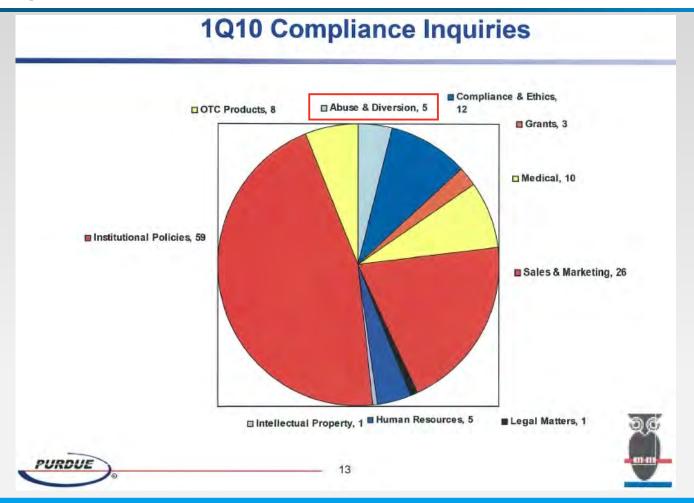
- DEA "Inspections/Audits"
 Wilson and Coventry no deficiencies
- Totowa Transition no significant security related incidents

4Q 2009 Corporate Security Dept. Report at 4-6 (Jan. 21, 2010 Board Agenda at PPLPC044000024003-005)

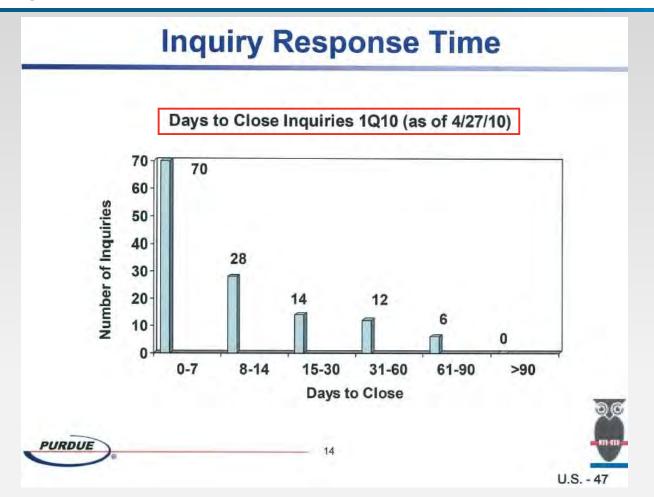
Purdue Pharma Corporate Security Department

OVERVIEW

- Law Enforcement Liaison and Education Program (LELE)
- · RxPatrol / Crime Stoppers Program
- · Supply Chain Security Program
- Physical Security Program
- · Brand Protection & Investigations Program

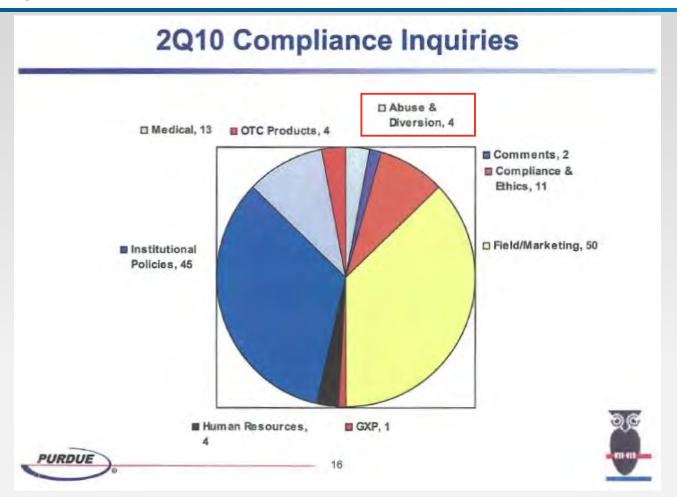




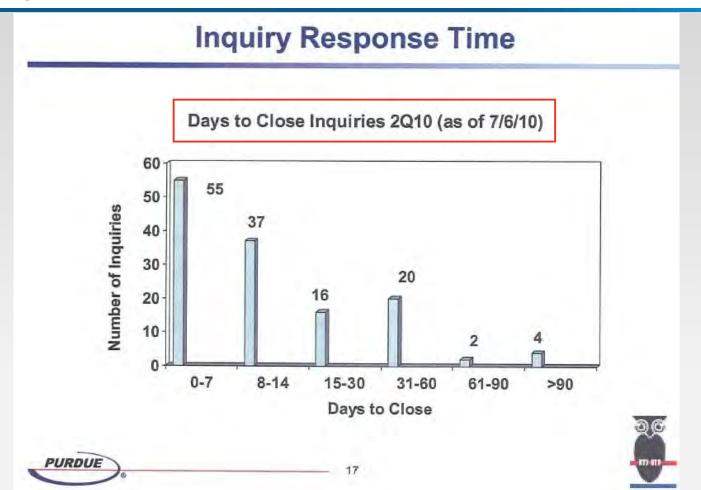




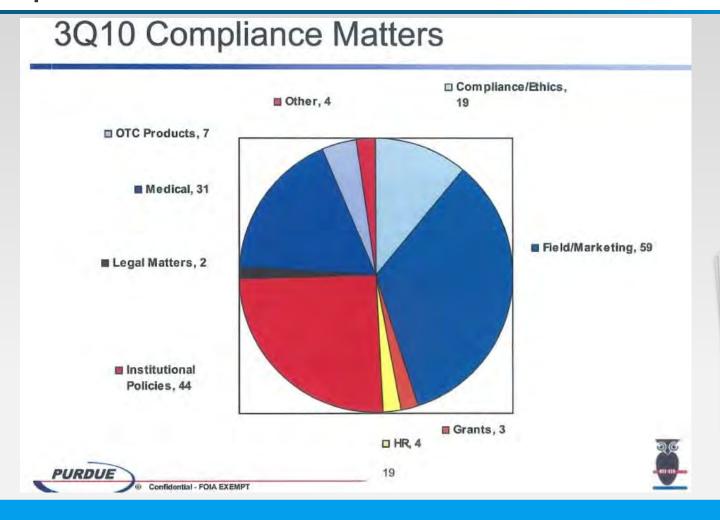
Report at PPLP004404115











Abuse and Diversion, 0

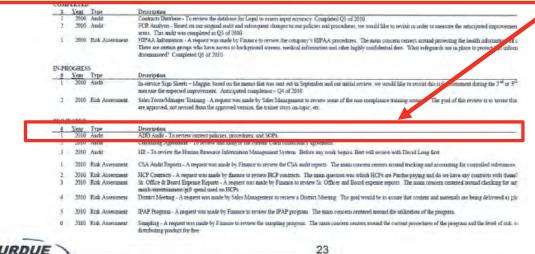


2010 Audit Schedule Snapshot



Year Type Description

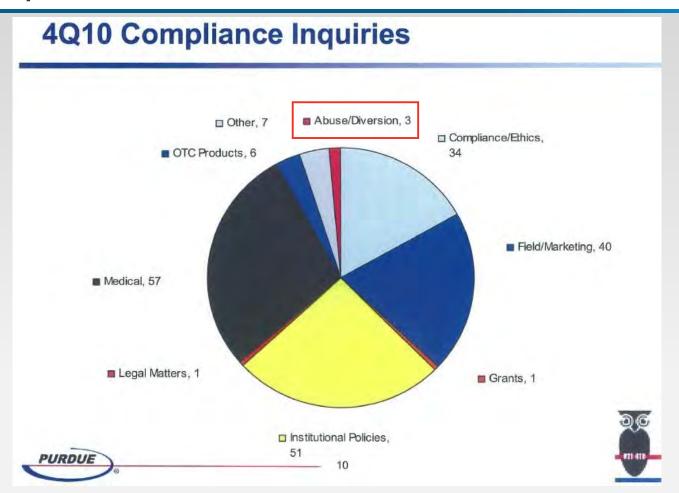
1 2010 Audit ADD Audit – To review current policies, procedures and SOPs



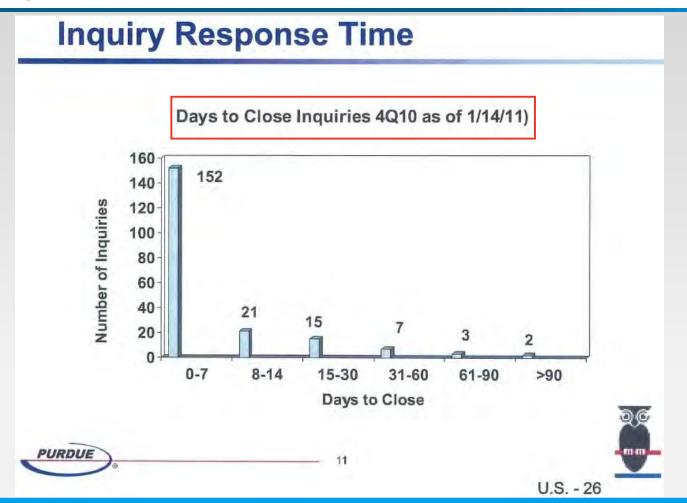


Corporate Compliance

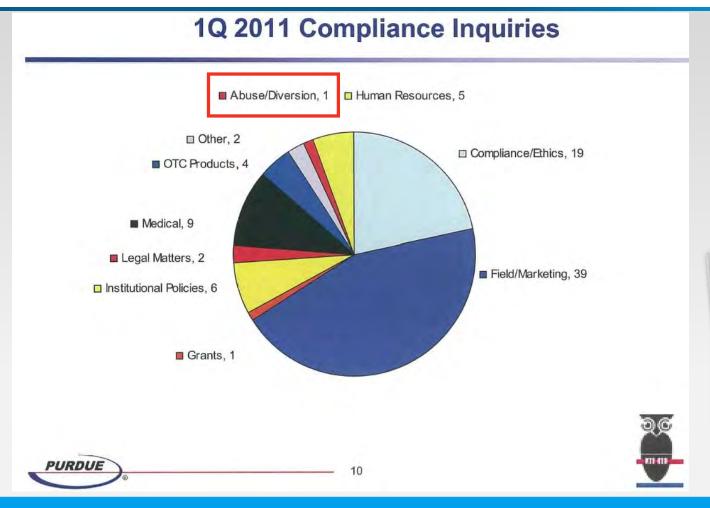




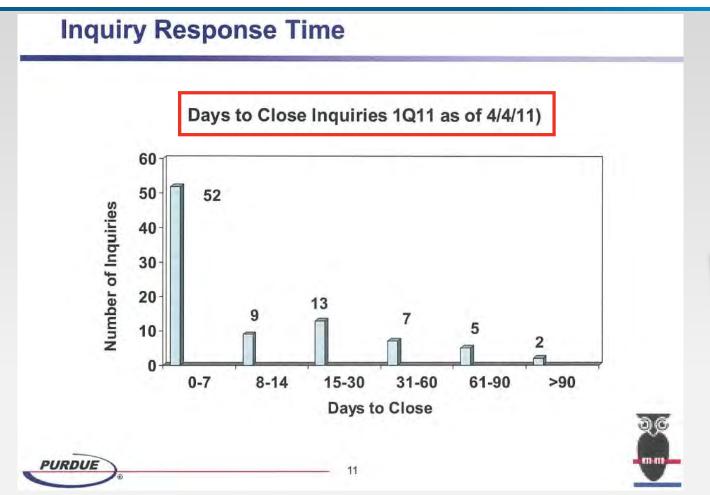














Sales and Marketing

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



Sales Force Monitoring

- PLUS:
 - Adverse Event Reporting
 - Medical Information Requests
 - Product Complaints
 - Abuse, Diversion Detection Reporting
 - Expense Reporting
 - Speaker Program monitoring
 - Live Training / Sales meetings
 - · Hotline matters
 - Direct contacts to Compliance

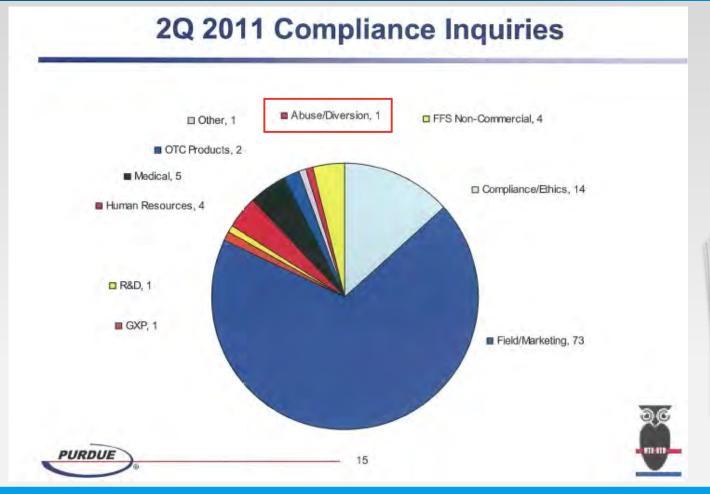


Corporate Compliance
Quarterly Report to
Board of Directors
2Q2011

July 21, 2011

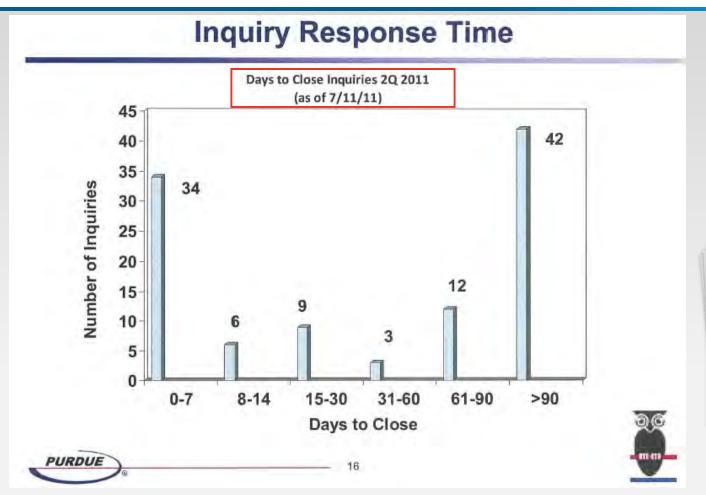
Bert Weinstein
Vice President, Corporate Compliance



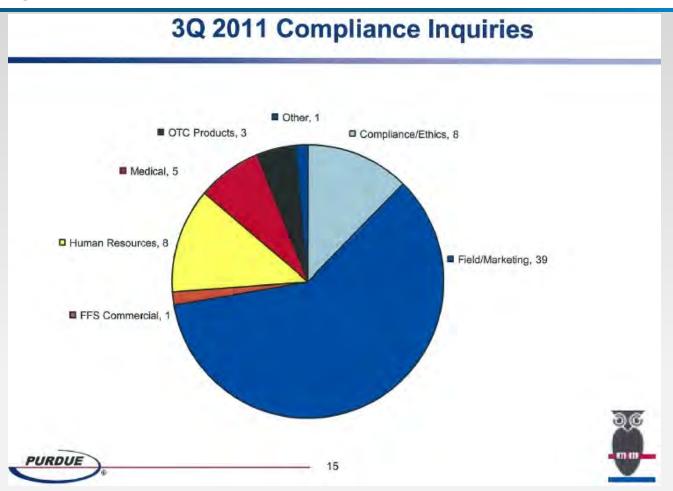




2Q 2011 Quarterly Compliance Report at PPLP004406480





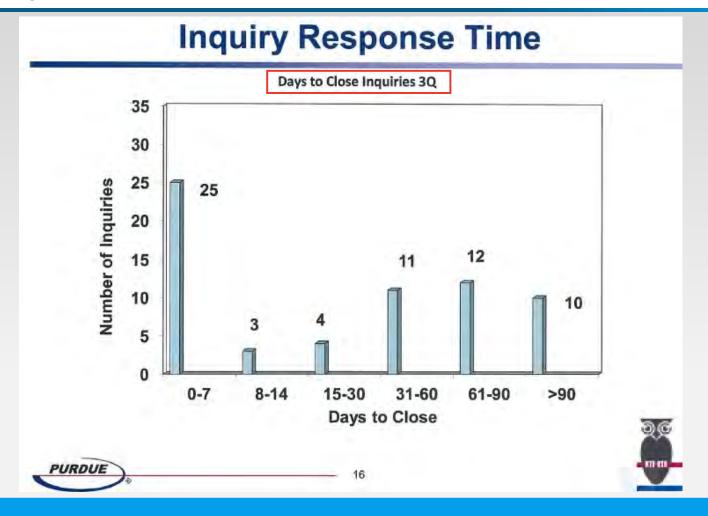


Abuse and Diversion, 0

Corporate Compliance
Quarterly Report to
Board of Directors
3Q2011

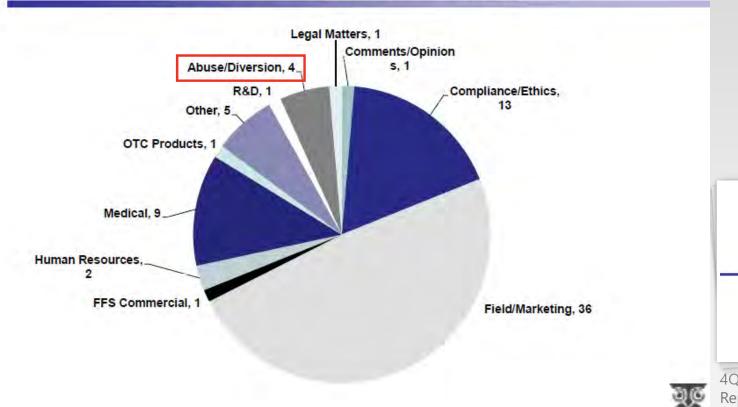
November 2, 2011

Bert Weinstein
Vice President, Corporate Compliance





4Q 2011 Compliance Inquiries



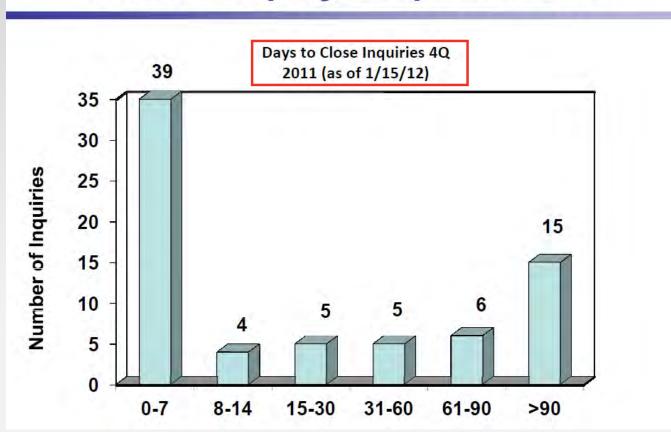
Corporate Compliance Quarterly Report to Board of Directors 4Q2011

January 19, 2012

Bert Weinstein Vice President, Corporate Compliance



4Q 2011 Inquiry Response Time



Corporate Compliance
Quarterly Report to
Board of Directors
4Q2011

January 19, 2012

Bert Weinstein
Vice President, Corporate Compliance

Attorneys General Agreement

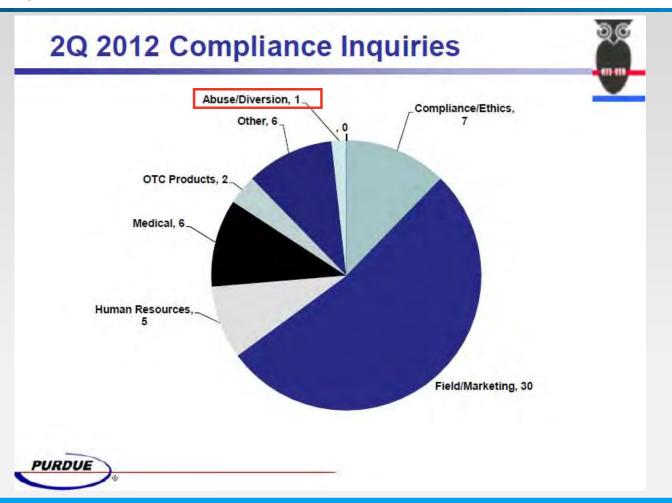


- * 10 year AG Agreement, started in May 2007
- * Purdue committed to continue OxyContin Abuse and Diversion Detection Program predicated on RSOP 1.7.1
- * Annual reminder and training to employees continues
- * Dear HCP Letter and Brochure providing written, non-branded education on abuse and diversion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

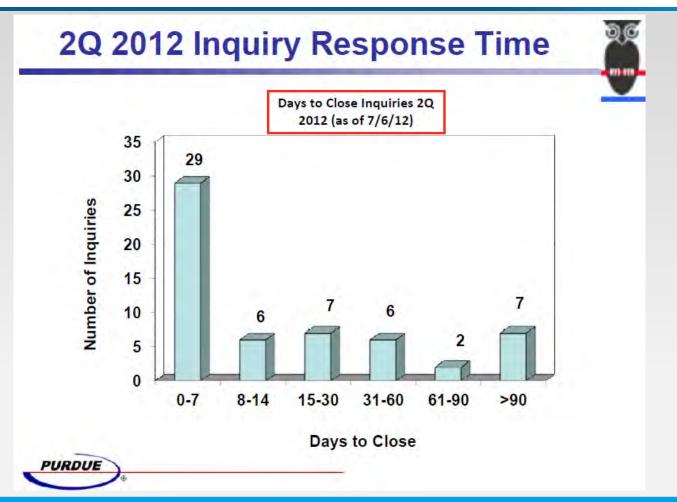
Post-CIA Compliance Program

Corporate Compliance Department
July 19, 2012

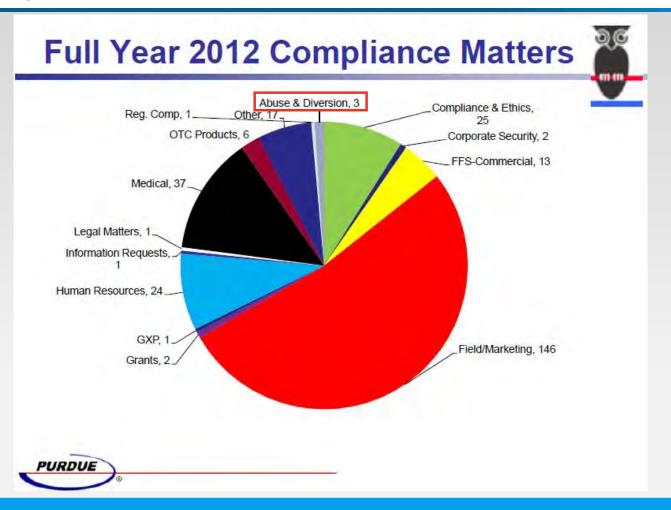




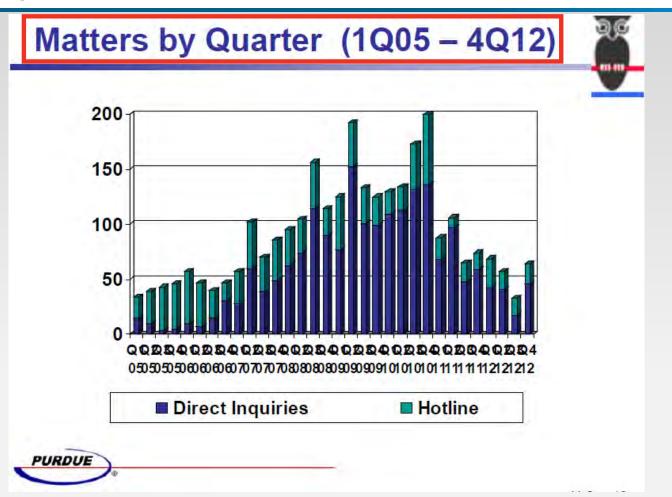




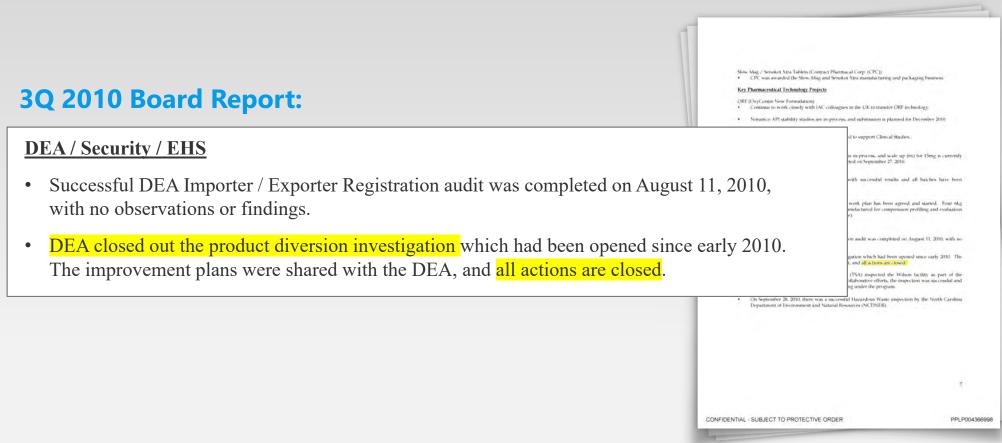












4Q 2011 Board Report:

- The Cranbury site hosted a DEA audit in 4Q 2011. Data from the extended Controlled Substance Inventory System was verified against our paper based inventory and used to support the audit. The audit result was 'Adequate', the highest determination given by the DEA.
- The IT team in collaboration with Corporate Compliance implemented an Aggregate Spend solution named WholeSum to manage all company related HCP spend in preparation for the Sunshine Act. Although the final regulations have been delayed, the company has implemented a flexible solution for over 17 different sources of HCP related spend that can readily be adapted once the regulations are finalized.
- Purdue IT supported all phases of the successful effort to launch generic Tramadol for Rhodes Pharma by December 31, 2011, using Purdue's existing SAP business process environment and shipping functionality out of the UPS Louisville located design and process testing

at into the Louisville facility. The design g Purdue, Rhodes, and UPS operations the Purdue and Rhodes businesses iff monitored the faunch over the holiday

nortal, including Purche clinical study tegrated with a new partner, Phlex tronic trial master file) structure and uments for review, saving the company odel. In a typical Phase 3 study, this ny 5200,000 per year.

2 2011. Data from the extended a verified against our paper based to audit result was "Adequate", the

osted and trusted public key intrastructure network to support their iPad deployments, including wireless and VPN connectivity. Leveraging the use of trusted certificates ensures that interoperability and security among the associated companies is maintained while allowing the use of the new devices in Asia Pacific.

• When DB Schenker, a highly-specialized controlled substance transport, abruptly cossed service to Purdue in August 2011 with only a 30 day notice top priority was to ensure business continuity of customer shipments in a secure manner. Purdue IT participated in the vendor selection for a controlled substances transportation provider, selecting UPS Express Critical. The team scoped, planned, and fully integrated this shipping service into both of Purdue's Wilson and Louisyilled distribution center's SAP systems without impact to customer shipments by end of September, During 4Q the IT department further integrated the now external UPS Express Critical service with the internal SAP shipping functionality for increased.

1

Feb. 2, 2012 Board Report at PPLPC012000362905

3Q 2012 Board Report:

DEA Requirements / Compliance

• July 2012: Successful DEA Inspection of Manufacturing and Analytical Registrations resulted in no observations or violations. Inspection included an extensive review and approval of the Tablet Counting and Reconciliation process.

Support to IAC's

- . Ongoing support of Supply Chain Management for Dilaudid supplies from Halo.
- Wilson site continues to manufacture Oxy/NEO for Purdue Canada.
- Wilson site and Anderson will execute the packaging to provide ONF tablets to support stability / dissolution studies for MAP territories (Mundipharma, Asia Pacific) and Latin America.
- All Latin America labeling will be revised to include a new dyeline that will add a no luction, and countries with greater forecast jolombia).

ioniomy.

Anufacturing and Analytical Registrations
Inspection included an extensive review Reconciliation process.

request to increase our Morphine quota to

tivity on MsContin has led to some exposure challenges and potential ring evaluated and closely ons are underway to address the situation.

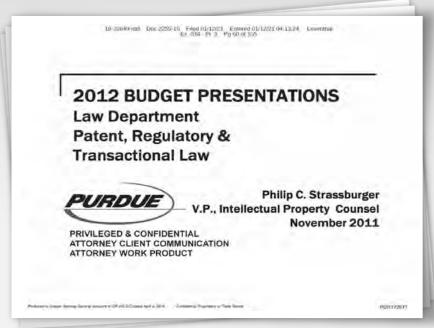
Wilson Region: Local Wilson businesses unty to request an environmental study on lity. At this point, it is unlikely that a full undertaken.

34

2012 Budget Presentation to Board (Nov. 2011):

Avoiding Risks – Dialogue with DEA regarding ORF

- Sharing data based upon transition to ORF
 - Prescriber data analysis shared in April 2011
 - Pharmacy data analysis shared in October 2011
- DEA feedback on ORF
 - Statements of Barbara Boockholdt, Chief, Regulatory Section, DEA, Office of Diversion Control
 - ORF has made a tremendous difference
 - No longer hear about OxyContin from field offices
 - ORF is saving lives
- Plan presentation on epidemiology study results



The Directors Responsibly Monitored But Did Not Personally Participate in Purdue's Anti-Diversion Efforts And Are Not Liable For Any Failures

- Directors are not liable for the torts of their corporation unless they personally participate in some wrongdoing
 - There is no claim and not evidence that the directors participated in Purdue's anti-diversion activities or took any steps to undermine them
- The directors received continual reports from Purdue management about its vigorous implementation of the anti-diversion programs on which they were entitled to rely
- The Board understood that Purdue's anti-diversion efforts were succeeding based on presentations from management and the findings of the auditor reporting to the New York Attorney General
- The Controlled Substances Act and similar state statutes impose duties on companies, not their directors

In re Purdue Pharma LP, et al.

Joseph Hage Aaronson LLC

Counsel to Raymond Sackler Family ("Side B")

Defense Presentation Part 3: Diversion

April 26, 2021