

# Exhibit 7

**To:** Gasdia, Russell[/O=PURDUE/OU=Purdue US/cn=Recipients/cn=58B02E32]; Rosen, David (Sales and Marketing)[/O=PURDUE/OU=Purdue US/cn=Recipients/cn=rosend]; Gadski, Kimberly[/O=PURDUE/OU=Purdue US/cn=Recipients/cn=GadskyK]  
**Cc:** Mahony, Edward[/O=PURDUE/OU=Purdue US/cn=Recipients/cn=MahonyE]; Mallin, William[/O=PURDUE/OU=Purdue US/cn=Recipients/cn=MallinW]  
**From:** Stewart, John H. (US)  
**Sent:** Wed 5/22/2013 7:57:59 PM  
**Subject:** Edits to 2013 Mid-Year Sales Update  
[20130522195347948.pdf](#)

Attached are my edits to the mid-year update slides. However, as you are making the edits, please also look to ensure that the terminology is consistent throughout, that heading are consistent and that the slides all have the same basic "look" - as opposed to being a random collection from several different presentations. Some that I feel could be improved from this perspective are #10, #19 (compare it to the look of #s 20 and 21).

Thanks - JS

---

# Purdue US

## 2013 Mid Year Sales Update



June 2013

---

CONFIDENTIAL

---

# OxyContin® Sales Update



Year to date April sales were below budget by \$162 million: ~~due to:~~

■ \$57 million ~~of lower sales~~ is attributed to lower demand

- \$21 million due to lower number of <sup>5 TABS</sup> tabs per script than assumed in budget;
- \$11 million due to lower overall script volume than budgeted ~~and~~
- \$25 million due to higher strengths scripts declining more rapidly than lower strength scripts.

■ \$101 million attributed to trade inventory changes.

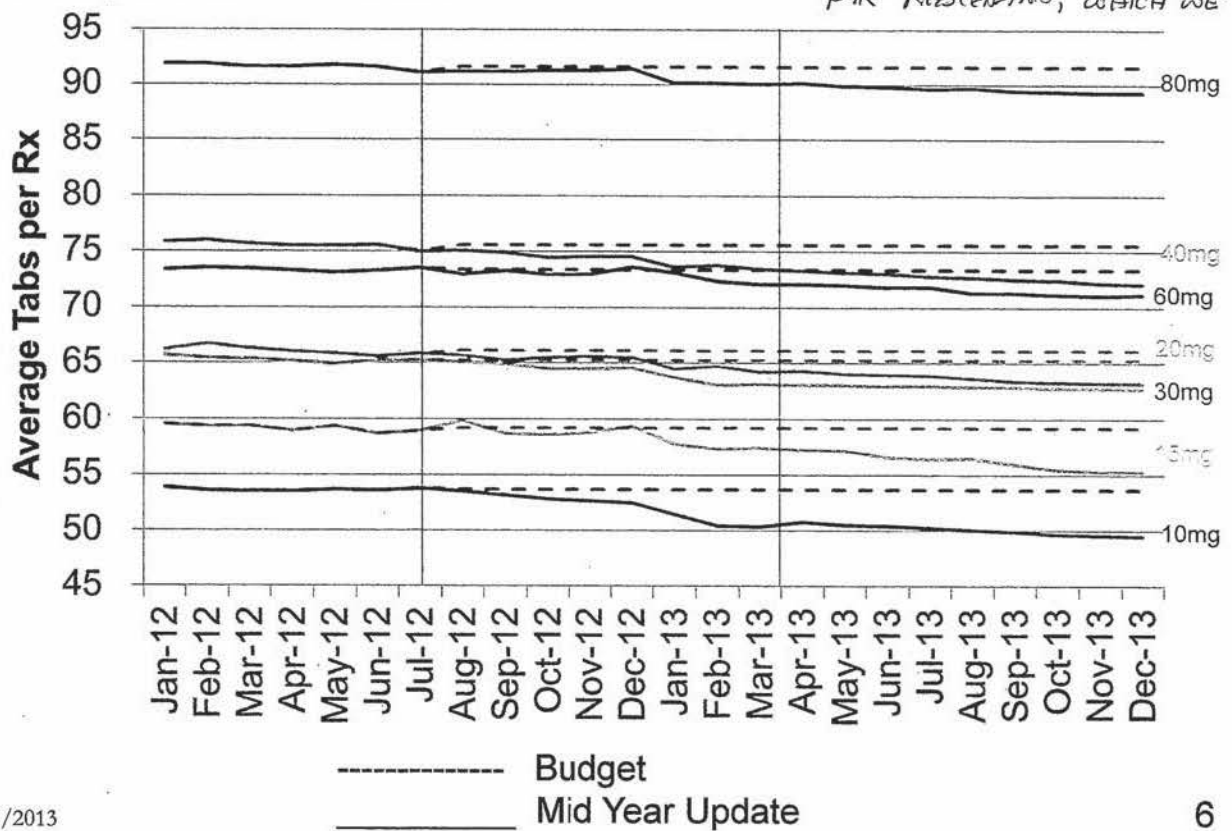
□ \$ 4 million due to (fill in please)

Reconciliation of OxyContin sales from Budget to <sup>LATEST ESTIMATE</sup> ~~actual/forecast~~  
~~due to the following~~ more detail in the following pages

	Year to Date April <del>2013</del>		Full Year Latest Estimate vs. Budget	
	\$ millions	%	\$ millions	%
<b>Budget</b>	<b>\$961</b>	<b>100%</b>	<b>\$2,916</b>	<b>100%</b>
Number of Tablets per script lower than Budget	(\$21)	(2.2%)	(\$79)	(2.9%)
Lower total scripts than Budget	(\$11)	(1.2%)	(\$110)	(3.4%)
Impact of mix and in particular lower sales of higher strengths	(\$25)	(2.5%)	(\$79)	(2.8%)
Other	(\$4)	(0.5%)	\$0	(0.1%)
<b>Sub-total demand</b>	<b>(\$61)</b>	<b>(6.4%)</b>	<b>(\$268)</b>	<b>(9.2%)</b>
Impact of Trade Inventory Contraction	(\$101)	(10.5%)	(\$95)	(3.3%)
<b>Total Variance to Budget</b>	<b>(\$162)</b>	<b>(16.9%)</b>	<b>(\$363)</b>	<b>(12.4%)</b>
<b>Actual / Latest Estimate</b>	<b><u>\$799</u></b>	<b><u>83.1%</u></b>	<b><u>\$2,553</u></b>	<b><u>87.6%</u></b>

AWAITING INFO FROM DAVID R & KIM BEFORE "LOCKING - DENW" 5

Reducing the number of tablets per script is being advocated by Managed Care, PROP and others. In January ~~we saw a dramatic reduction~~ <sup>there was</sup> ~~and we now forecast~~ <sup>in the number of tablets</sup> ~~PROJECT~~ <sup>per prescription, which we</sup> will for these pressures to continue.



5/21/2013

This decline in tablet per script is also impacting major competitors

Product	Jan 12 - Feb 13 Tab Per Rx Trend	Avg Tab Per Rx Jan - Feb 2012	Avg Tab Per Rx Jan - Feb 2013	Difference
OxyContin		69.4	66.8	-2.6
Generic 2x per day morphine		69.4	68.1	-1.2
Kadian + generics		59.1	58.9	-0.2
Avinza		44.2	44.4	0.2
Opana ER + generics		67.3	65.1	-2.2
Methadone		148.6	143.0	-5.7
Exalgo		46.0	43.5	-2.6
ERO Market (oral solids)		86.0	82.5	-3.4

Product	Jan 12 - Feb 13 Tab Per Rx Trend	Avg Tab Per Rx Jan - Feb 2012	Avg Tab Per Rx Jan - Feb 2013	Difference
IR oxycodone		106.3	101.4	-4.8
oxycodone combos		63.4	63.7	0.3
hydrocodone combos		57.0	58.3	1.3



<sup>E</sup>  
 This decline in tablets per script is projected to reduce 2013 gross sales by \$78.8 million vs. budget

	Tablets per Rx			Variance Budget versus Forecast			
	YTD April	Full Year		Tablets	%	\$ Millions	%
		Budget	Forecast				
10mg	50.7	53.6	50.2	-3.4	-6.3%	\$ (8.9)	-6.3%
15mg	57.4	59.2	56.5	-2.6	-4.5%	(1.7)	-4.5%
20mg	63.3	65.3	63.0	-2.3	-3.5%	(13.5)	-3.4%
30mg	64.4	66.1	63.8	-2.2	-3.4%	(7.7)	-3.2%
40mg	73.5	75.5	72.9	-2.6	-3.5%	(20.5)	-3.4%
60mg	72.4	73.3	71.7	-1.6	-2.2%	(7.8)	-2.0%
80mg	90.1	91.6	89.7	-1.8	-2.0%	(18.6)	-1.8%
<b>Total*</b>	66.6	69.0	66.1	-2.9	-4.2%	\$ (78.8)	-2.8%

\*Tablets per Rx total is a weighted average.

12  
↓

~~Potential~~ Causes of the decline in tablets per script are being ~~immediately~~ researched to quantify impact and ~~design appropriate~~ corrective actions IDENTIFY

- Potential increased and more aggressive ~~use~~ <sup>ENFORCEMENT</sup> of quantity limits ~~enforced~~ by managed care organizations
- Potential impact of PROP's ~~tactics~~ <sup>MESSAGING</sup> and other ~~environmental changes~~ <sup>FACTORS</sup> discouraging ~~the~~ use of opioids
- Medicare Part D opioid drug utilization review program for 120mg morphine equivalent Rx's
- Increased DEA/law enforcement scrutiny of physicians, pharmacies and wholesalers
- ~~Potential~~ Impact of Walgreens pharmacists calls to physicians to verify C2 prescription details

Year to date scripts are ~~running~~ 1.2% behind budget. By the end of the year scripts are forecast to be 3.9% behind budget. At the budgeted value per script, this is projected to result in \$110 million ~~in sales lower than~~ budget.

^  
A

AVERAGE

SHORTFALL FROM

2011 Actual Scripts	2012 Actual Scripts	Actual YTD April Scripts	YTD Budget Scripts	Script Variance	Variance %	Full Year Budget Scripts	Full Year Forecast Scripts	Script Variance	Variance %
6,481,879	6,197,937	1,978,294	2,001,958	(23,664)	-1.2%	6,037,235	5,804,624	(232,611)	-3.9%

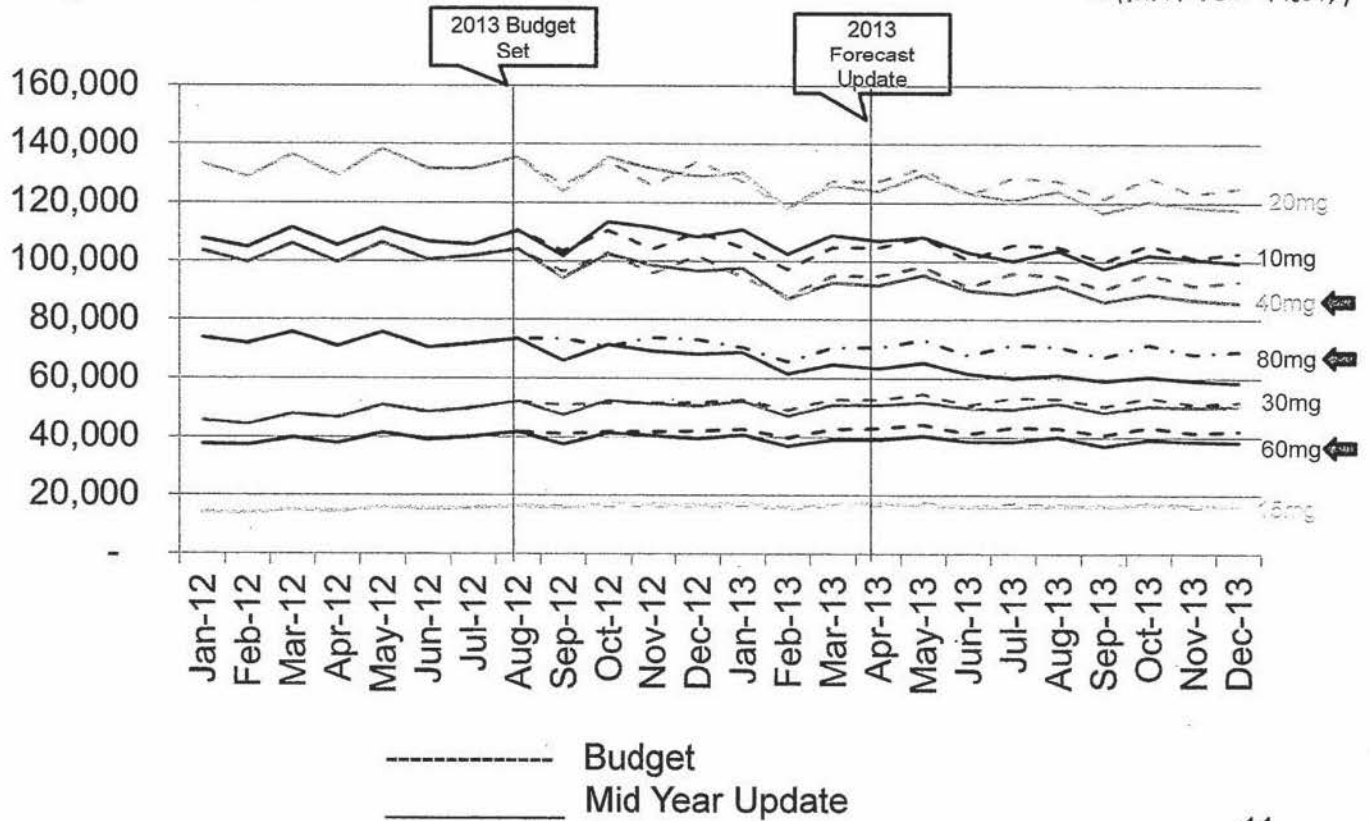
Budget price per Rx \$ 468.70

Budget price per Rx \$ 472.91

Variance due to lower scripts \$ (11,091,451)

Variance due to lower scripts \$ (110,003,799)

Scripts of the higher ~~my name~~ strengths are ~~filling~~ *DECLINING THE MOST RAPIDLY.* This is changing the mix of prescriptions by strength, and is projected to result in \$79 million in sales ~~lower than~~ *AN ADDITIONAL SHORTFALL FROM* budget.



Potential Causes of <sup>THE</sup> decline in scripts --- especially the higher strengths

- Direct switches from other products to the 80mg strength (in particular) are declining ~~rapidly~~ (6 months ended Feb 2013 versus previous 6 months ~~saw~~ a decline of 30.8%). ~~Underlying causes are being researched~~ <sup>SHOWED</sup>
- Titration up to higher strengths, especially the 40mg and 80mg strengths is declining. ~~Underlying causes are being researched~~ <sup>TO</sup>
- Potential causes which are being researched:
  - ~~on PROP and environmental changes~~
  - State and Medicare mg equivalent limits
  - Increased coinsurance/higher deductibles for employees
  - Increased DEA/law enforcement scrutiny of physicians, pharmacies and wholesalers
  - OxyContin primary sales calls ~~in the last 4 months being 40%~~ below budget. This is likely impacting scripts because ~~the~~ calls ~~are~~ <sup>are</sup> having a positive impact. For example,
    - The loss in higher ~~strengths~~ in called on physicians is 33% ~~lower~~ <sup>LOWER</sup> than those not called on.
    - High dose prescribing grew in physicians we began calling over the last year.

## Planned Analyses

POTENTIAL IMPACT OF

- ~~Study~~ reducing number of calls/quarter <sup>ON</sup> to highest prescribing physicians, and initiate <sup>ION OF</sup> calls <sup>ON</sup> to physicians not currently reached.
- ~~Undertake~~ Analysis to determine what physician characteristics are associated with lower tabs/Rx and ~~higher dose volume~~. *lower strength/Rx*
- ~~Undertake~~ health plan ~~level~~ analysis to determine the extent to which individual plans are driving ~~the~~ changes in number of tablets/script, lower scripts, strength mix.
- ~~Evaluate/monitor the~~ Impact of generic Opana ER
- ~~Study~~ How lack of patient access to pain medications impacts healthcare costs. For example, reports of an increase in ER visits.
- ~~Undertake research to determine impact of PROP, Walgreens pharmacy actions and DEA actions.~~
- ~~Undertake physician level analysis of the impact of local PROP activity.~~

## Planned Actions

- Ensure <sup>THE</sup> sales force <sup>DELIVER</sup> ~~achieve~~ the budget number of primary OxyContin sales calls.
- Implement Marketing Initiatives
  - "Individualize the Dose" campaign
  - Titration – via iPad case studies
  - Reiterate patient savings programs/managed care formulary messaging
- Continue publishing impact of <sup>THE</sup> abuse deterrent <sup>FORMULATIONS</sup> ~~formula~~ on ~~abuse~~ and cost to ~~society.~~ <sup>INFORMATION ON THE</sup>
- Actions will be ~~also~~ <sup>also</sup> implemented where analyses ~~performed~~ <sup>performed</sup> indicate.

Trade Inventory contraction in 2013 is now estimated at \$131 million versus budgeted contraction of \$36 million

- ~~End of year wholesaler inventory was higher than expected at 37 days.~~ We estimate that wholesaler inventory will return to 28 days by the end of 2013. The result is a reduction from \$296 million at end of 2012 to \$250 million at end of 2013 (inventory at the end of April was \$246 million).
- Pharmacy inventory is expected to reduce from \$239 million (31 days) at the end of 2012 to \$154 million (20 days) at the end of 2013. Inventory at end of April 2013 was \$192 million. Reductions are due to:
  - CVS and Walgreens have made public announcements targeting inventory reductions of \$1 billion and \$360 million, respectively.
  - Walgreens switch ~~from self warehousing to Cardinal~~ to ABC to improve store service levels. As a result ~~of~~ Walgreens closed their Perrysburg distribution center. ABC is moving Walgreens pharmacies from a 3 times to a 6 times a week delivery schedule.
  - Like Walgreens other chains are increasing their reliance on wholesaler just in time deliveries to reduce carrying cost ~~of higher priced branded products.~~
  - Fewer stores are purchasing / stocking OxyContin -- in 2011, 2012 and YTD 2013 -- 28,817, 24,744 and 22,823 stores, respectively, purchased OxyContin.
  - ~~Outside~~ Consultants have reported other clients having similar levels of inventory contraction.



# Exhibit 8

# PMR #3075

Purdue, One Stamford Forum, Stamford, CT 06901-3431

Product Managers, PMRs for quarterly visual aids should be accompanied by draft of instruction sheet for rep. which describes purpose, features, benefits and audiences.

<b>Brand</b>	<b>OxyContin</b>	<b>Job #</b>	_____
<b>Description</b>	<b>OxyContin Campaign Refresh for 2014</b>	<b>Lit. Code</b>	_____
<b>PMR Date</b>	9/12/2013	<b>FDA Code</b>	POT
<b>Requestor</b>	R. Cadet	<b>Budget Code 1 (non taxable)</b>	208-611210-8600ORF (non taxable)
		<b>Budget Range</b>	73,500.00
		<b>Budget Year</b>	2013
		<b>Print Due Date</b>	2/1/2014
		<b>Act Plan Qtr</b>	
		<b>Quantity</b>	1

## Physical Characteristics:

Format	Other
Colors	Black
Paper Stock	Glossy Finish, Cover Weight

## Handling of Disclosure:

N/A

## Shipping Instructions:

Band	None
------	------

## Literature List Category Heading:

## Creative Brief:

PURPOSE of PMR:

Evolve the current OxyContin creative campaign, "Individualize the Dose" to address an emerging market dynamic  
HCPs

WHO Audience:

WHAT Message:

WHERE it will be used:

PROMO statements:


Promotion

Estimate and Creative Brief

## DESCRIPTION

Status:	New Item
Develop Job:	Outside
Agency:	Rosetta

## SIGNATURES

	9/12/13
Requestor	Date
Director, PM	Date
VP, Marketing	Date
Mrkt. Services Manager	Date
Group VP	Date
Sr. Traffic Coordinator	Date
Exec. Dir. Creative Services	Date

## COST ESTIMATE

Outside Art: \$	_____
Agency:	_____
Printing: \$	_____
TOTAL: \$	_____

## SPECIAL APPROVAL

Requestor	Date
Director, Marketing	Date
VP, Marketing	Date
Group VP	Date

## Routing

# ROSETTA

## Creative Brief

Date: 9/3/13

Client Account: Purdue OxyContin

Client Contact: Ron Cadet

Project Name: Campaign Refresh

Account Contact: John Dwyer/Michele Ferrall

Rosetta Job #: PUROXC13SIRXXXXX

SOW Line item: start 2014 projects in 2013

PO: 4500069913

### Background

The mean patient dose of OxyContin has fallen significantly over the past several years. This is happening across all EROs. We have established this is *not* a managed care-driven phenomenon.

The consensus opinion is that many prescribers— despite deciding to treat with an ERO— are ever more cautious and conservative with the starting dose, and reluctant to increase it when additional analgesia is clinically indicated. As a result, it stands to reason that today many patients' pain is being treated sub-optimally.

It is also important to note that the current conversion/dosing recommendations currently listed in the FPI are extremely conservative in comparison to the previous conversion ratios. Thus making it difficult to provide HCPs with guidance on how to convert patients to OxyContin from other opioids.

### Objectives

Evolve the current OxyContin creative campaign, "Individualize the Dose" to address an emerging market dynamic

### Assignment

Agency to present 5-7 concepts in "adcepts" format. Of the presented concepts the client will choose 3-4 to take into testing. This estimate includes time for minor revisions to be made prior to testing. This estimate also includes time for revisions to final concept to reflect research findings. It does not include time (or OOPs) required for a photoshoot. It also does not include time for attendance (or watching) market research. Message refresh work will also be covered under a separate SOW.

### Executional Mandatories

As the creative campaign, this evolution will live across all promotional materials (online and offline). Agency to leverage people/pill imagery look and feel as much as possible.

### Timing

Detailed timeline to come.

**Estimate**

Expense Type	Hours	Cost
Copy	150	\$ 20,625.00
Art	275	\$ 37,812.50
Editorial	20	\$ 2,750.00
Project Management	75	\$ 10,312.50
Subtotal of internal expenses	520	\$ 71,500.00
Out of Pocket	FedEx & Color Proof	\$2,000
Total Project Cost		\$ 73,500.00

*RES*  
9/12/13



## Cover Sheet

CLIENT	Purdue	PROJECT	Creative Campaign Evolution
BRAND	OxyContin	DAY-TO-DAY CONTACT	Michele Ferrall
DATE	August 27, 2013	JOB NUMBER	
TIMING	Insert full project timeline		
SCOPED CCX HOURS			

BRIEF TYPE

CONCEPTUAL

X

EXECUTIONAL

REVISIONS

### CREATIVE BRIEF APPROVALS (SIGNATURES REQUIRED)\*

ACCOUNT LEAD		PLANNING LEAD	
CREATIVE LEAD		CLIENT	

\* NO WORK CAN BEGIN UNTIL BRIEF IS SIGNED BY ACCOUNT, CREATIVE, STRATEGIC PLANNING AND CLIENT LEADS

#### CREATIVE TEAM CONTACT LIST

CD	A. Reichenberg / J. Drosnes / S. Sager
AD	Otto Soontarodom
CW	Paul Lucas

#### DEVELOPMENT TEAM CONTACT LIST

UX LEAD	NA
UID LEAD	NA

#### SEARCH/MEDIA CONTACT LIST

MEDIA LEAD	Eileen O'Brien
------------	----------------

#### CRM CONTACT LIST

CRM LEAD	Alvaro Luna
----------	-------------

#### ACCOUNT TEAM CONTACT LIST

ACCOUNT DIRECTOR	Michele Ferrall
ACCOUNT MANAGER	Pamela Fishman
PM	Kristen Byvoets

#### TECH TEAM CONTACT LIST

TECH LEAD	NA

#### SOCIAL MEDIA CONTACT LIST

SOCIAL MEDIA LEAD	NA
-------------------	----

#### REPORTING CONTACT LIST

REPORTING LEAD	
----------------	--

ROSETTA

Pilots, inventors and builders for a connected world.™





# Conceptual Creative Brief

## BACKGROUND

### ASSIGNMENT: What have we been tasked with?

Evolve the current OxyContin creative campaign, "Individualize the Dose" to address an emerging market dynamic

### MEASURABLE IMPACT: How are we defining success?

Shift in trend of declining mean dose of OxyContin

## CHALLENGE

The situation, problem or behavior we are addressing, changing, challenging or solving:

The mean patient dose of OxyContin has fallen significantly over the past several years. This is happening across all EROs. We have established this is *not* a managed care-driven phenomenon.

The consensus opinion is that many prescribers—despite deciding to treat with an ERO—are ever more cautious and conservative with the starting dose, and reluctant to increase it when additional analgesia is clinically indicated. As a result, it stands to reason that today many patients' pain is being treated sub-optimally.

It is also important to note that the current conversion/dosing recommendations currently listed in the FPI are extremely conservative in comparison to the previous conversion ratios. Thus making it difficult to provide HCPs with guidance on how to convert patients to OxyContin from other opioids.

## BRAND

The idea, belief or behavior that anchors the brand, that we are to leverage to solve the challenge:

With the flexibility of 7 dose strengths, OxyContin can be finely individualized to the analgesic need of a patient throughout his or her treatment.

## AUDIENCE INSIGHT

The focused truth about your audience that we are to leverage? The belief, motivation, need, behavior, or feeling that can be exploited.

Prescribers want to effectively treat their patient's pain. And they believe they still do. But they are clearly responding to pressure to be cautious and conservative with opioid treatment. This is appropriate and responsible. But prescribers need to be reminded that patients in pain deserve effective analgesia, and that requires fine tuning dosage throughout treatment.

To effectively manage patient pain, a HCP needs to ask the patient how they feel. We hypothesize they are not asking because it would require them to respond by titrating when they would rather not and often times are pressed for time and therefore don't ask.

## TRANSFORMATIVE IDEA

### THE STRATEGY: The plan, method, or series of maneuvers for obtaining specified goal

Remind prescribers that effectively treating pain means ongoing patient assessment to inform ongoing dose adjustments (first).

Reinforce the ability to Individualize analgesia with the flexibility of 7 available doses of OxyContin

### THE IDEA: The form the strategy will take

The right dose, at the right time, for the right patient.



## EXECUTIONAL CONSIDERATIONS

### Channel/Program Requirements: Where will this idea live and any thought starters?

As the creative campaign, this evolution will live across most promotional materials, from the print ad to HCP eMarketing initiatives to trade communications

### Client/Brand/Audience Considerations: Client mandates copy/imagery needs and assets and audience watch outs

- Leverage people/pill imagery look and feel
- This is intended for prescribers only– not patients
- Develop in landscape “adcepts” format

## S>T>A>R>T

**Supplement**  
with IR analgesic

**Titrate**  
every 1-2 days

**Adjust**  
dose 25%-50%

**Reassess**  
pain

**Tailor**  
dose

### **S**upplement with an immediate-release analgesic, such as:

- IR oxycodone for patients being converted to OxyContin from other opioids to manage inadequate analgesia
- IR opioid or non-opioid medication for patients who experience breakthrough pain that may require rescue medication

### **T**itrate every 1-2 days as needed

- Steady-state plasma concentrations are approximated in 1 day

### **A**adjust the dose by 25%- 50%

- Total daily dose usually can be increased by 25% to 50% of current dose as clinical need dictates while maintaining q12h dosing

### **R**eassess the patient's analgesia and tolerability throughout treatment

- If the level of pain increases, attempt to identify the source of increased pain, while adjusting the OxyContin dose

### **T**ailor the dose based on the reassessment, titrating up or down

- If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced
- Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions





## Individualize the dose



Tablets not actual size. Not actual patients.

### Q12h OxyContin Tablets

Available in 7 tablet strengths to meet the individual therapeutic needs of your appropriate patient



# Exhibit 9



## Health Policy Memorandum

**Date:** 9 July 2009

**From:** J. David Haddox, DDS, MD

**To:** John H Stewart

**CC:** Board of Directors

**Re:** Massachusetts General Hospital (MGH) Purdue Pharma Pain Program

---

This memo was prepared at the request of Dr. Raymond, who asked me to review the situation as it developed with the MGH and to provide a basis for dealing with the remainder of this grant commitment.

### Background:

An Agreement between Purdue Pharma L.P. (PPLP), MGH and Harvard Medical School (HMS) became effective on 24 September 2003. The Agreement had several provisions, which are summarized in Appendix 1. In brief, the situation is that a Purdue Pharma Fund for Pain Education and Research was established and Purdue has made payments totaling \$1.5 million of the total funding commitment of \$3.0 million - with funding being suspended in 2003 due to the company's financial situation. Now that the financial situation has improved, the question arises as to whether or not we should restart the funding - presumably at the level of \$500,000 for each of 2009, 2010 and 2011 - which would complete our obligation.

### Meetings and Personnel Update:

Although the funding by Purdue has not been restarted, several of the contract-defined interactions between the Program and PPLP have occurred, including visits by the then-Chair of the Department of Anesthesia and Critical Care (DACC), Dr. Warren Zapol, and the then-Director of the MGH Purdue Pharma Pain Program (hereinafter, "the Program"), Dr. Jane Ballantyne to Purdue, and a few visits by Purdue staff to MGH. In addition, I have personally met with various physicians involved in the Program and attended some of the required committee meetings.

The leadership of the DACC and the Program has changed since the Agreement was executed. The new DACC Chair, who I have yet to meet, is Jeanine Wiener-Kronish, MD, who is board-certified in Internal Medicine, Pulmonary Medicine, Critical Care Medicine and Anesthesiology. Her clinical interests include Critical Care Medicine and preoperative assessment. Her research interests include *Pseudomonas aeruginosa* pulmonary infections (a significant complication following lung surgery) and the molecular identification of bacteria.

The new Director of the Program is James P. Rathmell, MD, Chief, Division of Pain Medicine and Associate Professor, HMS. I have known Jim for well over a decade. He is very active in the anesthesiology-pain community, including being an examiner for the American Board of Anesthesiology, a member of the Anesthesiology Residency Review Committee of the Accreditation Council on Graduate Medical Education, an Associate Editor of *Anesthesiology* (the premier publication in the field, and the

official organ of the American Society of Anesthesiologists) and the Associate Editor-in-Chief of *Regional Anesthesiology and Pain Medicine* (the official organ of the American Society of Regional Anesthesia). I have met with Jim in his capacity as the new Director of the Program and he is eager to have John Stewart and me meet with him and Dr. Wiener-Kronish - to update us on the Program's progress and potential future activities. Dr. Rathmell also raised with me the issue of Purdue's resumption of payments toward the fund/project.

### **Progress of the Program:**

Specific accomplishments of the Program to date include:

The official designation of the MGH Purdue Pharma Pain Program, including a plaque displayed in the MGH Center for Pain Medicine.

MGH publishes a series colloquially referred to as "the Handbooks." These are quite popular with medical students and residents - and provide an in-depth, outlined-based approach to a particular discipline, such as Psychiatry or Surgery. The following is an exact quote of the Acknowledgement page of the third edition of the Massachusetts General Hospital Handbook of Pain Management (© 2006):

"We are greatly indebted to Purdue Pharma for their generous and unrestricted grant toward establishing the MGH Purdue Pharma Pain Program. Purdue's support strengthens our academic mission and is a mark of their recognition that discovery and knowledge form the foundations of good clinical care. Purdue has been committed to promoting appropriate pain management for more than two decades, working closely with MGH and a number of other organizations to increase awareness of the problem of persistent pain and its cost to individuals and to society."

As of the last written report, dated 22 May 2005, the MGH Purdue Pain Program had offered approximately 200 lectures to various MGH groups, including palliative care, internal medicine, neurology, neurosurgery, psychiatry and pharmacy, as well as anesthesia. Other medical institutions, such as the Tufts University Schools of Medicine and Dentistry, and the Boston Pain Forum (an informal collaborative of persons in the Boston health care community with interests in pain care and research), have often attended these lectures.

There has also been an effort to create an active educational collaboration between the Program and Beth Israel Harvard Review Course in Pain Medicine (in which I have lectured on several occasions), to increase the visibility of the Program.

The Program has been studying ways of predicting risk in patients receiving opioid analgesics, has been tracking outcomes of non-cancer patients receiving opioid analgesics, and has conducted a survey of physician attitudes towards opioid prescribing (the results of which I do not have). The Program also has put out a newsletter (*Pain Management Frontline*) that is typically devoted to a pain topic and includes brief summaries of articles of interest, as well as notices of upcoming meetings. In each of these newsletters, PPLP's support is acknowledged, per the Agreement.

Perhaps the most significant achievement of the Program to date is the award of a multi-year NIH grant to fund translational research on the effects of opioid analgesics correlating basic science research with clinical use, based on pilot studies made possible by the monies from PPLP.

### **Observations:**

MGH has been very understanding of our commercial situation, but is interested in our reactivating the schedule.

The Boston media created a frustrating series of stories when they learned of the grant, insinuating that Purdue was going to be controlling the educational content offered by the Program, which, of course, is neither allowed nor is it in any way Purdue's intent. The New England Journal of Medicine joined the fray, suggesting that it might not publish any research that came out of the program, implying that Purdue's funding created too great a conflict of interest for the research conclusions to be unbiased.

At the time of the press assault on our funding of this project, the individuals at MGH and Harvard who had responsibility for the Program were essentially silent in defending the agreement and in pointing out both its propriety and the enormous public health interest it supported. Those individuals (who disappointed us at that time) are no longer involved with the Center, and I believe their successors see the project's great value, are committed to it, and will continue its progress in the manner we contemplated at the outset.

There has been a great deal of legislative activity/debate in Massachusetts around the issues of whether or not OxyContin® (oxycodone HCl controlled-release) Tablets should remain available to persons in the Commonwealth. Some legislators have suggested that the product should be classified as a banned substance under the Commonwealth's controlled substances regulation – in the same class as heroin and LSD – by introducing a total of five bills to this end. Alan Must and I testified at the *Massachusetts OxyContin and Other Drug Abuse Commission* (that became known in the media as the OxyContin Commission) several years ago. In the most recent legislative session a newly-formed *OxyContin and Heroin Commission* has been active; evidence that the legislative focus on Purdue and OxyContin continues (see Appendix 2). I believe that these activities are relevant, since our actions regarding the continued support of this project may have an impact on those in the legislature. I fear that a termination of support might fuel the efforts of those already hostile to us, or reduce the willingness of those who have supported our positions to continue to do so.

#### **Recommendations for Consideration:**

Dr. Rathmell has indicated a willingness to meet with representatives of PPLP to discuss the way forward. I think it would be worthwhile for you and I to make a trip to Boston to meet with Dr. Rathmell and Dr. Wiener-Kronish, along with Dr. Jianren Mao, the lead basic researcher in the Program, to chart the future of this grant. I think there is the potential for excellent, relevant science to derive from our funding of the Program. However, I believe that we should only meet with MGH representatives if we are prepared to restart the funding to the Pain Program - unless our visit raises issues of concern.

I welcome the opportunity to hear your thoughts.

## Appendix 1

### Summary of the Agreement between PPLP, MGH and HMS

The Agreement established the Harvard Medical School Purdue Pharma Fund for Pain Education and Research (hereinafter, "the Fund").

The Fund was to be created from \$3,000,000 cash from PPLP, payable according to the following schedule:

\$1,000,000 paid on 18 January 2002, acknowledged in the schedule as part of the \$3,000,000 commitment.

\$500,000 within 15 days of execution of the Agreement, paid on 1 October 2003.

\$500,000 due in December 2003; still outstanding

\$500,000 due in December 2004; still outstanding

\$500,000 due in December 2005; still outstanding

The purpose of the Fund is to support pain-related projects through the Program, which is currently housed in the MGH Department of Anesthesia and Critical Care (DACC). Specifically, the Fund is to be used for recruitment and salaries, equipment and capital needs, and on-going educational or research programs or projects within the Program. An amount of the Fund, not to exceed 15% (\$450,000), can be used as defray overhead expenses.

The details of any specific educational program are overseen by an Educational Program Committee (EPC), comprising the DACC Chair, three (3) members of the HMS faculty selected by the DACC Chair in consultation with the Dean of the Faculty of Medicine HMS (hereinafter, "the Dean"), and one person appointed by PPLP. Historically, I have been the PPLP appointee.

The EPC makes recommendations for funding educational programs to an Oversight Board (hereinafter, "the Board"), of no more than five (5) members, which is responsible for overall administration of the Fund. This Board is constituted as follows: The Chair is the DACC Chair; one member shall be the President of MGH or his/her designee; with the remainder being HMS faculty chosen by the DACC Chair in consultation with the Dean. Members of the Program, the MGH Pain Center and, with the exception of the Chair, the EPC are not eligible to sit on the Board. In making decisions, the Board shall consult with a person designated by PPLP, provided that such consultation is purely advisory and all final decisions shall be made by the Board. Historically, I have also been that PPLP designee. The Board was envisioned to meet quarterly and to provide PPLP with a comprehensive annual update that provides a detailed outline of how monies from the Fund were expended.

It also established, in perpetuity, the MGH Purdue Pharma Pain Program (hereinafter, "the Program"). The Program's obligations under the Agreement include:

The Director of the Program shall be appointed by the DACC Chair.

The area to be utilized by the program is to be marked with a plaque, to remain in perpetuity, that bears the name of the Program.

Any publications, programs or public events resulting from the Program shall publicly and conspicuously identify its relationship to the Fund or the Program.

Other provisions of the tri-lateral Agreement included:

Neither party may publicly disclose the terms of the Agreement or contributions thereto without consent of the other.

If, in the judgment of HMS or MGH, it becomes impossible or impractical to expend the Fund in the manner envisioned in the Agreement, the principal and any interest can be used for similar purposes, as determined by the Dean with the advice of MGH Trustees.

The Agreement supersedes any other letters, Agreements, etc. between PPLP and HMS or MGH.

The Agreement cannot be modified, except with the written, signed Agreement of party that is bound by the modification.

## Appendix 2

### Recent Media Accounts of the OxyContin and Heroin Commission

#### ***OxyContin and Heroin Commission Officials tackle drug problem***

By David Pepose

Posted: 06/01/2009 01:01:15 AM EDT on:

[http://www.thetranscript.com/ci\\_12492202](http://www.thetranscript.com/ci_12492202)

*North Adams Transcript (New England Newspapers)*

PITTSFIELD -- Officials will analyze a statewide drug problem at Berkshire Community College on Friday, as the Massachusetts OxyContin and Heroin Commission will be holding their third hearing.

"It is an enormous problem in the Commonwealth, and one that often doesn't receive the attention that it should," said State Sen. Benjamin B. Downing, D-Pittsfield. "This is not so much a public safety issue, but rather a public health issue, and we need to address that in that way."

According to Downing, there were more than 3,300 opioid-related overdoses in Massachusetts between 2002 and 2007. The National Drug Intelligence Center stated in May that overdoses cost medical insurers an estimated \$72.5 billion per year.

"The key is bringing light to the issue that is out there, an issue that is statewide," Downing said. "It's about access to a drug that is taken without supervision that can not only become addictive, but kill individuals."

"I would say that the abuse of prescription medications is the fastest growing form of substance abuse that we're seeing," Berkshire County District Attorney David Capeless said.

"Despite the fact that we in the commission are focusing on drugs which are extremely dangerous, there is a perception that because of their initial use as medication that they are considered 'safe,' " he added. "In fact, they are still as dangerous as heroin or cocaine."

Dr. Alex Sabo, chairman and program director of the Department of Psychiatry and Behavioral Sciences at Berkshire Medical Center, agreed. "The No. 1 initiate drug is prescription pain relievers -- this is past even marijuana," he said.

To fight this war at home, the Berkshire County District Attorney's Office, as well as law enforcement officials and Berkshire Health Systems, has put together what Sabo calls the Community Pain Management Initiative.(sic)

"We've put together nonaddictive options for pain treatment," he said, including the Brien Center's buprenorphine (sic) clinic, an alternative to methadone that helps addicts wean themselves from opioids without getting an addictive euphoric high.

Among the systems being prescribed is an electronic prescription system, "to make sure that people don't 'doctor shop,' don't go to four different doctors, four different pharmacies."

Sabo hopes that this hearing will both bring in additional funds for fighting opioid abuse, as well as showcase the more innovative methods Berkshire County has employed.

"The drugs have a very narrow margin of safety -- that's what its (sic) so important," Sabo said. "It's going to cost money, but we think solving this problem will reduce the overall price to society dramatically."

***Heroin, OxyContin commission in city Friday***

By Will Richmond

Posted May 14, 2009 @ 09:19 PM on:

<http://www.heraldnews.com/archive/x1518881096/Heroin-OxyContin-commission-in-city-Friday>

*The Herald News*

Fall River — A legislative commission analyzing the state's growing rate of heroin and OxyContin addiction will be in the city today.

Sen. Joan Menard's office announced the Massachusetts OxyContin and Heroin Commission will hold the third in a series of hearings at the University of Massachusetts Dartmouth's Advanced Technology and Manufacturing Center at 11 a.m.

The Massachusetts OxyContin and Heroin Commission was created during the 2007-2008 legislative session and will hold regular public hearings across the commonwealth through August. The group is chaired by state Sen. Steven A. Tolman, D-Boston.

Public attendance and participation is vital, according to Menard's office, as the commission needs to hear the public stories and experiences to develop relevant policy recommendations. The commission will release a final report of its findings in the fall.

"Substance abuse is a vital public health concern in the commonwealth," Menard said. "The work of this commission will focus on the various elements of prevention, treatment and intervention. I am pleased that the commission is visiting the SouthCoast so that our region may also have an opportunity to participate in these important policy discussions."

Tolman said the Fall River hearing will provide an opportunity to a wide range of commenters from experts in the field to the general public.



# Exhibit 10

**To:** Sackler, Beverly[Beverly.Sackler@pharma.com]; Sackler, Jonathan[Jonathan.Sackler@pharma.com]; Sackler, Dr Kathe[Dr.K.A.Sackler@pharma.com]; Sackler, Dr Mortimer[mdsackler@chsquare.co.uk]; Sackler, Mortimer JR[msackler@pharma.com]; Sackler, Dr Raymond R[DrRaymondR.Sackler@pharma.com]; Sackler, Dr Richard[DrRichard.Sackler@pharma.com]; Sackler, Theresa[Theresa.Sackler@mdsackler.co.uk]; Sackler Lefcourt, Ilene[Ilene.SacklerLefcourt@pharma.com]; Boer, Peter[Peter.Boer@pharma.com]; Lewent, Judy[Judy.Lewent@pharma.com]  
**Cc:** Stewart, John H. (US)[John.H.Stewart@pharma.com]; Gasdia, Russell[Russell.Gasdia@pharma.com]; Kyle, Don[Don.Kyle@pharma.com]; Landau, Dr. Craig[Dr.Craig.Landau@pharma.com]; Dolan, James[James.Dolan@pharma.com]; Kaiko, Dr Robert[Dr.Robert.Kaiko@pharma.com]; Long, David[David.Long@pharma.com]; Rosen, Burt[Burt.Rosen@pharma.com]; Lundie, David[David.Lundie@pharma.com]; Mallin, William[William.Mallin@pharma.com]; Haddox, Dr. J. David[Dr.J.David.Haddox@pharma.com]; Strassburger, Philip[Philip.Strassburger@pharma.com]  
**Bcc:** Stewart, John H. (US)[John.H.Stewart@pharma.com]  
**From:** Mahony, Edward  
**Sent:** Tue 12/22/2009 5:01:35 PM  
**Subject:** Notes and Actions Follow Up from November Board Meeting  
2010 Budget Presentation Notes and Actions 12-22-09B sent to JHS (2).docx

At John Stewart's request, attached is a list of questions raised at the November Board meeting and answers or actions on each.

In certain cases, the action is for a presentation to the Board. Bill Mallin is scheduling those presentations into the 2010 Board calendar.

Regards,  
Ed

**Purdue Pharma L.P.**  
**Budget Presentation 2010 – November 2<sup>nd</sup> and 3<sup>rd</sup>, 2009**

**Notes and Actions**

---

**1.0    OxyContin**

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

**A:**

- i. Response to questions i-v were provided to Dr. Kathe and Dr. Richard by e-mail from Mike Innaurato 12/3/09 13:45h – copy attached.



MI FW 2010 Budget  
v10 0 revised order\_1



2010 Budget v10 0  
revised order (2).ppt



LASEO OER and Oxy  
Historical Data (2).xls



Market Forecast  
100709 (2).xlsx



Nucynta Forecast v1  
0 summary (2).xlsx

- ii. The 2010 gross sales target has been increased by \$56 million due to expected delays in marketing of Covidien's Exalgo and Endo's significant reduction in S&P in support of Opana ER.
- iii. The McKinsey report referred to in question v. will be available in Q2 2010.

**Action: Russ Gasdia**

- b. **Q:** OxyContin Pediatric – provide the Board with a detailed update on the program, timing, impact on exclusivity and value created.

**A:** The R&D group is currently developing the OxyContin pediatric clinical program with input from the FDA to ensure that the trials can be executed on a timely basis and that the additional exclusivity is earned. Enrollment in the studies will likely begin in 1Q 2011. Once the studies are complete, submitted and accepted by the FDA, Purdue will apply the additional 6 month exclusivity to one of the patents then listed in the Orange Book – preferably the "042" patent.

- c. **Q:** Report back on the status of the development of a next generation formulation OTR (e.g. polycapalactone), including IP.

**A:** The Purdue research team is evaluating two new TR platforms – polycapalactone and eudrogit NE. The important next steps are to secure manufacturing capability, prepare small sample batches, and test prototype formulations. This project is budgeted in 2010, has adequate resources and detailed progress will be included in our R&D report to the Board in mid 2010.

**Action: Don Kyle**

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

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

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

Specific comments by product are:

- i. Opana ER has unfavorable alcohol sensitivity, elderly PK, hepatic PK, and food effects.
- ii. Duragesic needs to be titrated more slowly and has only 5 strengths.
- iii. Morphine products
  - a. Oxycodone has higher oral bioavailability
  - b. Oxycodone plasma levels are more predictably related to drug dosage.
  - c. Oxycodone bioavailability is less affected by age
  - d. Renal dysfunction has less of an influence on the disposition of oxycodone (the active metabolite, morphine-6-glucuronide accumulates with renal impairment)
  - e. Fewer hallucinations with oxycodone
  - f. Less pruritis with oxycodone
  - g. Have fewer strengths in the case of MS Contin and Avinza
  - h. Avinza has an alcohol effect in in-vitro studies
  - i. Kadian is not consistently either a 12 or a 24 hour product
  - j. MS Contin has pH dependency of delivery
- iv. Exalgo is not yet approved, so we do not yet know its details
- v. Nucynta does not have evidence of efficacy for the group of patients requiring high dose OxyContin. It also has the potential for serotonin syndrome, given its mechanism of action.

Methods of communication

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

- e. **Q:** Reconsider the 3% OxyContin price increase planned for 2010 – i.e. consider a higher price increase in recognition of the increased COGS and cost of royalties with OTR.
- A:** Over the last 3 years OxyContin list price has been increased a total of 23%. A further increase of at least 3% is anticipated in 2010. The logic for the proposed price increase will be discussed at that time, but management believes it is important not to have any price increase timed directly with the switch from the current to new OxyContin formulation. A history of recent OxyContin list price increases is attached.



Microsoft Office  
Word 97 - 2003 Docu

## 2.0 **BuTrans**

- a. **Q:** Compare proposed USA price (gross and net) with international prices by strength.

**A:** This analysis is underway as part of the overall BuTrans launch planning and will be reported in 2010 as part of the BuTrans review presentation.

**Action: Russ Gasdia**

- b. **Q:** Provide the Board with copies of the market research that supports the proposed pricing.

**A:** This analysis is underway as part of the overall BuTrans launch planning and will be reported in 2010 as part of the BuTrans review presentation.

**Action: Russ Gasdia**

- c. **Q:** Regarding the BuTrans pediatric program – provide the Board with a detailed update on the program, timing, impact on exclusivity and value created.

**A:** Successful completion of the pediatric studies will extend the patent life for the BuTrans product. For instance, it will extend the life of the 7-day patch patent from September 29, 2017 until March 29, 2018.

The Proposed Pediatric Study Request (PPSR), submitted as part of Purdue's complete response package sent to the FDA on September 30, 2009, describes 3 studies to be conducted in children between birth and 16 years of age. The 3 proposed studies are as follows:

- i. Study 1: A Multicenter, Inpatient, Open-label Study to Characterize the Pharmacokinetics, Safety, and Efficacy of a Continuous Intravenous Infusion of Buprenorphine in Children from Birth to up to 6 Years of Age Who Require Opioid Analgesia for Acute Moderate to Severe Pain
- ii. Study 2: A Multicenter, Randomized, Double-blind, Active Comparator-controlled, Multiple-dose, Titration Study with an Open-label Extension to Evaluate the Efficacy, Safety, and Pharmacokinetics of Buprenorphine Transdermal System (BTDS) in Opioid-

tolerant Children from 6 to 16 Years of Age Who Require Continuous Opioid Analgesia for Moderate to Severe Persistent Pain

- iii. Study 3: An Open-label, Multicenter Study of the Safety, Pharmacokinetics, and Efficacy of Buprenorphine Transdermal System (BTDS) in Opioid-naïve Children from 6 to 16 Years of Age Who Require Continuous Opioid Analgesia for Moderate to Severe Prolonged or Persistent Pain Anticipate up to 4 year enrollment periods, particularly for double-blind and open-label studies.

The third BuTrans™ patent U.S. 6,344,212, et. al. covers 7-day use of patches and expires Feb. 24, 2017 w/ possible pediatric exclusivity until Aug. 24, 2017. The final study reports for pediatric clinical trials conducted must be sent to FDA by no later than November 2015 to allow the FDA sufficient time to review the reports in support of exclusivity. As double-blind and open-label pediatric pain trials may take up to 4 years to enroll, the plan is to initiate work on the program immediately in order to have the potential to gain pediatric exclusivity.

Protocol development and the contracting process with PRA are targeted for completion by the PDUFA date (March 30, 2009). All tasks up to dosing of first subject are planned to be completed by September 30, 2009, consistent with an extended PDUFA date. \$4.5 M is currently budgeted for BuTrans™ pediatrics in 2010, sufficient to cover planned activities. The regulatory environment for pediatric study conduct and progress towards approval of BuTrans™ will be monitored closely as at-risk work proceeds.

- d. **Q:** In preparation for the launch, be sure the US Sales and Marketing group is fully aware of international marketing strategies and sales force activity.

**A:** Gary Lewandowski will meet with colleagues in markets where BuTrans/Norspan has been launched. The trip schedule is now being developed.

**Action: J. Stewart/R. Gasdia**

- e. **Q:** Report US sales projections vs. international sales history in both dollars and numbers of patches by strength.

**A:** This analysis is underway as part of the overall BuTrans launch planning and will be reported in 2010 as part of the BuTrans review presentation.

**Action: Russ Gasdia**

- f. **Q:** Explain the nature of the spend and output expected from the proposed \$6.9 mm BuTrans 2010 marketing spend.

**A:** The BuTrans 2010 budget of \$6.9 mm is for pre-DDMAC approval related expenses and is comprised of the following:.

- \$2.6 mm - Agency fees (Abelson Taylor)
- \$1.4 mm - Promotional items (sell sheets, brochures, presentations)
- \$1.4 mm – Market research
- \$1.2 mm – Advisory board and website development

- \$0.3 mm - REMS

### 3.0 Ryzolt

- a. **Q:** Ryzolt sales are far below expectations - the Board asked for an analysis of how/why this occurred.

**A:** Once December sales are available a final report/presentation will be developed for review with the Board - most likely in February 2010.

**Action: Russ Gasdia**

- b. **Q:** Evaluate converting Ryzolt primary position calls to secondary position calls starting 1Q 2010.

**A:** Subject to agreement with Labopharm, which we expect shortly, Ryzolt will be promoted in second position, behind OxyContin, in 1Q 2010.

**Action: Russ Gasdia**

### 4.0 POA

- a. **Q:** Provide the Board with results of POA 1001, when available.

**A:** Data will be circulated when available.

**Action: Craig Landau**

### 5.0 R & D General

- a. **Q:** Please evaluate developing CR hydromorphone & naloxone and CR hydrocodone & naloxone vs. CR single entity formulations of hydromorphone or hydrocodone.

**A:** In process.

**Action: BDC**

- b. **Q:** Include an update on the FAAH project in future R & D presentations.

**A:** Infinity's draft FAAH IND is under review at Purdue. An update on the FAAH project will be included in the next R&D update to the Board.

**Action: Jim Dolan**

- c. **Q:** Circulate the FDA DDMAC Embeda warning letter to the Board.

**A:** Attached is the warning letter.



Embeda Warning  
Letter 2009-10-08.pc

d. **Q:** Provide the Board with names and biographies of External Advisory Board members and plans for the Advisory board in 2010.

- A:** The External Advisory Board is made up of 15 specialists in the areas of pain management and sleep. Specialties represented are in alignment with our Comprehensive Analgesic Plan (and related therapeutic areas). The Comprehensive Analgesic Plan generally calls for expertise in:
- i. Management of pain secondary to osteoarthritis, surgery, chronic back disorders, fibromyalgia, and diabetic peripheral neuropathy
  - ii. Adjunctive and combination therapies to address opioid-induced adverse effects such as constipation, sedation, tolerance, and withdrawal
  - iii. Abuse liability and abuse-resistance
  - iv. Related therapeutic areas (e.g. sleep)

The Advisory Board is charged with providing external, unbiased recommendations regarding the clinical application/implications of new products/agents. Such expert commentary provides guidance regarding potential acquisitions and new drug development based on clinical unmet needs, new medical trends, and economic benefits.

Specifically: to provide expert opinion regarding:

- i. New product opportunities that Purdue is in the process of evaluating
- ii. Products currently under development by Purdue, as well as those already marketed by Purdue
- iii. Areas of unmet medical need for which new treatments might be acquired and/or developed and applied

So that we can make more informed decisions regarding:

- i. New product opportunities
- ii. Research and development
- iii. Education of health professionals
- iv. The development of long-range plans and a strategy to achieve our goals

The first face-to-face meeting of the board is scheduled for January 29<sup>th</sup>.

The members and biographies are attached



Microsoft Office  
Word Document



**Action: C. Landau/R. Kaiko**

- e. **Q:** R & D should develop metrics on industry wide FDA review performance (e.g. first cycle approval, etc.) and measure Purdue performance against those metrics.

**A:** In process

**Action: C. Landau, D. Long, E. Mahony**

- f. **Q:** The Board suggested holding an international R & D meeting focused on overall strategy and identification of new products.

**A:** John Stewart is working to arrange the meeting, with input from Craig Landau, Karen Reimer and Ake Wikstrom.

**Action: J. Stewart/C. Landau**

## **6.0 External Affairs**

- a. **Q:** What specific messages does Purdue want picked-up? How are those messages developed, what are those messages and how will they be presented to the target communities?

**A:** Burt Rosen will present this information as part of the upcoming CEAC presentation to the Board.

**Action: Burt Rosen**

## **7.0 Supply Chain**

- a. **Q:** The Noramco oxycodone API contract provides back-up to Rhodes, but at a cost to Purdue. How can Purdue ensure the same back-up protection, but at a lower cost?

**A:** This analysis will be coordinated with Rhodes and will be completed in late 2010, in time for contract renewal negotiations with Noramco. No new oxycodone API orders will be placed with Noramco until that negotiation is complete.

**Action: E. Mahony/D. Lundie**

- b. **Q:** Negotiate with LTS now to incorporate Rhodes Technologies API in the BuTrans patch once that API becomes available.

**A:** LTS just signed a new 5-year exclusive supply agreement with Tasmanian Alkaloids/Noramco. If Rhodes can manufacture buprenorphine, validate the process, generate drug substance/drug product stability in 3-4 years the timing may be good to negotiate the API switch at that time. The only other possibility is if DEA closes the borders to the importation of buprenorphine and Rhodes has API available and qualified sooner than Noramco.

**Action: B. Mallin/E. Mahony**

- c. **Q:** Can the Wilson plant serve as a Targin backup for Napp Laboratories?

Page 7 of 10

**A:** There are no technical reasons why Wilson could not serve as backup to Cambridge for supply of Targin. There may be regulatory and/or fiscal considerations that should be more fully explored.

d. **Q:** Report on development of a back-up supplier for polyethylene oxide. Consider Rhodes Technologies as a possible supplier.

**A:** To become a back-up supplier for polyethylene oxide, Rhodes would have to invest up to \$10mm in capital. Purdue supply chain is evaluating less expensive, but still very reliable third party alternatives. In the meantime, Purdue is keeping approximately 2 years safety stock.

**Action: David Lundie**

## **8.0 Finance**

a. **Q:** Explain the nature of the \$19.3 mm Discovery budget, particularly as it relates to the increase over the prior year.

**A:** The budget for Discovery Research in 2010 of \$19.3 mm comprises the following key components:

People Costs (39 positions)	\$6.4
Depreciation	1.3
Occupancy costs	1.7
Environmental Health and Safety	0.1
Security	0.3
IT, Finance and Facility Services	0.4
Outsourced IND enabling studies	5.4
Lab supplies	1.7
Annual maintenance on software and equipment	0.7
Other	1.3
Total	\$19.3

This budget is expected to deliver the following:

- Complete the IND-enabling studies & GMP manufacturing of V116957 (ORL-1 agonist) and complete substantial authoring of the IND in preparation for filing early Q1 2011.
- Discover new chemotype, establish IP, and create an advanced SAR to support a backup program for the ORL-1 program.
- Nominate a developmental candidate from either the sodium channel blocker program or the novel opiates exploratory research activities.

b. **Q:** Explain the nature of the \$51.1 mm “other R & D” spending.

**A:** The following table summarizes the major elements:

Health Policy – includes Medical Liaisons, non branded medical education, medical services, library and health policy	\$19.4
Risk Management – includes \$8.3 mm in support of marketed products including a placeholder budget of \$5.0 mm for REMS and expert consulting	8.3
Regulatory support of marketed products	2.1
Drug Safety processing of adverse events	12.0
Support of due diligence	1.6
All Other (largely represents a portion of costs not allocated to projects such as cost of facilities, depreciation, non-project consulting etc)	7.7
Total	\$51.1

- c. **Q:** Explain the reasons for the decline in the operating margin ratios from 2009 LE to 2010 Budget.

**A:** The decline in operating margin from 2008 to 2010 is summarized as follows:

<b>2008 Operating Margin</b>	<b>69.6%</b>
Line Items impacting margin	
COGS – favorable	0.3%
Royalty expense – Gruenenthal, McGinity	-3.7%
Legal Fees	1.3%
R&D – increase spend as more programs enter Phase 3	-2.4%
S&P – increased sales force	-2.0%
Other, Net	0
<b>2010 Operating Margin</b>	<b>63.1%</b>

- d. **Q:** What will it cost the group in 2010 to use Noramco API vs. the variable supply cost at Rhodes Technologies?

**A:** The additional cost has been about \$4.0 mm annually.

- e. **Q:** Adjust the Gruenenthal royalty expense in the budget to assume the patents issue later in the year.

**A:** Done – We assume the patent will issue 9/1/2010 and the 2010 budget has been reduced by \$38.7 million to \$33.3 million.

- f. **Q:** Consider recasting OTR Medicaid budget (sales and rebate) to include the lower rebate rate that the NDA is entitled to.

**A:** Done – the impact reduced the Medicaid rebate expense by \$39.4 mm

## 9.0 General

a. **Q:** Organize “Welcome Home” activities for returning Summer Street staff.

**A:** Current thinking is that we will hold two “welcome home” events. The first will be in the second quarter celebrating the first returning group, and the second one celebrating the return of the last group of the SS residents. The “welcome home” events will likely be a BBQ on the Plaza level.

b. **Q:** Circulate the America Academy of Pain Medicine article.

**A:**



c. **Q:** Determine whether or not it would be appropriate to reinitiate funding of the Mass. General Pain Center.

**A:** John Stewart is working with David Haddox and the CEAC on this issue.

**Action:** J. Stewart/D. Haddox

# Exhibit 11

**To:** MNP Consulting Limited - Board of Directors[MNPConsultingLimited-BoardofDirectors@pharma.com]; Baker, Stuart[sbaker@chadbourn.com]  
**Cc:** Must, Alan[Alan.Must@pharma.com]; Haddox, Dr. J. David[Dr.J.David.Haddox@pharma.com]; Erensen, Jennifer[Jennifer.Erensen@pharma.com]; Petro, Melissia[Melissia.Petro@pharma.com]; Damas, Raul[Raul.Damas@pharma.com]  
**From:** Timney, Mark  
**Sent:** Wed 5/14/2014 2:39:28 PM  
**Subject:** ADF in MA.

Dear all,

I wanted to alert you to a positive development in Massachusetts, a state from which we've seen significant anti-opioid activity in recent months. Yesterday, the Massachusetts Senate passed legislation that included a provision developed by Purdue, prohibiting a non-abuse-deterrent formulation from being dispensed if an abuse-deterrent formulation is available. The Massachusetts House has already passed similar legislation and, while procedural hurdles remain, we consider this an important step toward broader government support for abuse-deterrent formulations.

I applaud the Health Policy and State Government Affairs teams for proactively crafting this model legislation and advocating it through the state legislative process, respectively. This initiative, so closely aligned with our commercial strategy and being replicated in several other states, helps ensure that patients continue to have access to our medicines and that broader public health goals are served.

Below I've linked to a new story about the legislation, highlighting mention of our policy provision.

I look forward to keeping you updated on our progress.

Mark

***Drug treatment bill has Senate's green light***

Worcester Telegram & Gazette (MA)

5/14/2014

<http://www.telegram.com/article/20140514/NEWS/305149925/1116>

The Senate on Tuesday unanimously adopted a bill to require insurers to cover drug and alcohol treatment without prior approval for admissions, a move expected to greatly increase access to treatment and that state Sen. Stephen M. Brewer predicted "will make a quantum leap forward" in treating opiate addiction.

The legislation also would require pharmacists to substitute drugs with abuse-deterrent coatings for highly abused drugs without abuse-deterrent qualities, unless a physician specifies otherwise...

# Exhibit 12



**To:** Motahari, Saeed[Saeed.Motahari@pharma.com]; Strassburger, Philip[Philip.Strassburger@pharma.com]; Robinson, Susie[Susie.Robinson@pharma.com]; Charhon, JJ[JJ.Charhon@pharma.com]; Butcher, Alan[Alan.Butcher@pharma.com]; Cawkwell, Gail[Gail.Cawkwell@pharma.com]; Mahony, Edward[Edward.Mahony@pharma.com]; Dunton, Alan[Alan.Dunton@pharma.com]; Lundie, David (US)[David.Lundie@pharma.com]; Feltz, Margaret[Margaret.Feltz@pharma.com]; Perlman, Zach[Zach.Perlman@pharma.com]; Baker, Stuart[sbaker@chadbourn.com]  
**Cc:** Damas, Raul[Raul.Damas@pharma.com]  
**Bcc:** David.Lundie@mundipharma-cbd.com[David.Lundie@mundipharma-cbd.com]  
**From:** Josephson, Robert  
**Sent:** Tue 11/1/2016 8:48:19 AM  
**Subject:** Boston Globe: Purdue's Letter to the Editor: Boston Globe

Good Morning-

I want to ensure you have seen Mark's response to the Boston Globe's article on rebating in West Virginia. The letter to the editor published today.

Thanks,  
Bob

Letter: Drug maker offers context on advances in opioid safety

The Boston Globe (MA)

11/1/2016

<https://www.bostonglobe.com/opinion/letters/2016/10/31/drug-maker-offers-context-advances-opioid-safety/71RHm8O2mTuSNx2LJ16AnN/story.html>

RE "DRUG maker foiled antiopioid effort" (Page A1, Oct. 26): I write to provide necessary context to <<https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/>> your article regarding Purdue Pharma's 2001 contracting practices. Given the gravity of the opioid epidemic, it's critical your readers know that not all reductions in opioid prescribing result in reduced opioid abuse.

Opioid prescribing in the United States has been declining since 2013. Yet the problem persists because it requires a comprehensive approach, not just the blunt instrument of prior authorizations, which often impede prescribing to appropriate patients in pain. Opioid manufacturers must promote products responsibly, helping to ensure that our medicines are prescribed only to the right patient for the right reason.

In the past, Purdue failed to meet this standard, but we accepted full accountability for those missteps, and for the past 14 years we've worked tirelessly to help reduce opioid abuse and diversion of opioids to those for whom they were not prescribed. We led the industry in developing medications with abuse-deterrent properties and advocated for the establishment of prescription drug monitoring programs.

Today, thanks in part to Purdue's contribution, Massachusetts' prescription drug monitoring program shares prescribing data with neighboring states to help reduce misprescribing of opioids.

To best serve public health, the Globe should recognize the impactful efforts companies like Purdue have taken to address the opioid epidemic.

Mark Timney

President and CEO

Purdue Pharma

Stamford, Conn.

# Exhibit 13

**To:** Gasdia, Russell[Russell.Gasdia@pharma.com]  
**Cc:** Motahari, Saeed[Saeed.Motahari@pharma.com]  
**From:** Timney, Mark  
**Sent:** Thur 12/18/2014 10:58:50 AM  
**Subject:** RE: Call Center Up and Running

Thanks Russ.

I will be watching it closely.

Regards, Mark.

---

**From:** Gasdia, Russell  
**Sent:** Thursday, December 18, 2014 9:51 AM  
**To:** Timney, Mark  
**Cc:** Motahari, Saeed  
**Subject:** FW: Call Center Up and Running

Mark

Thanks for your time yesterday afternoon.

As I mentioned, in addition to the significant work on the IDN Initiative, I've been as focused on the Purdue Product Information Center (PIC).

We established a goal of launching the PIC by end of 2014, which I can now report has been accomplished! We had targeted October, but as we got deeper into the process, it became evident that we needed to do this right, not fast...

The 8 Customer Service Representatives (CSRs) began making outbound calls the week of December 1<sup>st</sup>. The 9 Professional Representatives (PSRs) are receiving their training (same as our new field-based representatives) and will initiate outbound calls next week.

We have identified ~22,000 high decile prescribers for OxyContin/Butrans, who our field-based representatives have indicated as "no see". Based on the analogues that MediMediaHealth (Call Center CSO) and our previous experiences with an outbound call center 10 year ago, we have assumed ~\$4mm upside for OxyContin and ~\$1mm for Butrans over the 6 month pilot. If we hit those assumptions, this should be more than self-funding and you'll be able to continue with Phase II, which can expand the way this is deployed. This will also support vacant territory management, so we will track results with those HCPs as well.

A full eMarketing campaign is in place to support this, as are updated websites that promote the PIC, and journal ads will now call out the PIC. This should promote inbound calls.

Some photos below were taken by me earlier in the week, while I attended a day of the PSR training. Nice to see it in action!

Russ Gasdia

Head of Strategic Initiatives  
Purdue Pharma L.P.  
203-588-7399

---

**From:** Gasdia, Russell

**Sent:** Wednesday, December 17, 2014 4:24 PM

**To:** Cabral, Heather; Justason, Peter; Everett, Mary Ann; Deng, David; Byrd, Erric; Perrone, Gina; McMacken, Tiffany; Orapello, Dahlia; Morello, Tony; Bacco, Danielle; Runge, Christopher; Catlow, Patricia A; Daniel, Sanil (Sanil.Daniel@pharma.com)

**Subject:** Call Center Up and Running

All (I think I got everyone of core team)

- As you know, CSRs started calls the week of Dec 1st
- PSR training resumed this week
- Yesterday I was able to meet the CSRs and see the call center, along with Dahlia, Tony and Tiffany
  - The CSRs were positive and provided some encouraging feedback on how it was going so far
  - It was exciting to see this in action and brought all your hard work to life
- I sent some pictures to some of you yesterday, but thought I share these for the team

As I transition out of Purdue, Tony is taking on more leadership of the Call Center, as Lisa wants this to be a sales function, which makes sense.

Thank you for your hard work and efforts on this pilot/initiative. I am very confident that this will be successful...I'll be checking in to watch the progress!

Russ Gasdia  
Head of Strategic Initiatives  
Purdue Pharma L.P.  
203-588-7399

-----  
<< File: IMG\_0666.JPG >> << File: IMG\_0665.JPG >> << File: IMG\_0664.JPG >> << File: IMG\_0662.JPG >>  
>> << File: IMG\_0660.JPG >>