High impact interventions to rapidly address market access challenges

Innovative Contracts
DRAFT

December 2017

Privileged: This presentation contains draft proposals for discussion by Management and are subject to appropriate Purdue legal and regulatory review before they can be considered final. These materials are confidential and proprietary.

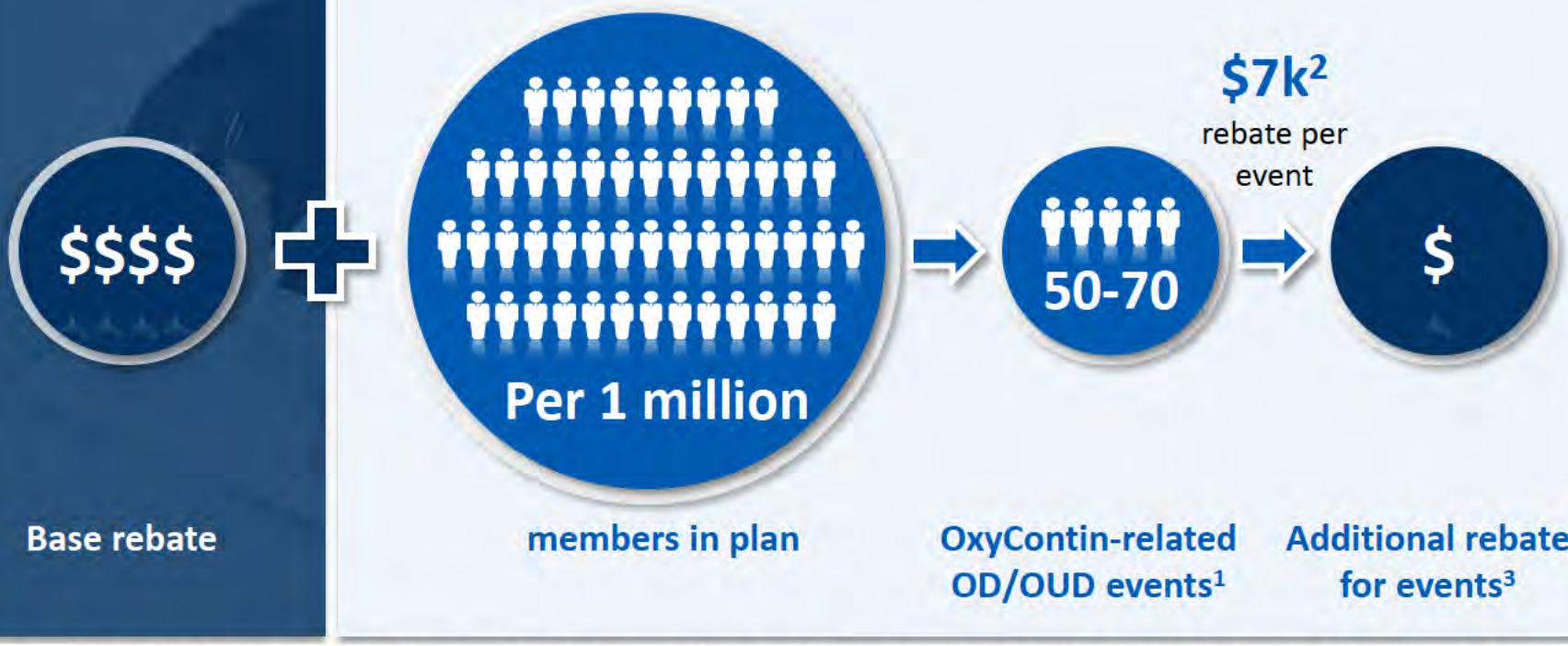
Purdue's Event-Based Contract offering

We believe in our technology: We will pay additional rebates on any new OxyContin related overdose or opioid use disorder diagnosis

Provide a base agreed-upon rebate

Provide an additional rebate based on actual incidence

Illustrative



- **Disclaimer:** First diagnosis of opioid-related overdose (OD) or opioid use disorder (OUD) based on ICD codes and OxyContin script within 1 month of event
  - ICD-10 codes F11, T40.0 , T40.2, T40.3, T40.4F11
  - ICD-9 codes 304.0, 304.7, 305.5, 965.00, 965.02, 965.09
- Rebate is linked to excess medical costs (e.g. ~$14K over 1 year, or OxyContin prescription costs per year ~$6K)

High impact interventions to rapidly address market access challenges

Ad hoc support synthesis
DRAFT

December 2017

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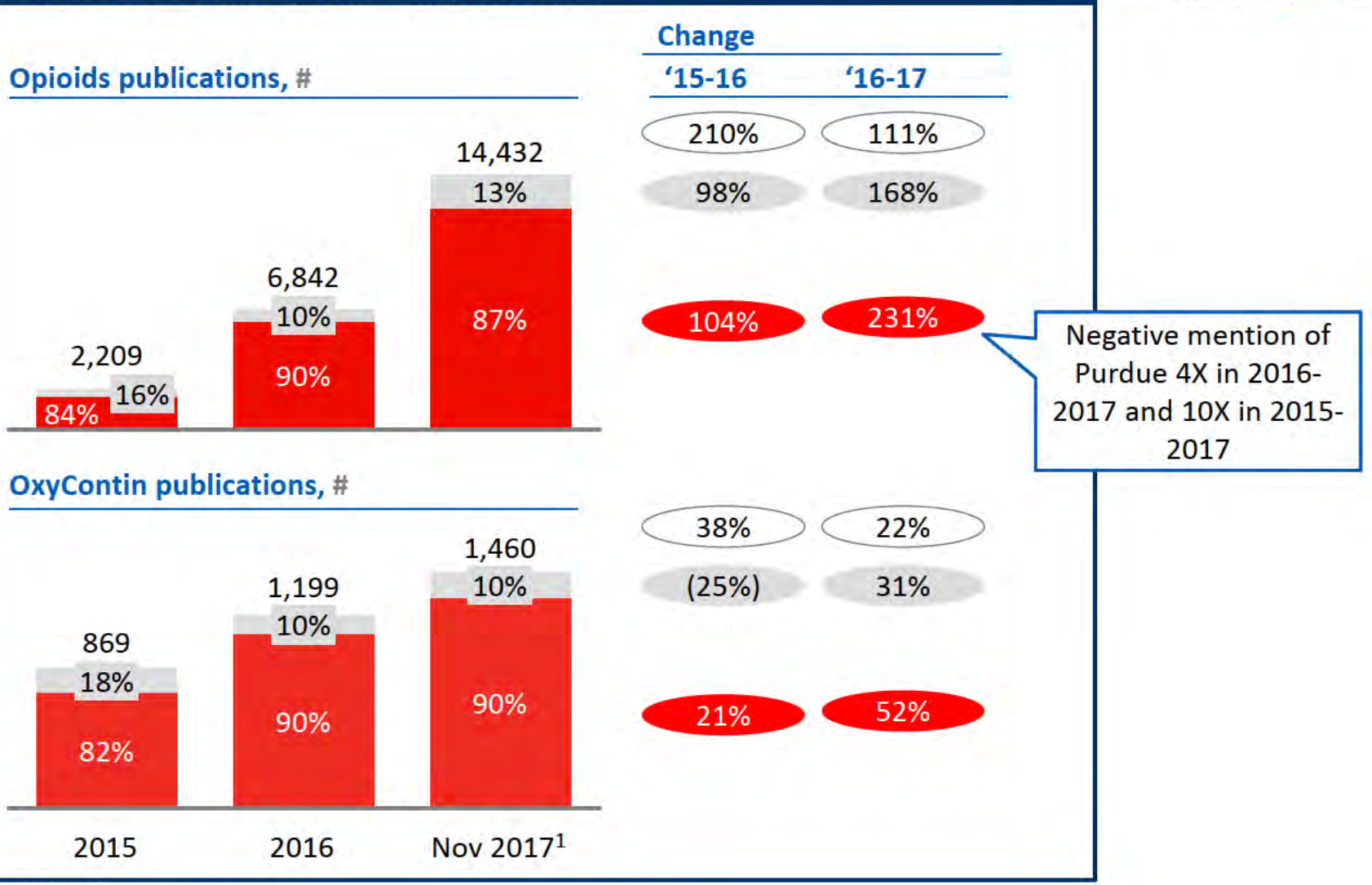
Headwinds Purdue is facing are stronger than ever

Media	**14, 432** publications mentioning opioids to date in 2017. This is 2x 2016 and 7x 2015 number **4x** increase in negative mentions of Purdue vs 2016 **52%** increase in negative publications on OxyContin vs 2016 with several now implying that **OxyContin may have been a driver** of the opioid crisis (e.g. New Yorker article)
PBM/ Payer	**Cigna and BCBS of FL formulary exclusions** coming in the last month **Exclusion** of OxyContin being framed as a public health initiative with Miami Herald positioning BCBS FL's move as "**To fight opioid crisis, Florida's largest insurer stops covering OxyContin**" **Payors and PBMs** are now openly communicating this perception back to Purdue; "Excluding OxyContin may be the best thing we can do in current context" (Anthem)
Agencies	**CDC** guidelines increasingly **caution against higher MMEs** **ICER** reported OxyContin as only having , "**comparable or better" net health benefit (C+)** in reducing the risk of abuse and addiction among patients
Xtampza	**Xtampza label (sNDA)** now has Category 2 ADP labelling for oral abuse **Cigna innovative contract** changing the perception of the brand towards a "**safer opioid**" **Up to ~70% rebates** is qualitatively what team believes Xtampza is offering to gain advantage
State/ local	**128 federal, state and local lawsuits** filed against Purdue this year

Media: Publications around opioids and OxyContin have increased significantly and are overwhelmingly negative

SUBJECT TO LEGAL REVIEW

Publications volume by sentiment, 2015-2017



1 2017 to date (11/9/2017)

SOURCE: press releases, web news, publications, blogs

These headwind are accelerating risks for Purdue

Reputation risk: Company brand and OxyContin name is publicly associated as a cause of the opioid crisis

Exclusion risk: Further exclusions of OxyContin in 2019 are likely as payors see an opportunity for a public perception win by removing OxyContin from formulary

Share risk: Xtampza's new label and aggressive promotion adds to the misperception that Xtampza is the safer opioid and increases risk of losing share

Legal risk: Increase in negative press mentions add to the risk for further law suits by government entities looking for ways to fight the opioid crisis

WORKING DRAFT
Last Modified 1/26/2011 11:01:26 AM Eastern Standard Time
Printed 1/26/2011 10:37:37 AM Eastern Standard Time

Hair testing project: working session

PURDUE

Discussion document
3 February 2011

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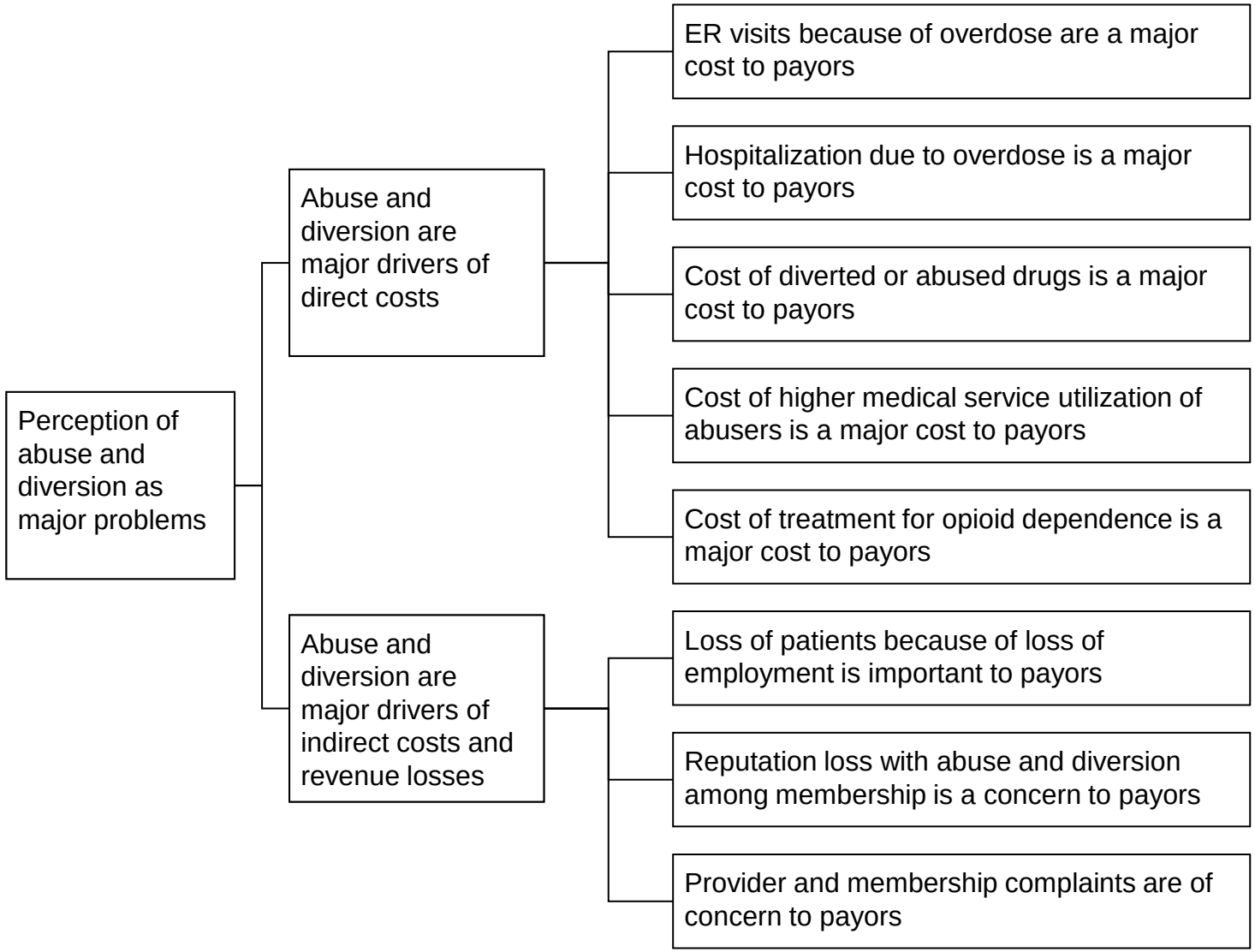
Issue tree: Abuse and diversion of ER schedule II opioids is important to payors

WORK IN PROGRESS



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Last Modified 8/22/2013 1:32 PM Eastern Standard Time
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OxyContin growth opportunities

Progress update
August 20, 2013

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The sales force transformation will likely face several key challenges

Common challenges	Key factors for success
 ▪ Reps do not see the need to change	▪ **Reps understand** why the new approach benefits them ▪ **Field is involved** and their buy-in is sought throughout the process ▪ New behavior is modeled by **'natural pilots'** of high-performing reps who already behave in line with recommendations ▪ Transformation is sequenced to secure **'quick wins'** first and gain momentum
 ▪ Reps see transformation as a 'zero sum game' of winners and losers, demotivating them	▪ Reps work in teams to **share success stories** and build on each other's strengths ▪ **Field competitions** and rewards to motivate buy in
 ▪ Performance and excitement are difficult to sustain over the long term	▪ Strong **EXCO-level leader owns program** ▪ **Accountability** throughout the organization ▪ **Weekly time commitment of CxO and top team** is "locked in" from very beginning ▪ Analytics group produces **performance metrics** in a timely manner throughout transformation ▪ Build in mechanisms for rep feedback and **continual improvement**
 ▪ Field feels inundated and paralyzed by excess of training and targeting materials	▪ HQ central team manages the program and owns deployment **of targeted, synthesized training materials** to field

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Reps will need a full suite of tools and support

Incentive compensation

- Rep's incentive for OxyContin relative to other products aligned with Purdue's economics
- Incentive compensation also tied to adherence to target list and call volume

Managers

- Calling on high-value doctors as a consistent theme in one-on-one and group conversations
- Managers trained to train reps on the value of adhering to call list and on approaching high-value doctors that have not been called on

Successful sales rep

Peers

- Those who adhere to call list and hit required call volumes identified as 'model reps'
- Team-level programs and incentives exert peer influence on reps to change behavior
- Reps share best practices in their regions and districts

Tools and training

- New tools make it easier to achieve high-value calls (e.g., call route planner, 'points' system to weigh low-value vs high value prescriber, refreshed OxyContin messages)
- Training supports reps in approaching high-value doctors who have not been called on

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Turbocharging Nucynta

Discussion with [redacted]

July 20, 2011

3 Maximize payor pull-through – objectives, ownership and key next steps

PRELIMINARY

Objectives

- Explore building an IM wide pull through system that enables appropriate share building based on managed care contracting investments that includes:
  - Tools to identify the appropriate accounts
  - Sales force equipped/trained to message and execute
  - Inclusion in the sales force incentive/monitoring system
  - Targeting that quickly adjusts to changes in market access

Ownership and next steps

- Strategic Customer Group
  - Understand feasibility/ROI of potential effort across IM
  - Develop tool that can be rapidly tested and deployed
  - Design pilot and roll out in select territories / regions
  - Identify any challenges for implementing across brands
- McKinsey
  - Organize workshop with key McKinsey experts who have implemented similar efforts in other pharmaco-s
  - Develop preliminary project plan and timeline for initiative (based on potential IM franchise interest)

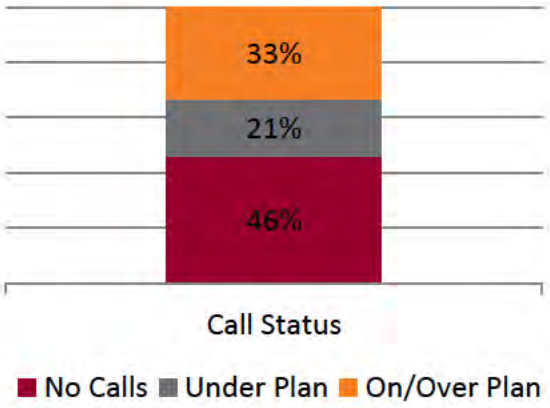
Hot Spot Birmingham

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

	2463804-Birmingham N, AL	2463806-Birmingham S, AL	2463803-Birmingham E, AL	3352201-Birmingham, AL	Total Hot Spot (de-duped)
# Targets	104	128	85	76	476
% of National Nucynta 13wk TRx's	0.32%	1.45%	1.12%	0.97%	1.7%
4 wk Nucynta TRx Growth	5%	-6%	-13%	-3%	-5%
13 wk Active %	35%	48%	47%	33%	33%
Ever Written %	54%	63%	61%	49%	48%
Concentration (% of targets accounting for 80% TRx volume)	13%	16%	17%	11%	11%
AVG SAO MS	7.0%	10.3%	9.8%	6.6%	6.6%

CPA % Targets

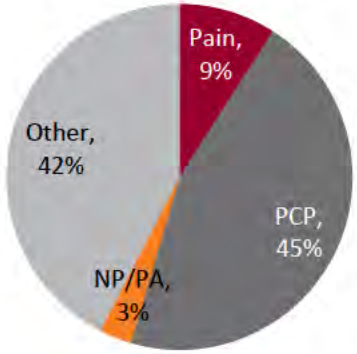


HIGH POTENTIAL	
# Targets	87
% of SAO 13 wk TRx's	24%
% of Nucynta 13 wk TRx's	6%
13 wk Active %	36%
Ever written %	100%
Avg SAO MS	3.7%

NEW WRITER POTENTIAL	
# Targets	67
% of SAO 13 wk TRx's	19%
% of Nucynta 13 wk TRx's	1%
13 wk Active %	21%
Ever written %	22%
Avg SAO MS	1.9%

MAINTAIN	
# Targets	221
% of SAO 13 wk TRx's	57%
% of Nucynta 13 wk TRx's	93%
13 wk Active %	51%
Ever written %	51%
Avg SAO MS	12.7%

Specialty % Targets



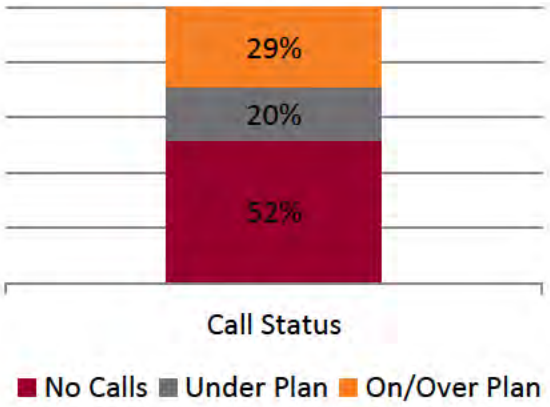
NUCYNTA® CII
tapentadol

Hot Spot Jacksonville, FL

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

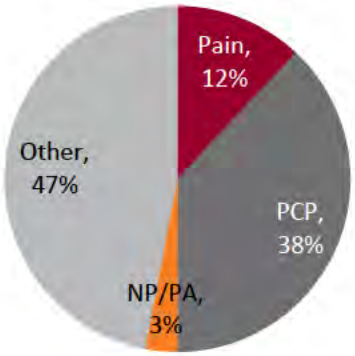
	2462906-Jacksonville N, FL	2462907-Jacksonville S, FL	3351805-Jacksonville W, FL CSO	3351806-Jacksonville E, FL	Total Hot Spot (de-duped)
# Targets	122	109	72	41	316
% of National Nucynta 13wk TRx's	0.5%	0.2%	0.1%	0.02%	0.8%
4 wk Nucynta TRx Growth	-19%	-13%	-16%	-14%	-16%
13 wk Active %	41%	38%	22%	24%	33%
Ever Written %	52%	51%	33%	37%	44%
Concentration (% of targets accounting for 80% TRx volume)	14%	11%	6%	10%	9%
AVG SAO MS	8.1%	7.4%	4.5%	2.0%	5.9%



HIGH POTENTIAL	
# Targets	62
% of SAO 13 wk TRx's	26%
% of Nucynta 13 wk TRx's	6%
13 wk Active %	42%
Ever written %	100%
Avg SAO MS	2.9%

NEW WRITER POTENTIAL	
# Targets	105
% of SAO 13 wk TRx's	36.5%
% of Nucynta 13 wk TRx's	4%
13 wk Active %	16%
Ever written %	17%
Avg SAO MS	4.0%

MAINTAIN	
# Targets	154
% of SAO 13 wk TRx's	37.5%
% of Nucynta 13 wk TRx's	90%
13 wk Active %	42%
Ever written %	42%
Avg SAO MS	9.1%



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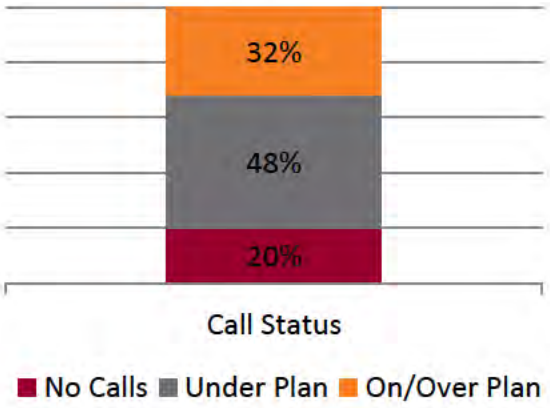
Hot Spot Miami, FL

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

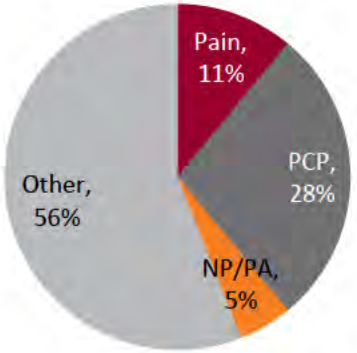
Source: IMS Xponent & Call Activity data through 4/15/11

	2463006-Miami, FL	2463008-Miami SW, FL	2463005-Miami S, FL	3352105-Miami S, FL	3352107-Miami, FL	Total Hot Spot
# Targets	114	83	92	34	17	323
% of National Nucynta 13wk TRx's	0.2%	0.1%	0.08%	0.04%	0.02%	0.5%
4 wk Nucynta TRx Growth	1%	-13%	-9%	14%	-23%	-7%
13 wk Active %	17%	41%	23%	29%	41%	26%
Ever Written %	26%	55%	30%	41%	47%	36%
Concentration (% of targets accounting for 80% TRx volume)	5%	17%	5%	12%	24%	7%
AVG SAO MS	4.7%	3.8%	4.0%	3.4%	7.9%	4.1%

CPA % Targets



Specialty % Targets



HIGH POTENTIAL	
# Targets	53
% of SAO 13 wk TRx's	29%
% of Nucynta 13 wk TRx's	6%
13 wk Active %	40%
Ever written %	100%
Avg SAO MS	0.7%

NEW WRITER POTENTIAL	
# Targets	114
% of SAO 13 wk TRx's	48%
% of Nucynta 13 wk TRx's	5%
13 wk Active %	16%
Ever written %	16%
Avg SAO MS	0.4%

MAINTAIN	
# Targets	158
% of SAO 13 wk TRx's	23%
% of Nucynta 13 wk TRx's	89%
13 wk Active %	29%
Ever written %	29%
Avg SAO MS	13%

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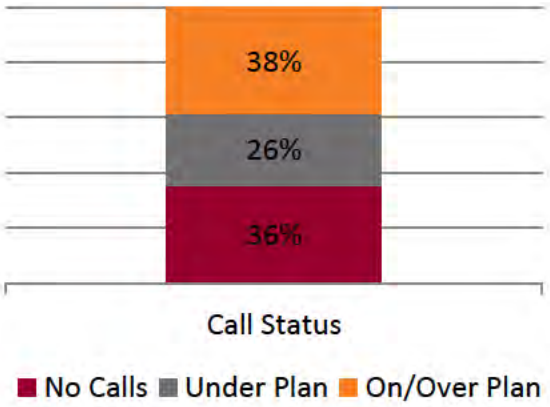
Hot Spot ORLANDO

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

	2463114-Orlando S, FL	2463115-Orlando, FL	3351904-Orlando, FL	3351905-Orlando S, FL	Total Hot Spot
# Targets	75	131	45	53	281
% of National Nucynta 13wk TRx's	0.1%	0.4%	0.1%	0.05%	0.5%
4 wk Nucynta TRx Growth	-6.5%	0.0%	-5.1%	-2.6%	-2.4%
13 wk Active %	27%	53%	36%	28%	37%
Ever Written %	43%	66%	44%	49%	52%
Concentration (% of targets accounting for 80% TRx volume)	7%	21%	9%	4%	12%
Avg SAO MS	3.6%	14.0%	10.6%	7.7%	8.8%

CPA % Targets

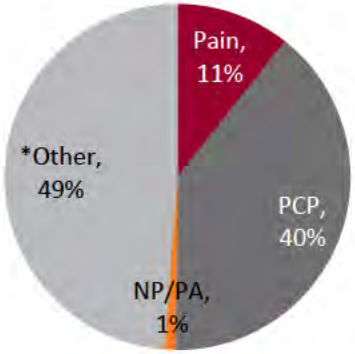


HIGH POTENTIAL	
# Targets	69
% of SAO 13 wk TRx's	30%
% of Nucynta 13 wk TRx's	16%
13 wk Active %	42%
Ever written %	100%
Avg SAO MS	2.1%

NEW WRITER POTENTIAL	
# Targets	117
% of SAO 13 wk TRx's	59%
% of Nucynta 13 wk TRx's	15%
13 wk Active %	24%
Ever written %	25%
Avg SAO MS	5.4%

MAINTAIN	
# Targets	102
% of SAO 13 wk TRx's	11%
% of Nucynta 13 wk TRx's	70%
13 wk Active %	53%
Ever written %	53%
Avg SAO MS	17.8%

Specialty % Targets



*Other driven by Surgery & OB/Gyn

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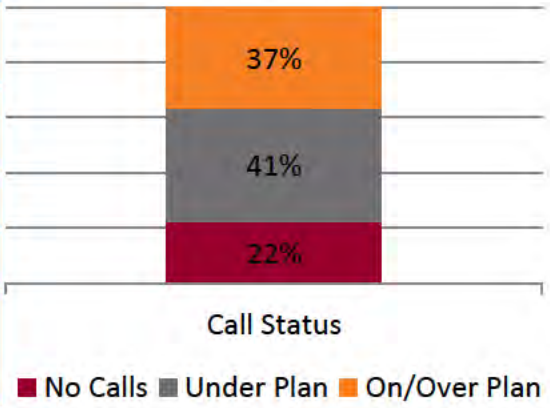
Hot Spot HOUSTON

	2764301-Houston, TX	2764302-Houston N, TX	2764303-Houston E, TX	3653901-Houston NW, TX	3653902-Houston W, TX	3653903-Houston E, TX CSO	3653904-Houston Medical Ctr, TX	3653905-Houston N, TX	Total Hot Spot
# Targets	106	100	91	60	46	52	24	53	501
% of National Nucynta 13wk TRx's	0.3%	0.5%	0.2%	0.04%	0.05%	0.01%	0.0%	0.01%	1.0%
4 wk Nucynta TRx Growth	8.3%	-13.2%	7.8%	2.6%	0.0%	-23.1%	11.8%	-2.6%	-0.4%
13 wk Active %	39%	51%	36%	15%	17%	12%	4%	6%	28%
Ever Written %	49%	63%	38%	23%	20%	12%	8%	9%	34%
Concentration (% of targets accounting for 80% TRx volume)	14%	18%	10%	7%	7%	8%	4%	2%	9%
Avg SAO MS	14.4%	15.2%	8.0%	5.3%	8.6%	2.9%	3.1%	1.8%	9.0%

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

CPA % Targets

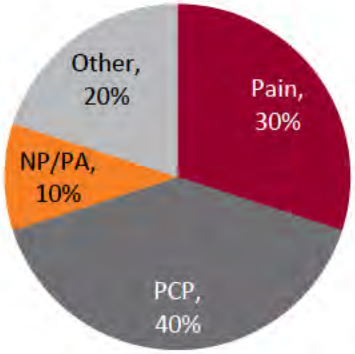


HIGH POTENTIAL	
# Targets	45
% of SAO 13 wk TRx's	19%
% of Nucynta 13 wk TRx's	2%
13 wk Active %	31%
Ever written %	100%
Avg SAO MS	0.6%

NEW WRITER POTENTIAL	
# Targets	65
% of SAO 13 wk TRx's	29%
% of Nucynta 13 wk TRx's	4%
13 wk Active %	51%
Ever written %	51%
Avg SAO MS	14.0%

MAINTAIN	
# Targets	392
% of SAO 13 wk TRx's	52%
% of Nucynta 13 wk TRx's	94%
13 wk Active %	24%
Ever written %	24%
Avg SAO MS	9.2%

Specialty % Targets



NUCYNTA® (tapentadol)

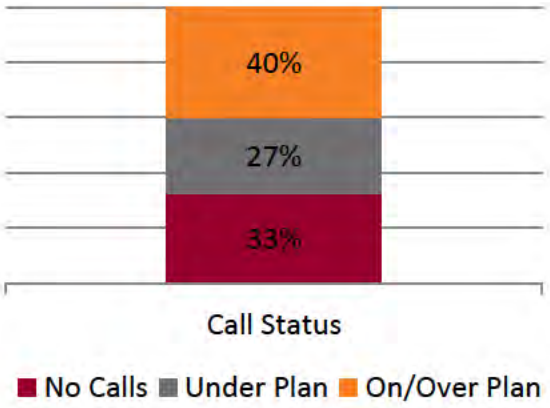
Hot Spot LOS ANGELES, CA

	2865107-Los Angeles W, CA	2865108-Beverly Hills, CA	3854906-Los Angeles SW, CA	3854907-Los Angeles E, CA	3855004-Beverly Hills, CA	3855005-Los Angeles, CA	Total Hot Spot (de-duped)
# Targets	101	113	61	29	40	37	371
% of National Nucynta 13wk TRx's	0.4%	0.3%	0.1%	0.01%	0.1%	0.05%	0.7%
4 wk Nucynta TRx Growth	-12%	-15%	-12%	-15%	-14%	-23%	-15%
13 wk Active %	50%	37%	20%	7%	25%	30%	30%
Ever Written %	57%	46%	23%	7%	28%	32%	36%
Concentration (% of targets accounting for 80% TRx volume)	15%	12%	5%	3%	8%	8%	9%
AVG SAO MS	10.8%	8.5%	10.1%	3.6%	10.0%	8.8%	7.8%

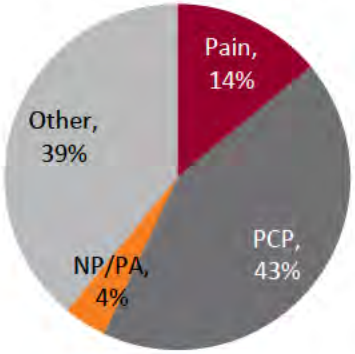
National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

CPA % Targets



Specialty % Targets



HIGH POTENTIAL	
# Targets	37
% of SAO 13 wk TRx's	25.9%
% of Nucynta 13 wk TRx's	5%
13 wk Active %	49%
Ever written %	100%
Avg SAO MS	2.5%

NEW WRITER POTENTIAL	
# Targets	39
% of SAO 13 wk TRx's	16.6%
% of Nucynta 13 wk TRx's	3%
13 wk Active %	54%
Ever written %	56%
Avg SAO MS	14.8%

MAINTAIN	
# Targets	278
% of SAO 13 wk TRx's	57.5%
% of Nucynta 13 wk TRx's	92%
13 wk Active %	26%
Ever written %	26%
Avg SAO MS	8.1%

NUCYNTA® CII
tapentadol

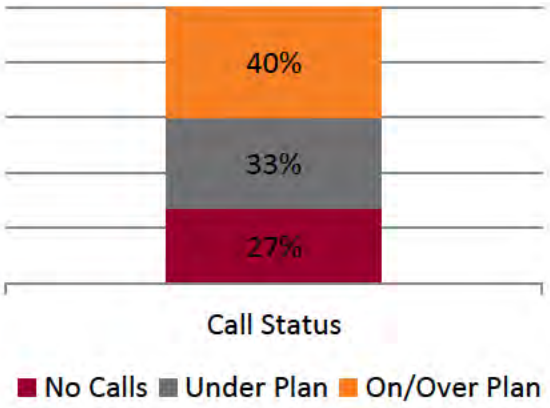
Hot Spot North Jersey

	2160710-Edison, NJ	2160708-Newark, NJ	2160705-Jersey City, NJ	3050610-Edison, NJ	Total Hot Spot (de-duped)
# Targets	79	121	108	35	335
% of National Nucynta 13wk TRx's	0.3%	0.2%	0.2%	0.05%	0.7%
4 wk Nucynta TRx Growth	5%	-11%	-17%	3%	-5%
13 wk Active %	54%	37%	31%	43%	39%
Ever Written %	72%	54%	42%	71%	54%
Concentration (% of targets accounting for 80% TRx volume)	22%	12%	14%	20%	15%
AVG SAO MS	5.2%	5.0%	7.1%	3.3%	5.5%

National Avg Targeted Nucynta MS	3.2%
National Avg Active Writer %	28%
National Avg Concentration	10%

Source: IMS Xponent & Call Activity data through 4/15/11

CPA % Targets

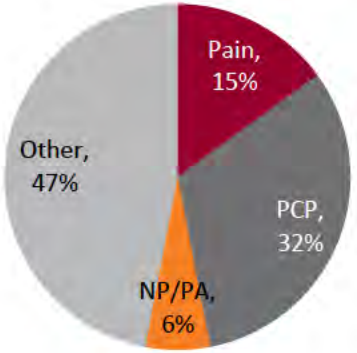


HIGH POTENTIAL	
# Targets	80
% of SAO 13 wk TRx's	43%
% of Nucynta 13 wk TRx's	13%
13 wk Active %	38%
Ever written %	100%
Avg SAO MS	1.2%

NEW WRITER POTENTIAL	
# Targets	109
% of SAO 13 wk TRx's	29%
% of Nucynta 13 wk TRx's	6%
13 wk Active %	27%
Ever written %	29%
Avg SAO MS	0.8%

MAINTAIN	
# Targets	153
% of SAO 13 wk TRx's	28%
% of Nucynta 13 wk TRx's	81%
13 wk Active %	52%
Ever written %	52%
Avg SAO MS	12%

Specialty % Targets



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NUCYNTA Action Plan
May 10, 2011

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Nucynta Action plan to "Power Ahead"

- **Situation**: Flat TRx trend
  - Growth territories offset by flat & declining territories.
  - Overemphasis on select targets, underemphasis on market/brand potential
- **Key actions**:
  1. Targeting tool developed & deployed to field leadership
  2. Hot Spot analysis & work sessions (Field, Business Analytics, Brand)
  3. "Power Ahead" Contest (request approval)
  4. Communications
     - Contest initiation 5/16
     - Weekly Hot Spot work sessions & other DM level engagement
     - Weekly touchpoints via Field IM News
     - FSABs
  5. Market Insights
     - User Study (May 20 w/ interim updates)
     - SFE
     - Segmentation

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Executive Summary

- NUCYNTA TRx's & share are flat since week ending March 11, 2011
  - Lack of TRx growth creating a gap between actuals and forecast

- Overemphasis on promotionally sensitive customers, with TRx volume leveling off for these prescribers in March 2011
  - Leveling of over-plan targets hard to see in weekly data
  - Underemphasis on some targets, including:
    - High decile non-writers
    - Discontinued writers
    - New Writers
    - Prescribers with < national average market share

- A shift in emphasis within target customers is recommended to recapture growth and establish a broader base of writers for the future
  - Recommended lists will be provided for DM discussions

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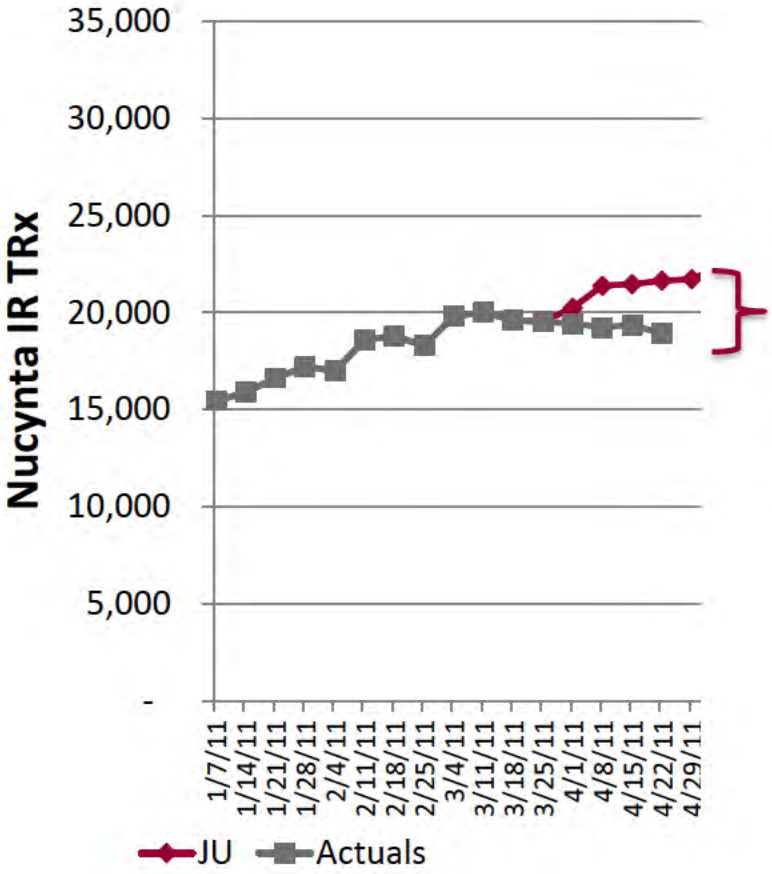
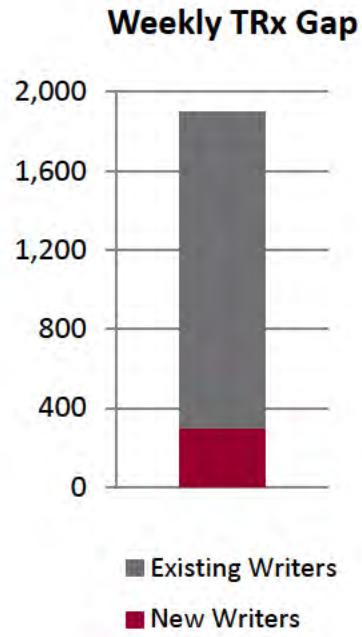
A focused effort on both existing & new writers needed to get us back on track





- Weekly TRx Gap vs forecast of 1,900 TRx's
- Two *more* TRx's per week per territory would get us back to forecast
- Current new targeted writers account for 300 weekly TRx's
- Once back on track, Field needs to avg one more weekly incremental TRx per month

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Actuals through 4-22-11

Areas of Focus to get back to growth

HIGH POTENTIAL

- All docs who have ever written (over/on/ under-plan) targets with < national avg. SAO market share*
- Active writers w/ zero calls logged

Opportunity / Impact : Immediate Growth

# Targets	13K (14 per)
13 wk Active %	66%
Ever written %	100%
Avg SAO MS	1.1%

NEW WRITER POTENTIAL

- New writers, prior 13 weeks
- Mkt Decile 4 & above never written

Opportunity / Impact : Cultivating future Growth

# Targets	22K (24 per)
13 wk Active %	19%
Ever written %	20%
Avg SAO MS	0.6%

MAINTAIN

- All docs who have ever written (over/on/ under-plan) targets with > national avg. SAO market share*
- Mkt Decile 3 & below; never written

Opportunity / Impact : Maintaining base

# Targets	31K (33 Per)
Active %	35%
Ever written %	35%
Avg SAO MS	10.7%

*Market Share based on National Targeted share 3.2%

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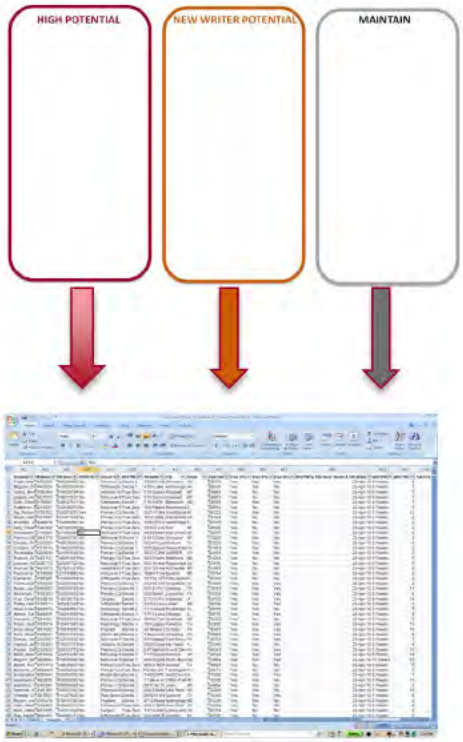
A hyper-focused list of target customers has been developed to help prioritize a focus back to growth



3 Tab spreadsheet filterable by:

- Pain or AI/GI
- RDT
- Decile
- Call status
- Market Share
- New writer status
- Ever written status

Further doc detail available in Physician Detail Report in Vital Signs

- Longitudinal call & TRx data

Lists will help drive focus & discussions at the local level; metrics will be refreshed monthly with weekly data to show progress

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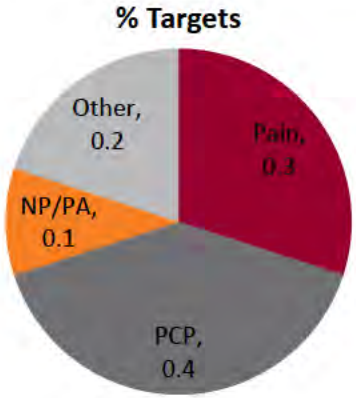
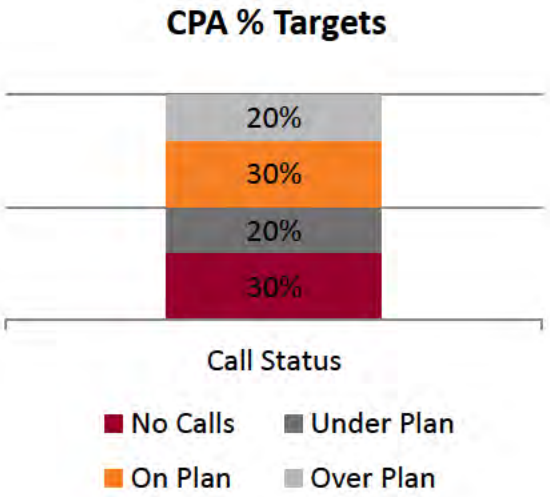
Hot Spot One Pager

National Avg Nucynta MS	
National Avg Active Writer %	

HOT SPOT X	
# Targets	17K
% of National Nucynta	
4 wk Nucynta TRx Growth	
13 wk Active %	
Ever Written %	
Concentration (% of targets accounting for 80% of Hotspot Nucynta)	





HIGH POTENTIAL	
# Targets	17K
% of SAO TRx's	
% of Nucynta TRx's	
4 wk Nucynta TRx Growth	
13 wk Active %	64%
Ever written %	100%
Avg SAO MS	3.2%

NEW WRITER POTENTIAL	
# Targets	22K
% of SAO TRx's	
% of Nucynta TRx's	
4 wk Nucynta TRx Growth	
13 wk Active %	19%
Ever written %	20%
Avg SAO MS	0.6%

MAINTAIN	
# Targets	24K
% of SAO TRx's	
% of Nucynta TRx's	
4 wk Nucynta TRx Growth	
Active %	15%
Ever written %	15%
Avg SAO MS	13.6%

- Comments:

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Hot Spots – initial reviews

Hot Spot	Los Angeles, CA
Pain Territory	2865107-Los Angeles W, CA
Pain Territory	2865108-Beverly Hills, CA
AI/GI District	3854906-Los Angeles SW, CA
AI/GI Territory	3855005-Los Angeles, CA
AI/GI Territory	3854907-Los Angeles E, CA
AI/GI Territory	3855004-Beverly Hills, CA

Hot Spot	Birmingham, AL
Pain Territory	2463804-Birmingham N, AL
Pain Territory	2463806-Birmingham S, AL
Pain Territory	2463803-Birmingham E, AL
AI/GI Territory	3352201-Birmingham, AL

Hot Spot	Miami, FL
Pain Territory	2463006-Miami, FL
Pain Territory	2463008-Miami SW, FL
Pain Territory	2463005-Miami S, FL
AI/GI Territory	3352105-Miami S, FL
AI/GI Territory	3352107-Miami, FL

Hot Spot	Orlando, FL
Pain Territory	2463115-Orlando S, FL
Pain Territory	2463114-Orlando, FL
AI/GI Territory	3351904-Orlando, FL
AI/GI Territory	3351905-Orlando S, FL

Hot Spot	Jacksonville, FL (Tallahassee)
Pain Territ	2462906-Jacksonville N, FL
Pain Territ	2462907-Jacksonville S, FL
AI/GI Terr	3351805-Jacksonville W, FL CSO
AI/GI Terr	3351806-Jacksonville E, FL

Hot Spot	Houston
Pain Territ	2764301-Houston, TX
Pain Territ	2764302-Houston N, TX
Pain Territ	2764303-Houston E, TX
AI/GI Terr	3653904-Houston Medical Ctr, TX
AI/GI Terr	3653905-Houston N, TX
AI/GI Terr	3653902-Houston W, TX
AI/GI Terr	3653903-Houston E, TX CSO
AI/GI Terr	3653901-Houston NW, TX

Hot Spot	North Jersey (Newark)
Pain Territ	2160710-Edison, NJ
Pain Territ	2160708-Newark, NJ
Pain Territ	2160705-Jersey City, NJ
AI/GI Terr	3050610-Edison, NJ

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Nucynta (IR) User Study

- Qualitative study designed to understand the “tipping points” driving new prescribers and discontinued Nucynta prescribers.
- Two separate Nucynta cohorts chosen for study:
  - Newer prescribers, those who started prescribing during the past 13 weeks (ending April 8)
  - Discontinuing prescribers, those who had written Nucynta within the past 26 weeks (e.g., ~ Q4/10), but whose prescribing had stopped within the past 13 weeks (ending April 8)
- In-depth interviews conducted via telephone and webcam (where available) among 48 physicians and NP/PAs, evenly divided between new and discontinued prescribers.
- Sample balanced among PCPs, Pain specialists, Surgeons, and NP/PAs.
- Study in field May 9
- Topline report and debrief: May 20

NUCYNTA® CII
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Message

From: Elena Mendez Escobar [redacted]

Sent: 7/31/2018 11:55:03 AM

To: Susann Stuttfeld [redacted] Ellen Rosen

CC: Aamir Malik [redacted] -Aamir Malik]; Arnab Ghatak [redacted] -Arnab Ghata]; Nicholas Donoghoe [redacted] Nicholas Do]; Kirsten Westhues [redacted] -Kirsten Wes]; Julie Lane [redacted] -Julie Lane]; Thomas Latkovic [redacted] Thomas Latk]; Razili Lewis [redacted] Sarun Charumilind [redacted] Sarun Charu]

Subject: RE: New article from the opioids insights team

Hi Susann,

Thanks again for your input here. Just realized that I had not replied to your other comments below explicitly. We have edited footnote #2 and implemented your other comments as follows. Let us know if any questions. Thanks so much again for your detailed feedback

1) While many parts are rooted in data, at times the article can read as op-ed, rather than factual analysis. I assume the article is/will be reviewed by Anna GB Yes reviewing., Public Sector Leadership and US/North America office managers to better evaluate that. We sent to public sector as well following this note from you, thanks for falgging
2) On the OUD prevalence, perhaps footnote 2 could be strengthened by providing the % they estimated actually had OUD. Updated footnote #2 (they found 4.4%)
3) Exhibit 5 and in the text, we are comparing the incidence of HIV and cancer with the prevalence of opioids – to compare apples to apples, it should be corrected for prevalence of HIV and cancer.
In addition the comparison made in the exhibit is not entirely "analogous", as the paper claims. Electric vehicles, HIV, cancer, are all global problems, whereas OUD is more localized. It is only natural that this is reflected in the investment numbers (even if they stem from the US, eg. I assume this includes R&D investments of US-headquartered MNCs). In addition, there are many other reasons why HIV and cancer research funding can't really be compared to that of OUD. For one, cancer is a group of multiple, very different diseases, whereas OUD is one, among others. It seems, that chart and the comparison are more thought to be provocative than providing an actually valid comparison, and I feel this is quite apparent to the reader Good point. We wanted to highlight the difference between those who need chronic healthcare intervention (eg, with HIV or OUD diagnosis) vs not (cancer diagnosis does not always require healthcare support for life). Propose the following:
* CANCER: "1.7m new diagnoses each year; 340k premature (< age 75) deaths annually" --- new diagnoses but no survivors, as proxy for people who need health care that year
* HIV: 1.1m individuals infected with HIV; 7k deaths annually – No new diagnoses (since this is chronic disease)

* OPIOIDS: 4-6M people with OUD and 42k overdose deaths (edited this number as 64k is overdose deaths from any drug, >42k is opioids were present)

4) On innovation, one could explicitely mention investment in creating better pain drugs, or opioids with less respiratory depression and addiction risks, and providing incentives to do so. For example, why is any opioid reimbursed today that lacks some kind of FDA approved abuse resistance? Or providing transparency around highest opioid prescribers to identify outliers. (I understand we need to walk a fine line here to avoid the appearance of lobbying). Good point. We did make more explicit pain management innovation

Elena

From: Elena Mendez Escobar
Sent: Tuesday, July 17, 2018 2:33 PM
To: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Redacted
Cc: Aamir Malik <aamir_malik@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>; Redacted; Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: RE: New article from the opioids insights team

Great, thanks for clarifying! We absolutely have that number and will add. Thanks Susan

Elena

From: Susann Stuttfeld
Sent: Tuesday, July 17, 2018 2:31 PM
To: Redacted
Cc: Aamir Malik <aamir_malik@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>; Redacted; Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: RE: New article from the opioids insights team

Hi Redacted

Footnote 2 says: "Massachusetts completed a study (its Chapter 55 project) to more accurately estimate the prevalence of OUD in the state" It would be interesting to understand, what this study came up with as the estimated OUD prevalence (which might be indicative for the entire country). The rest of the footnote focuses on overdosing and associated deaths. Since you lead into the footnote talking about a prevalence estimate, it simply piqued our interest to learn more. And I assume it would with other readers as well.
But this is more a suggestion, again to strengthen a footnote. Not an absolute necessity to address.

Best, Susann

Dr. Susann Stuttfeld
Global Reach & Relevance Manager | Pharmaceuticals and Medical Products Practice
McKinsey & Company | [redacted] susann_stuttfeld@mckinsey.com

---

From: Ellen Rosen
Sent: Dienstag, 17. Juli 2018 20:24

To: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>
Cc: Aamir Malik <aamir_malik@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>; Kirsten Westhues <kirsten_westhues@mckinsey.com>; Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: RE: New article from the opioids insights team

Hi Susann,

Elena and I are in the process of responding to your comments but need clarification about point #2.

As the authors acknowledge in the text, no one really knows how many Americans have OUD, given that the condition is under-diagnosed. The authors therefore developed an estimate based on what little data was available.

Is there something more specific you want us to add? If so, can you let us know what it is?

Thanks.

E

Ellen Rosen
Global Manager of Publications, McKinsey HSS Practice
[redacted]

From: Susann Stuttfeld
Sent: Wednesday, July 11, 2018 4:39 PM
To: Ellen Rosen <ellen_rosen@mckinsey.com>
Cc: Aamir Malik <aamir_malik@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>; Kirsten Westhues <kirsten_westhues@mckinsey.com>; Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: RE: New article from the opioids insights team

Dear Ellen and team

Thanks for sharing the article with the PMP practice. It is a very important and pressing topic and we are pleased with the intitiative to make change.

Overall, we believe the white paper provides a comprehensive overview of the issue at hand, and doesn't pose any particular risk to serving the clients in our practice. We do have a few points of feedback, and would like to discuss to what extent it makes sense to address those:

1) While many parts are rooted in data, at times the article can read as op-ed, rather than factual analysis. I assume the article is/will be reviewed by Anna GB, Public Sector Leadership and US/North America office managers to better evaluate that.
2) On the OUD prevalence, perhaps footnote 2 could be strengthened by providing the % they estimated actually had OUD

3) Exhibit 5 and in the text, we are comparing the incidence of HIV and cancer with the prevalence of opioids – to compare apples to apples, it should be corrected for prevalence of HIV and cancer.
In addition the comparison made in the exhibit is not entirely "analogous", as the paper claims. Electric vehicles, HIV, cancer, are all global problems, whereas OUD is more localized. It is only natural that this is reflected in the investment numbers (even if they stem from the US, eg. I assume this includes R&D investments of US-headquartered MNCs). In addition, there are many other reasons why HIV and cancer research funding can't really be compared to that of OUD. For one, cancer is a group of multiple, very different diseases, whereas OUD is one, among others. It seems, that chart and the comparison are more thought to be provocative than providing an actually valid comparison, and I feel this is quite apparent to the reader
4) On innovation, one could explicitely mention investment in creating better pain drugs, or opioids with less respiratory depression and addiction risks, and providing incentives to do so. For example, why is any opioid reimbursed today that lacks some kind of FDA approved abuse resistance? Or providing transparency around highest opioid prescribers to identify outliers. (I understand we need to walk a fine line here to avoid the appearance of lobbying).

Please reach out if you want to further discuss

Best, Susann

Dr. Susann Stuttfeld
Global Reach & Relevance Manager | Pharmaceuticals and Medical Products Practice
McKinsey & Company | Bleicherweg 30, 8002 Zurich | Switzerland
[redacted] | susann_stuttfeld@mckinsey.com

From: Kirsten Westhues
Sent: Mittwoch, 11. Juli 2018 13:17
To: Ellen Rosen <ellen_rosen@mckinsey.com>
Cc: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>
Subject: FW: New article from the opioids insights team

Hi Ellen – Aamir shared this, and we are gathering our response. I personally don't see any issues, unless someone feels that the chart that shows underinvestment in Opioids is factually wrong/misleading

Going forward, can you cc us? Or if easier just ping over anything that needs PMP input to Susann and me first and we take care of leadership approval

---

From: Aamir Malik
Sent: 11 July 2018 02:24
To: Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>; Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Kirsten Westhues <kirsten_westhues@mckinsey.com>
Subject: FW: New article from the opioids insights team

Thoughts?

From: Ellen Rosen
Sent: Tuesday, July 10, 2018 5:47 PM
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: New article from the opioids insights team

Hi Aamir,

Attached is the latest paper from our opioids insights team. They plan to release the paper on their website.

Please let us know if you have any concerns about it.

Thanks.

E

Ellen Rosen
Global Manager of Publications, McKinsey HSS Practice
[redacted]

Message

From: Susann Stuttfeld [redacted]

Sent: 7/11/2018 12:09:18 PM

To: Kirsten Westhues [redacted] Aamir Malik [redacted]

CC: Arnab Ghatak [redacted] Nicholas Donoghoe [redacted]

Subject: RE: New article from the opioids insights team

I agree with Kirsten's assessment that this is gearing towards lobbying. I assume if HSS, reputational risk (Anna GB), Public Sector and the US office manager sign off on this, this is a non-issue. Also overall, the tone and insights are very opinion-driven, but that is a call HSS needs to make.

However, I do feel that the comparison in figure five (comparing investment into OUD vs eclectric cars, cancer and HIV) is not entirely correct. These "analogous" (and I challenge that word) challenges are global, whereas OUD is more localized. Hence I feel like the comparison is not apples to apples, and can be interpreted as questioning the level of investments made in these areas (vs highlighting the need to invest more into OUD). It also invites the thought that multiple stakeholders (including pharmacos) are setting their R&D priorities inadequately. There are multiple other arguments one can make about not comparing cancer or HIV research to the opioid crisis (or the level or drug research needed vs adjusting treatment), but I assume we don't need to get into that. Overall, this is a minor point in the article though, and no real emphasis on pharma companies (and therefore our clients) is really placed.

So in total, I see limited risk, at least through the PMP lens.

Aamir, Arnab, let us know your thoughts and Kirsten and I can follow up with the team

Best, Susann

Dr. Susann Stuttfeld
Global Reach & Relevance Manager | Pharmaceuticals and Medical Products Practice
McKinsey & Company | Bleicherweg 30, 8002 Zurich | Switzerland
Direct: [redacted] | Mobile: Redacted | Fax: [redacted] | [redacted]

From: Kirsten Westhues
Sent: Mittwoch, 11. Juli 2018 13:14
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>
Subject: RE: New article from the opioids insights team

Please enjoy your time off (and moving you to bcc)

I have just had a read of the document. In style, it's indeed more of an op-ed or one could even say a lobbying paper, though it is very much fact based. This is in the end a decision for the HSS Practice to take, in my view. The lobbying is to a large extend targetting the US healthcare payors and providers.

The question for PMP is whether we feel our Pharma clients are appropriately represented. The paper makes the case that there is insufficient "innovation" in the system, both in terms of treatment protocols for opioid prescriptions, but also on the Pharma/research side. They make the case that while eg HIV and Cancer affect far fewer people than Opioid dependency, research spend is much smaller.

If we don't have a problem with that fact per se, I do not see any issues.

From: Nicholas Donoghoe
Sent: 11 July 2018 11:58
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Kirsten Westhues <kirsten_westhues@mckinsey.com>
Subject: Re: New article from the opioids insights team

Redacted

But my first quick reaction is the strongest portions have direct data and analysis to support them so wonder if there is a shorter version that keeps everything firmly grounded in a strong factbase to avoid appearance of a more broadly reaching op-ed style article. Depending on intended audience it also seems you could go deeper on some of the subtopics in dedicated articles while a shorter exec style summary of key facts that hit strongest points upfront. But that maybe more stylistic, I am sure they considered this. Let me know if helpful to follow up with Ellen or others directly

Redacted

Nicholas

On Jul 11, 2018, at 3:23 AM, Aamir Malik <aamir_malik@mckinsey.com> wrote:

Thoughts?

From: Ellen Rosen
Sent: Tuesday, July 10, 2018 5:47 PM
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: New article from the opioids insights team

Hi Aamir,

Attached is the latest paper from our opioids insights team. They plan to release the paper on their website.

Please let us know if you have any concerns about it.

Thanks.

E

Ellen Rosen
Global Manager of Publications, McKinsey HSS Practice
[redacted]

[redacted]

<20180501 Core beliefs - opioids_v07 (for review).docx>

Message

From: Arnab Ghatak [redacted]

Sent: 7/11/2018 2:30:36 PM

To: Aamir Malik [redacted] -Aamir Malik]; Nicholas Donoghoe [redacted]

CC: Susann Stuttfeld [redacted] Susann Kump]; Kirsten Westhues [redacted] Kirsten Wes]

Subject: RE: New article from the opioids insights team

Indeed, have a great time

On the article, overall its fine. A few thoughts:

1)on the OUD prevalence, perhaps footnote 2 could be strengthened by providing the % they estimated actually had OUD
2)exhibit 5 and in the text, we are comparing the incidence of HIV with the prevalence of Opioids – that's not really fair, the point is correct but we should use the prevalence # for HIV
3)on innovation, seems odd to not mention investment in creating better pain drugs, or opioids with less respiratory depression and addiction risks. On that, there could be a point made that the government and private payors could definitely do more to encourage a marketplace. For example, why is any opioid reimbursed today that lacks some kind of FDA approved abuse resistance?
4)Another simple idea that any state could do is to actually publish its highest opioid prescribers – they could have done this years ago and those that are outliers would feel some pressure to justify their prescribing. I'm honestly surprised no newspaper hasn't done this already.

Arnie

Arnab Ghatak
Senior Partner
McKinsey & Company
[redacted]

From: Aamir Malik
Sent: Wednesday, July 11, 2018 7:37 AM
To: Nicholas Donoghoe <nicholas_donoghoe@mckinsey.com>
Cc: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Kirsten Westhues <kirsten_westhues@mckinsey.com>
Subject: RE: New article from the opioids insights team

Redacted Thanks for the quick input. Now please stop working ☺
- Aamir

From: Nicholas Donoghoe
Sent: Wednesday, July 11, 2018 6:58 AM
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Susann Stuttfeld <Susann_Stuttfeld@mckinsey.com>; Arnab Ghatak <arnab_ghatak@mckinsey.com>; Kirsten

Westhues <kirsten_westhues@mckinsey.com>
Subject: Re: New article from the opioids insights team

Redacted

But my first quick reaction is the strongest portions have direct data and analysis to support them so wonder if there is a shorter version that keeps everything firmly grounded in a strong factbase to avoid appearance of a more broadly reaching op-ed style article. Depending on intended audience it also seems you could go deeper on some of the subtopics in dedicated articles while a shorter exec style summary of key facts that hit strongest points upfront. But that maybe more stylistic, I am sure they considered this. Let me know if helpful to follow up with Ellen or others directly when back **Redacted**

Nicholas

On Jul 11, 2018, at 3:23 AM, Aamir Malik <aamir_malik@mckinsey.com> wrote:

Thoughts?

From: Ellen Rosen
Sent: Tuesday, July 10, 2018 5:47 PM
To: Aamir Malik <aamir_malik@mckinsey.com>
Cc: Julie Lane <Julie_Lane@mckinsey.com>; Thomas Latkovic <thomas_latkovic@mckinsey.com>; Elena Mendez Escobar <Elena_Mendez_Escobar@mckinsey.com>; Razili Lewis <Razili_Lewis@mckinsey.com>; Sarun Charumilind <sarun_charumilind@mckinsey.com>
Subject: New article from the opioids insights team

Hi Aamir,

Attached is the latest paper from our opioids insights team. They plan to release the paper on their website.

Please let us know if you have any concerns about it.

Thanks.

E

Ellen Rosen
Global Manager of Publications, McKinsey HSS Practice
[redacted]

<20180501 Core beliefs - opioids_v07 (for review).docx>

Message

From: Laura Moran [redacted]
Sent: 9/11/2013 1:34:33 PM
To: John Goldie [redacted]
CC: Arnab Ghatak [redacted]
Subject: Re: John Stewart

I think that is a brilliant idea. let's think carefully about what we want to ask, I'm most curious to see..
- if high writers even noticed this. :)
-what portion of their current oxy patients (or all ER patients) are "severe" vs. moderate to severe, what portion are "as needed"
-if they think this will change their prescribing behavior (I'm guessing they'll say they already use it like this)

thx

Laura Moran
Principal
McKinsey & Company
Redacted (cell)
[redacted]fax)
[redacted]office)
[redacted]

From: John Goldie/NYO/NorthAmerica/MCKINSEY
To: Arnab Ghatak/NJE/NorthAmerica/MCKINSEY@MCKINSEY,
Cc: Laura Moran/NJE/NorthAmerica/MCKINSEY@MCKINSEY
Date: 09/11/2013 09:30 AM
Subject: Re: John Stewart

Looks like basic takeaways are:

- Class-wide labeling change applying to ER opioids (not IR)
- Should only be used for severe pain, not moderate-severe pain
- Should be reserved for patients for whom alternative treatment options are ineffective, not tolerated, or inadquate
- Not indicated for 'as needed' pain relief
- Requring drug companies to conduct further studies (postmarket)
- boxed warning for pregnant women

Do you want us to set up any prescriber interviews on this?

John

John Goldie
McKinsey & Co
55 e52nd St
New York, NY, 10022
o:[redacted]
m:Redacted

From: Arnab Ghatak/NJE/NorthAmerica/MCKINSEY
To: Laura Moran/NJE/NorthAmerica/MCKINSEY@mckinsey, John Goldie/NYO/NorthAmerica/MCKINSEY@mckinsey,

Date: 09/11/2013 09:00 AM
Subject: Re: John Stewart

What is the FDA announcement?

On Sep 11, 2013, at 1:51 PM, "Laura Moran" <[redacted]> wrote:

This is great news.

Outreach re: FDA makes sense. David is apparently on rep rides, we'll talk tho in core team and will make sure to get a few mins one on one to discuss FDA.

From: Rob Rosiello
Sent: 09/11/2013 08:11 AM EDT
To: Arnab Ghatak; Laura Moran; Martin Elling
Subject: John Stewart

Spoke with john...

1. FDA announcement has flooded him with emails and Board calls...we discussed that the announcement actually contains a number of positives...he said he's send us some materials...we should think about some prescriber interviews to help inform purdue's reaction...worth reading emails and WSJ article Mallin forwarded early this morning...

2. He has confirmed they want help...but wants to come back with specifics on exactly where...(he is still talking to individual executives about specifics of our support)...while not a full green light, do think this is the best you get with John...I asked if I should release the team and he said "no"

3. He has not reviewed Arnie's 3am email with revised memo and detailed answers to his questions...gave him overview and asked him to call back with any questions...

4. Think we are a go...worth reaching out to russ, david, (I'll get to ed and bill)...to see how we might help with latest FDA announcement...

5. All good

Rob

From: "Mallin, William" [[redacted]
Sent: 09/11/2013 10:18 AM GMT
To: Rob Rosiello; Arnab Ghatak
Subject: FW: WSJ: FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin

I am sure you have heard about this by now. Instead of forwarding the 760 e mails, I thought the WSJ summary was succinct and obviously, this will need to be taken into plans going forward. I wonder if Pixar has "challenges" like this?

Bill

Bill

From: Weingarten, Brianne
Sent: Tuesday, September 10, 2013 9:24 PM
To: Mallin, William; Burke, Dr. Brian; Richiger, David
Subject: Fwd: WSJ: FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin

Begin forwarded message:

From: [redacted]
Date: September 10, 2013, 9:14:12 PM EDT
To: [redacted] "Haddox, Dr. J. David" [redacted] "Weingarten, Brianne" [redacted]
Subject: Fwd: WSJ: FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin

The Wall Street Journal also says indication restricted to severe pain only.

Sent from my iPhone

Begin forwarded message:

From: [redacted]
Date: September 10, 2013, 8:19:46 PM EDT
To: [redacted]
Cc: [redacted]
Subject: FW: WSJ: FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin

From: [redacted]
Sent: Tuesday, September 10, 2013 7:05 PM
To: BM Pain Core Team
Subject: WSJ: FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin
Importance: High

The Wall Street Journal Online

FDA Toughens Warning on Pain Drugs; Agency Cites Serious Risks Associated With Pills Such as OxyContin

By Thomas Catan

10 September 2013

Federal regulators ordered tougher warnings on widely used painkillers responsible for what they called an epidemic of addiction and overdose deaths, saying the drugs should be reserved only for severe pain.

The Food and Drug Administration said that long-acting forms of "opioid" painkillers, such as OxyContin, should be used only when there is no alternative. Opioids are powerful narcotics that come from the same family as morphine and heroin.

Until now, the FDA had said the drugs were appropriate for the treatment of "moderate-to-severe" pain. The new drug label drops the word "moderate" and says it should be used only to manage "pain severe enough to require daily, around-the clock, long-term treatment."

The drugs will also contain a new boxed warning that cautions about using the drugs while pregnant. U.S. hospitals have seen a surge in newborns dependent on the drugs, according to a study in the Journal of the American Medical Association.

FDA Commissioner Margaret Hamburg said the agency was taking the action "to combat the crisis of misuse, abuse, addiction, overdose and death from these potent drugs that have harmed too many patients and devastated too many families and communities."

The new warnings only relate to extended-release forms of the drugs, which are often prescribed for months or years to treat chronic pain. They don't affect immediate-release forms, which include Vicodin or Percocet and are often used to treat acute pain, such as after surgery.

Extended-release painkillers like OxyContin have been heavily abused since they were introduced in the late 1990s, because they contain a much bigger load of the drug, designed to trickle into the bloodstream over several hours. Drug abusers learned to break the time-release mechanism by crushing, snorting or injecting the pills to get all the drug at once for a heroin-like high.

The labeling changes are the latest tentative effort by the FDA to get a handle on an explosion of overdose deaths from painkillers without restricting them for legitimate pain patients. More than 16,500 people died after taking the drugs in 2010, according to the Centers for Disease Control and Prevention, more than from heroin, cocaine and all illegal drugs combined.

Immediate-release forms of the drugs are also commonly abused and can also lead to addiction and overdose death even in patients who take them as prescribed.

The FDA is also considering whether to tighten restrictions on hydrocodone products like Vicodin.

Drug-safety campaigners had petitioned the FDA to make more sweeping changes to painkiller labels by including a suggested maximum dose and duration of treatment. The FDA declined to do so, saying there was insufficient evidence to set specific limits.

Instead, the FDA will require drug companies to conduct further research into the drugs' long-term safety. All sides in the debate agree that there is little scientific evidence at the moment to show the benefits of long-term use of such painkillers outweigh the risks, and for which patients.

Blaine Davis of Endo Pharmaceuticals Inc., which makes Opana ER, said, "The FDA decision will ensure that the medicine remains available to appropriate patients."

Patient advocates generally welcomed the changes but doubted they would have a major impact on the problem. Lynn Webster, president of the American Academy of Pain Medicine, said some changes, such as requiring more research and warning pregnant women, were long overdue. But, he said, "I am doubtful this will have much impact on diversion or the number of overdose deaths."

Write to Thomas Catan at thomas.catan@wsj.com and Timothy W. Martin at timothy.martin@wsj.com

Dow Jones & Company, Inc.

Description: Description: Description:
https://bmsource.bm.com/Resources/BrandSite/EmailSigImages/logo2.png

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[redacted]

Associate, Healthcare Practice

222 Merchandise Mart Plaza, [redacted]hicago, IL 60654

Office: [redacted] Mobile: Redacted

[redacted]

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[IMAGE]

Personal and Confidential
Memorandum

To Georges Desvaux
Cc Redacted

From Arnab Ghatak
Date March 28, 2014

EY2014 Impact Summary

Redacted

HIGHLIGHTS OF THE PAST YEAR

Over the last year, I aimed to make a step change in the scale of my impact and in my operating model.

Redacted

Redacted

- Purdue: Rebuilt the CST, working side-by-side with new CEO and entire EC to reshape entire company – from $3B brand ($500M+ opportunity) to ~~a~~ a new launch product regulatory approach to a radically different overall corporate strategy ~~to a new launch product regulatory approach~~

Redacted

Redacted

- Purdue: EDs – Laura Moran, Jeff Smith; Directors – Rob Rosiello, Martin Elling

Redacted

MCK-HCOR-0242335

Redacted

Purdue

I first served Purdue Pharma nearly 10 years ago and re-committed to serving them two years ago – a struggling mid sized company but I saw enormous opportunity to help and wanted to rebuild the CST. Since late spring last year, I have invested heavily to architect and lead an amazing transformation journey with their entire executive team, from fundamentally changing in their sales structure and go to market approach to get over $500M in opportunity to working with R&D leaders to prepare for their next meeting with the FDA to now working directly with their new CEO on a complete overhaul of the company.

- As part of re-committing, I met with their entire executive leadership team and discussed a range of projects and unfortunately the politics had become so intense that multiple confirmed studies were halted.
- Last spring their executive team finally reached out for the project we had long wanted – a full on diagnostic of their lead brand, OxyContin ($3B), which was 95% of their sales. I led the diagnostic effort, working closely with their sales and marketing leaders and reporting to a cross-functional executive team. Quickly we uncovered profound problems – from growth that was unrecognized to a field force that lacked direction to messaging that avoided their strongest

arguments. Everywhere we looked we found opportunity – over $500M. Given some peculiar dynamics with a lame duck CEO, we were requested to write a memo to the board. We were then invited to present our findings privately to the board (the first time in our 10 year history of service) and I led the discussion, engaging them for three hours. This meeting cemented our credibility and the board strongly encouraged us to continue our work.

- Post the conclusion of the diagnostic, I knew that the effort to rebuild the commercial effort would be a transformative journey. I brought in the leader of our PMP Sales service line, Laura Moran, to lead the work. In parallel, the client set up 13 teams with 60+ client team members. The goal was a full rollout at the National Sales Meeting (NSM) at the end of January.
- Six weeks prior to the NSM, Purdue finally announced a new CEO – Mark Timney from Merck. Rob Rosiello and I immediately began to build a relationship through private meetings and had multiple meals with him before he officially began. Mark wanted help on doing a fundamental overhaul corporate strategy but he made it competitive, with key board members having a long relationship with Bain and strong aversion to McKinsey from prior experiences. Still we invested heavily in strengthening our relationship and in the quality of the proposal. Finally at the NSM after observing the successful rollout of the new field approach, he approved a program of five studies, including choosing us for the strategy.
- The strategy is still very much ongoing but we have worked on nearly a daily basis with him and his team, including an offsite in our NYO where he met 6 other McK partners – an explicit goal of ours to change his narrow view of our Firm based on his experience at Merck. We have become close private counselors to him and are confident that the bold strategy we are developing will chart a new course for the company.

Redacted

CREATING HIGH IMPACT CLIENT OPPORTUNITIES

Redacted

Redacted

Purdue is another example of my entrepreneurial risk taking and persistence. Despite many challenges over the years, I have led a rapid transformation journey – from the rep's daily call plan to the CEO's strategy. I have brought in multiple colleagues with deep expertise to accelerate impact at scale and frankly re-built an energized CST.

Redacted

Redacted


Redacted

MCK-HCOR-0242341

I am very excited about the years ahead and hope to build on my record of entrepreneurial impact. A few themes and milestones stand out as areas of focus:

- Continue to grow and expand my four CSTs' dual impact and people missions

Redacted

  - Purdue: Continue to broaden the CEO's perception of our Firm and support him on his largest deals; build new relationship with Canada CEO; coordinate the CST globally (LatAm, Asia, Europe); continue to coach John Goldie's to designation as our core AP

Redacted

WORKING DRAFT
Last Modified 9/5/2013 12:52 AM Eastern Standard Time
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OxyContin growth opportuities

Update with John Stewart
September 5, 2013

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Calling on high decile physicians with appropriate frequency can have major impact on OxyContin TRx: physician "natural pilot"

True physician example

Specialty : **Anesthesiology**

Location : **Wareham, Massachusetts**

Market Decile : **8**

	12 months ending March 2012		12 months ending March 2013
Calls made on physician	**0 P1** **1 P2**	→	**18 P1** **1 P2**
OxyContin scripts written during 2nd half of year	**177**	→	**344**
OxyContin share of ERO Market	**26%**	→	**43%**

- This physician went from receiving 0 P1s to 18 P1s – this resulted in a 94% increase in TRx
- This is not an isolated case
  - **84 physicians** in deciles 7-10 went from receiving <4 PDEs to >14 PDEs
  - These physicians **increased** OxyContin TRx by **39%**, compared to a **17% decline** in physicians that continued to receive <4 PDEs

Last Modified 6/5/2013 12:52 AM Eastern Standard Time
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SOURCE: IMS; Purdue Sales Operations; team analysis

Reps who make more OxyContin P1s on high-decile prescribers generate more OxyContin growth in their territory

ACTUAL DATA

Relationship between TRx growth and P1s on high decile prescribers holds across territories

Sales rep B ***generated 7% more growth****…*

by ***making more Oxy P1s on high decile doctors****…*

despite operating in a ***similar territory to Sales rep A***

% change in Oxy TRx, H1 2012 vs H1 3013	0%	7.3%	+7300 bp
Oxy P1s on high decile MDs (5-10) per mo	23	28	+22%
State	TN	TN	
# of high-decile docs in territory	70	56	

Source: IMS; Purdue sales data

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Wildfire establishes significant upside for successful teams

CASE EXAMPLE

Place exceptional returns within reach of top performers to pull superstars out of regular champions

Significant rewards

- Unrivaled recognition for top champion team
- Winning teams get cash prize that is significant and meaningful

Big league play

- CEO to engage champions in the board room
- Weekly “league tables” across the company, garnering direct leadership attention

Celebrity status

- Champions become “household” names across company; enormous prestige attached to participation
- Spirit of competition

‘Once in a lifetime’ opportunity to springboard to success!

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Wildfire all comes together through CEO 'boardroom meetings' where results are celebrated and bottlenecks are addressed

CASE EXAMPLE

Monthly boardroom session chaired by CEO

Sales and other management responsible for busting obstacles

Senior management (cross-functional) attend sessions

Champion teams wait outside board- room and compare results

Select District Champions

Present	Receive
1 Results	1 Overall ranking
2 Tools deployed	2 Feedback on best practice shared by senior team
3 Issues challenges	3 Timeline and key support individual made responsible for busting obstacles

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Field feedback from previous field activation efforts

FIELD FEEDBACK

Common themes from field	Quotes
▪ It drives goal attainment	*"This allows me to focus on quality over quantity."*
	"I started heavily focusing on my top physicians last year and as a result I am won the President's club."
▪ Cuts through the data to find docs with most incremental upside	*"You are pulling in all this for us. Giving us something really simple that focuses on where the incremental growth is"*
	"This process built off of existing opportunities and focuses on where we have incremental opportunity
▪ Reps are excited to own their outputs	*"These are specific to our territory. VERY exciting!"*
	"This is exactly how we think but first time seeing actual data. Now I can tailor my approach"
▪ Reps ready to hit the ground running	*"Having the time to work at the meeting was PERFECT! It allowed us to act."*
	"I have everything I need to do today."

"Action plan x Buy in = Results"

Note: this field force achieved ~5% revenue growth above plan in 9 months in a mature primary care portfolio

Last Modified 9/5/2013 12:52 AM Eastern Standard Time

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Message

From: Laura Moran [redacted]
Sent: 5/7/2014 3:28:41 AM
To: Rob Rosiello [redacted] Arnab Ghatak [redacted]
[redacted] Pasha Sarraf [redacted]
[redacted]
Subject: convo w/ Bill today

Bill is meeting w/ Mark tomo (wed) evening to discuss consulting support requirements going forward

He has taken the pages we made for him on the mck projects and created his own pages from them. he was still drafting them this afternoon, but they don't include both standard rate and proposed, only the final amounts. he's also made minor changes to the comments and added in the ongoing projects too. we only partially discussed this meeting but I am going to try to meet w/ him directly after the 8am mark BD&L meeting to better understand the story he is planning to tell and ensure he understands our perspective on where the ongoing needs are.

He also shared that in the EC meeting this morning, someone on EC ("who talks out of both sides of his mouth") was complaining that mck has been here a long time and things haven't improved. Mark actually stood up for us and said, this is not true. there was no ADF strategy until McK put it on paper, there was no E2E until McK came in and identified the needs. Bill was really happy about that. (btw I think the person complaining was Ed, who I failed to see one on one this week, tho have been spending time w/ him on the financing w/ Goldie). I will try to see Ed too tomo morning.

will connect further tomo

Laura Moran
Principal
McKinsey & Company
[redacted](cell)
[redacted]fax)
[redacted]office)
[redacted]