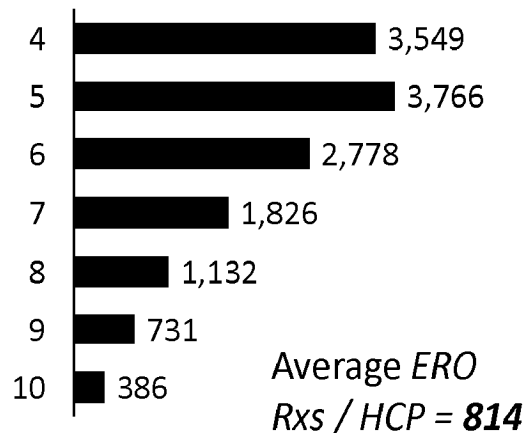
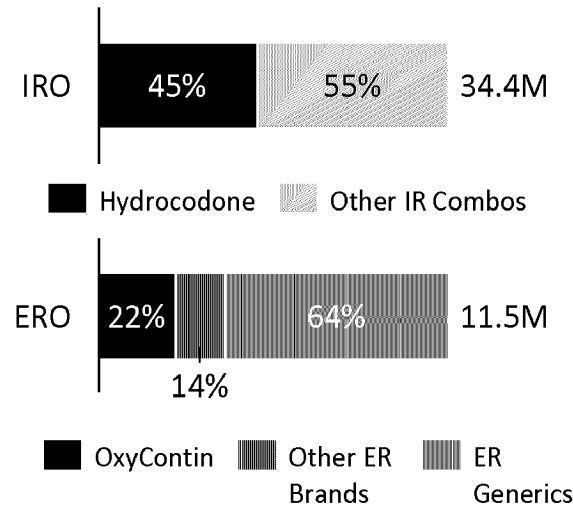
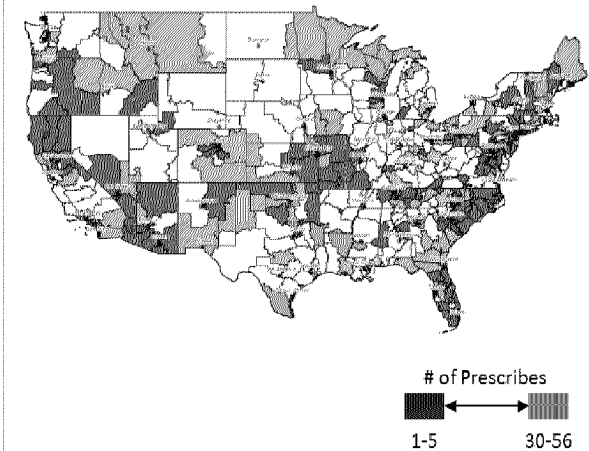


**a) Hysingla ER Proactives Profile (14K HCPs)****Key Insights**

- Proactives believe that **EROs provide better pain management** for eligible patients
- Specialists, PCPs see the advantages of **molecule-to-molecule switches**, but to varying degrees
- Ability to **add Hysingla ER into opioid options and rotation schedule** is attractive
- QD dosing is advantageous, although some concerned **will not last as indicated**
- **ADF** and lack of APAP offer **moderate appeal**

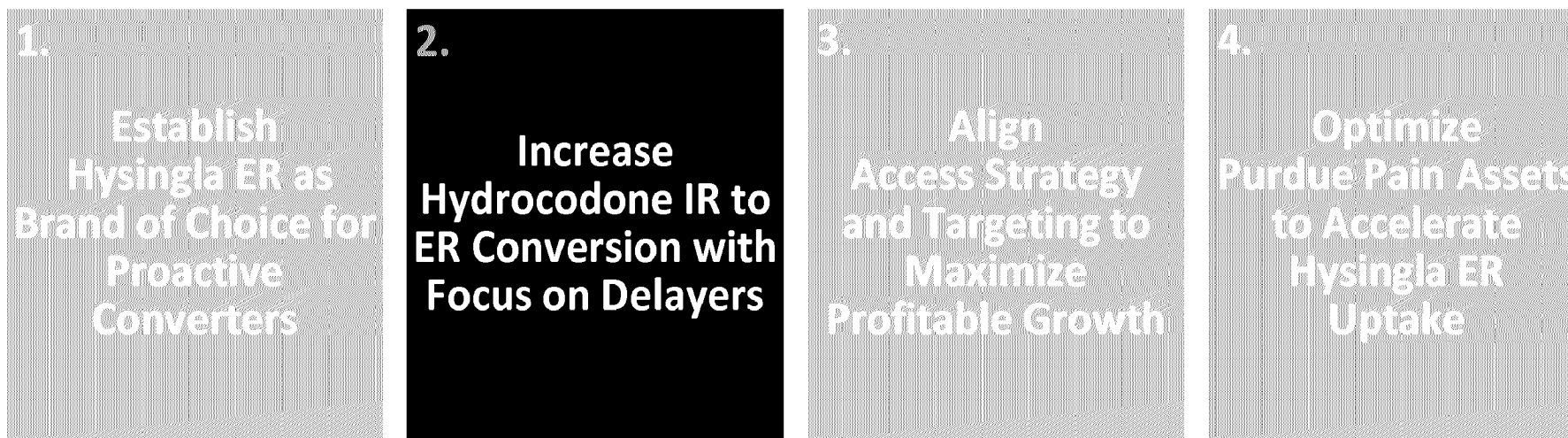
**Key Data Points**

# of HCPs	~14K
Branded ERO prescriptions	4.1M
% Current OxyContin targets	79%
Average IRO to ERO conversion rate	4.6%
% Specialists / PCPs	62%/38%
% Outpatient	61%
% No-see HCPs	15%

**HCPs by ERO Decile****Opioid TRx****Geographic Distribution**



## Strategic Pillar #2



- a) Develop scientific data and messages supporting the value of converting appropriate hydrocodone IR patients to EROs
  - Identify appropriate patient populations for conversion
  - Define treatment algorithms for conversion and monitoring of patients from hydrocodone IR to an ERO
- b) Launch unbranded and branded campaigns to increase Delayer and Proactive conversion rates
  - Leverage tech-driven solutions and longitudinal patient data to help HCPs identify appropriate chronic IRO patients for EROs
  - Launch unbranded patient educational campaign to highlight the advantages of EROs for around-the-clock pain relief

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## b) Hysingla ER Delayers Profile (2.4K HCPs)

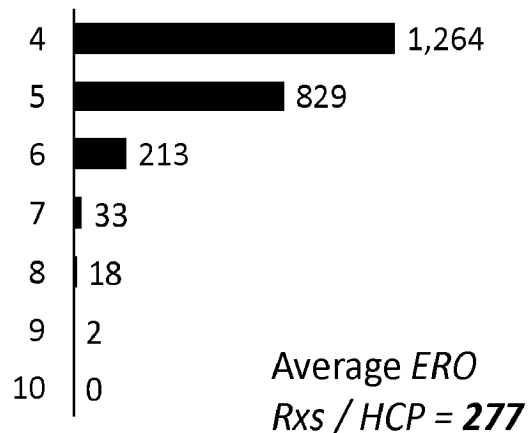
## Key Insights

- Delayers use EROs as escalation when other pain management approaches fail
- Delayers are **more likely to respond to patient requests** to switch to ER or stay on IR
- Some believe molecule-to-molecule conversion will accelerate **dependence and desensitization**
- **Good coverage** and **comparable costs** are crucial for uptake
- QD dosing is beneficial; **ADF is less relevant**

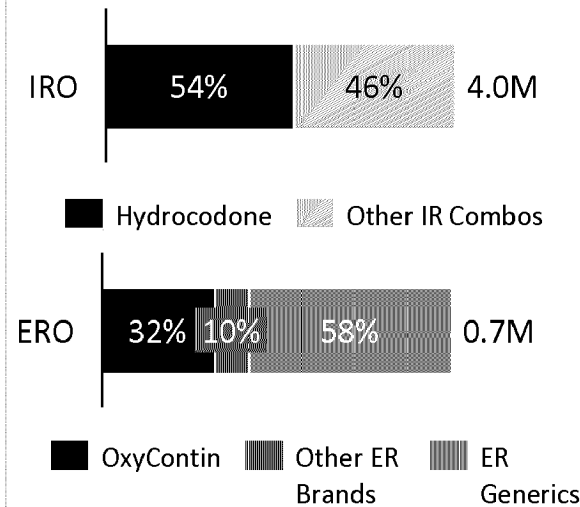
## Key Data Points

# of HCPs	~2.4K
Branded ERO prescriptions	274K
% Current OxyContin targets	70%
Average IRO to ERO conversion rate	0.8%
% Specialists / PCPs	28%/72%
% Outpatient	70%
% No-see HCPs	20%

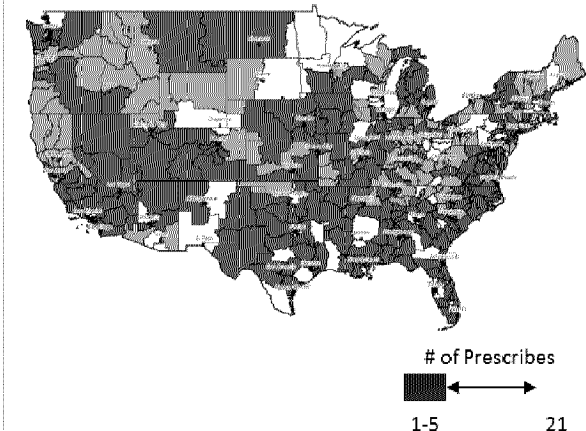
## HCPs by ERO Decile



## Opioid TRx

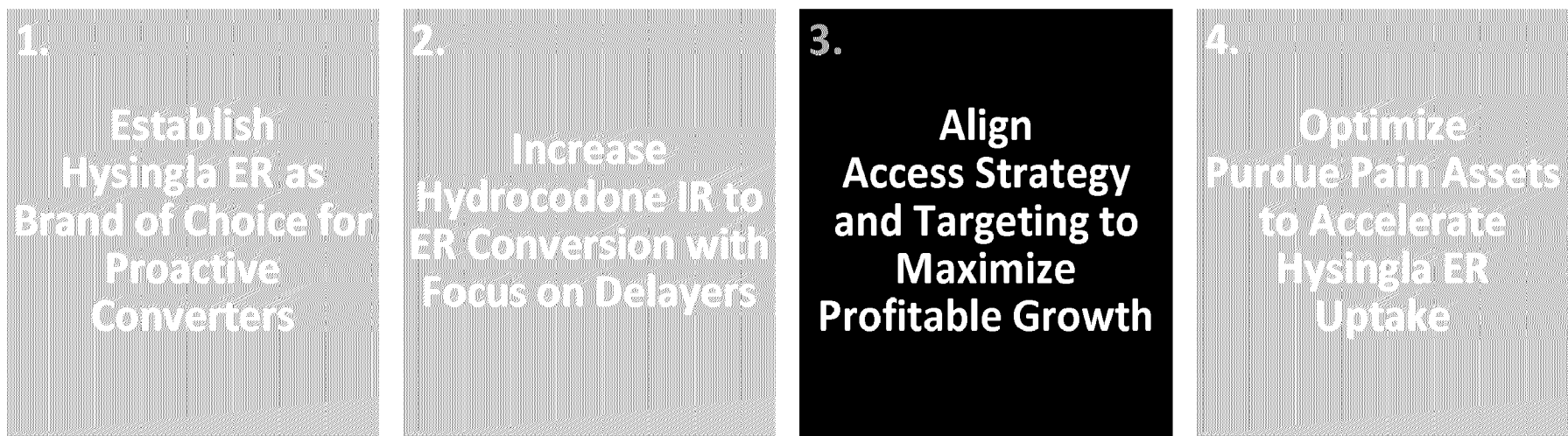


## Geographic Distribution





## Strategic Pillar #3



- a) Drive initial demand and favorable formulary coverage through payer segmentation and by ensuring predictability of payer budgets
  - Educate payers on how Hysingla ER aligns with their approach to IR/ER opioid category management and demonstrate limited impact to budget
  - Harness real-world evidence and value-added collaboration to demonstrate long-term commitment to better patient outcomes
- b) Leverage MSL knowledge base / relationships with payers and KOLs to support ADF messaging, drive access and provide input into formulary decisions
- c) Ensure access through copay support, access coordination and seamless fulfillment



## a) Access Strategy and Formulary Coverage

### Access Strategy

#### Pricing, Rebates

- **WAC price and rebate offers set at parity with OxyContin** (peak 26% blended rebate)

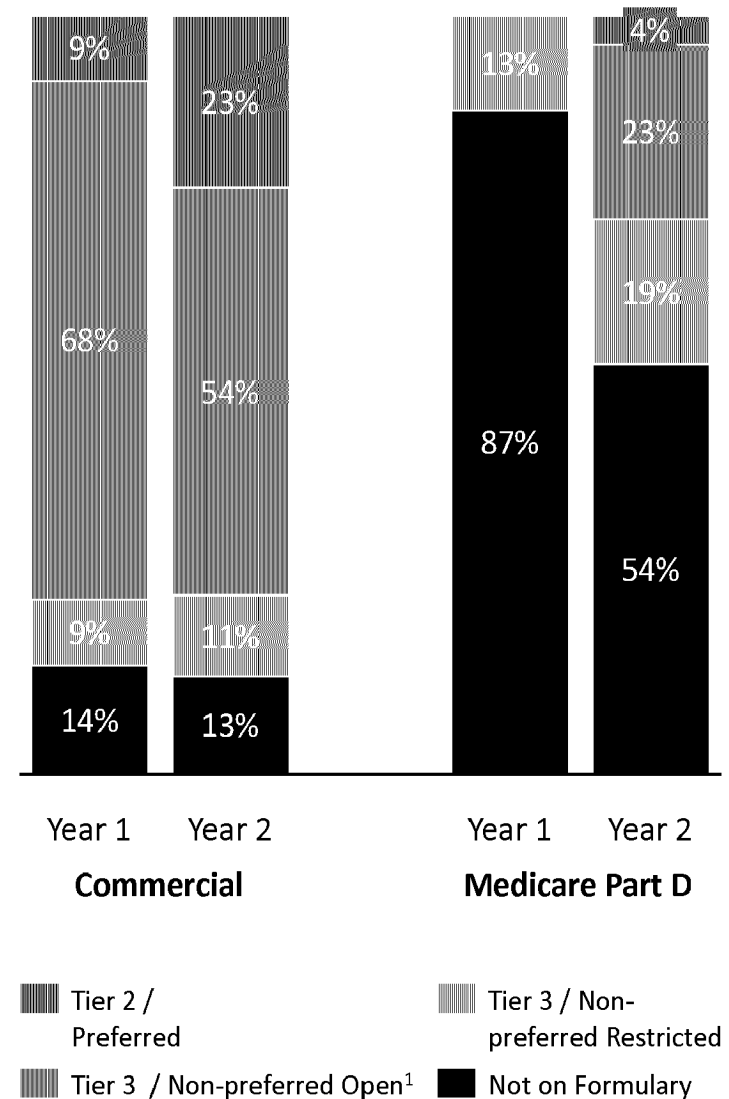
#### Contracting Strategy

- **Targeted contracting strategy** based on plan segmentation and profitability, i.e.,:
  - Guaranteed generic-to-branded ratio
  - Exclusive contracts (i.e., vs. Teva)
- **Aggressively drive initial demand** to grow volume and facilitate contracting

#### Payor Messages

- Hysingla ER aligns with current approach to IR/ER opioid category management—**will not grow the branded ERO market**
- **Budget impact of access to Hysingla ER is limited**

### Formulary Coverage



Note: 1) Tier 3 Open includes 30-day quantity limits and step edits through hydrocodone IR

Source: Managed Markets team projections

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PURDUE-COR-00017541

## a) Payer Budget Impact Model

### Develop Rationale for Switching to Hysingla ER

#### Identify

##### Expected patterns of ER hydrocodone use

Analyses of claims data from IR hydrocodone users, with subpopulations based on usage patterns and payer type

#### Determine

##### The current APAP burden in IR hydrocodone users

Based on analyses of claims data (prescription use only)

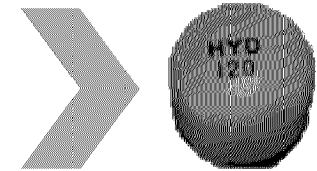
#### Estimate

##### Profile and costs of patients with excessive use of IR hydrocodone

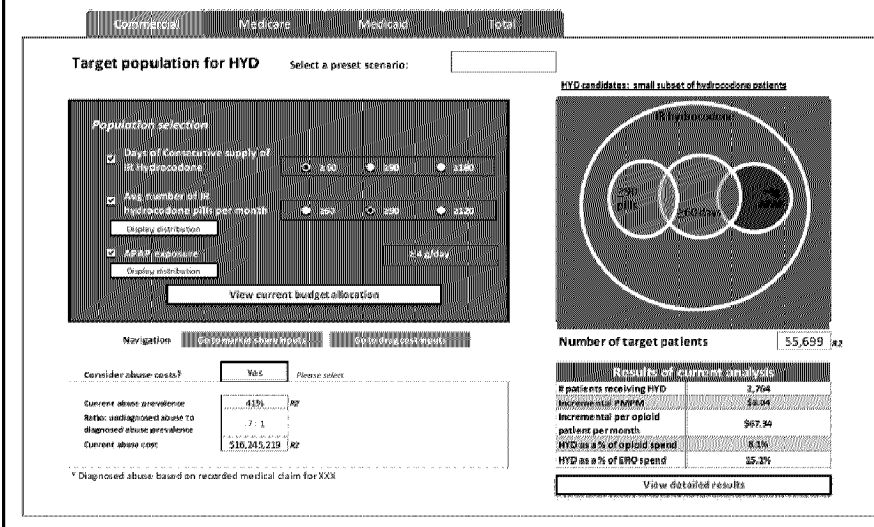
Excess cost of IR hydrocodone patients diagnosed with abuse

### Partner to Facilitate Appropriate Patient Access

- HC cost of opioid pop.
- Excess costs of abusers
- Impact PMPM
- APAP overuse
- PA management costs
- Total Hysingla ER budget impact



### Budget Impact Model

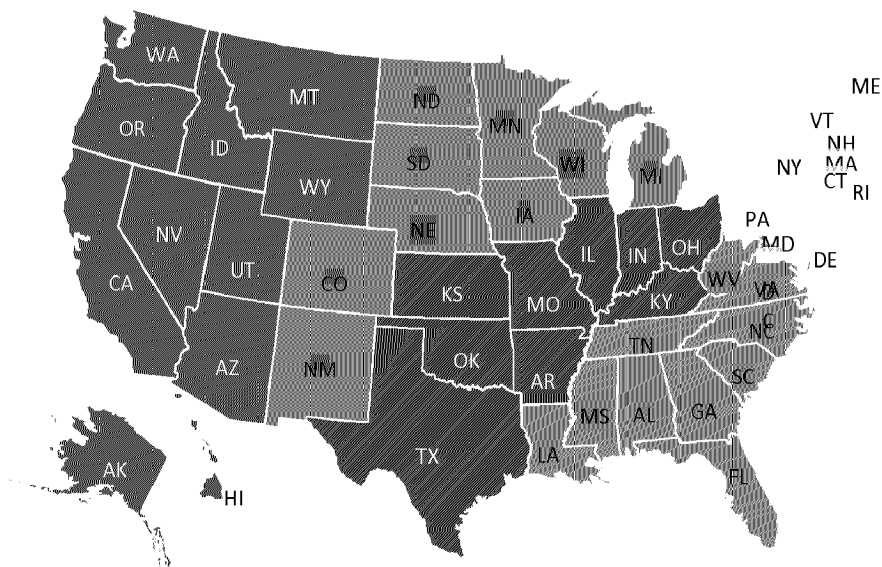




# Strategic Pillar #3

## b) Managed Care and KOLs

### Initial National and Regional Territory Assignments



Director



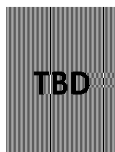
Pharm.D.



Pharm.D.



Pharm.D., BCPS



TBD



Pharm.D., BCPS

### Launch Activities

#### Material Preparation

- Full Clinical Slide Presentation
- “Responsive Only” modules based on anticipated inquiries
- Budget Impact Model Materials (from H.O.P.E.)
- State Medicaid packet and testimony

#### Internal Training & Development

- Review Rules of Engagement, customer-facing strategy and priorities
- Market plan & competition, launch strategy

#### Execution

- Schedule KOL meetings and begin Hysingla ER-specific support in the field

#### Feedback & Measures

- MSL presents to internal stakeholders (managed care), HOPE Mock P&T Ad Board, and at assigned conferences



## Strategic Pillar #4

1.

**Establish  
Hysingla ER as  
Brand of Choice for  
Proactive  
Converters**

2.

**Increase  
Hydrocodone IR to  
ER Conversion with  
Focus on Delayers**

3.

**Align  
Access Strategy  
and Targeting to  
Maximize  
Profitable Growth**

4.

**Optimize  
Purdue Pain Assets  
to Accelerate  
Hysingla ER  
Uptake**

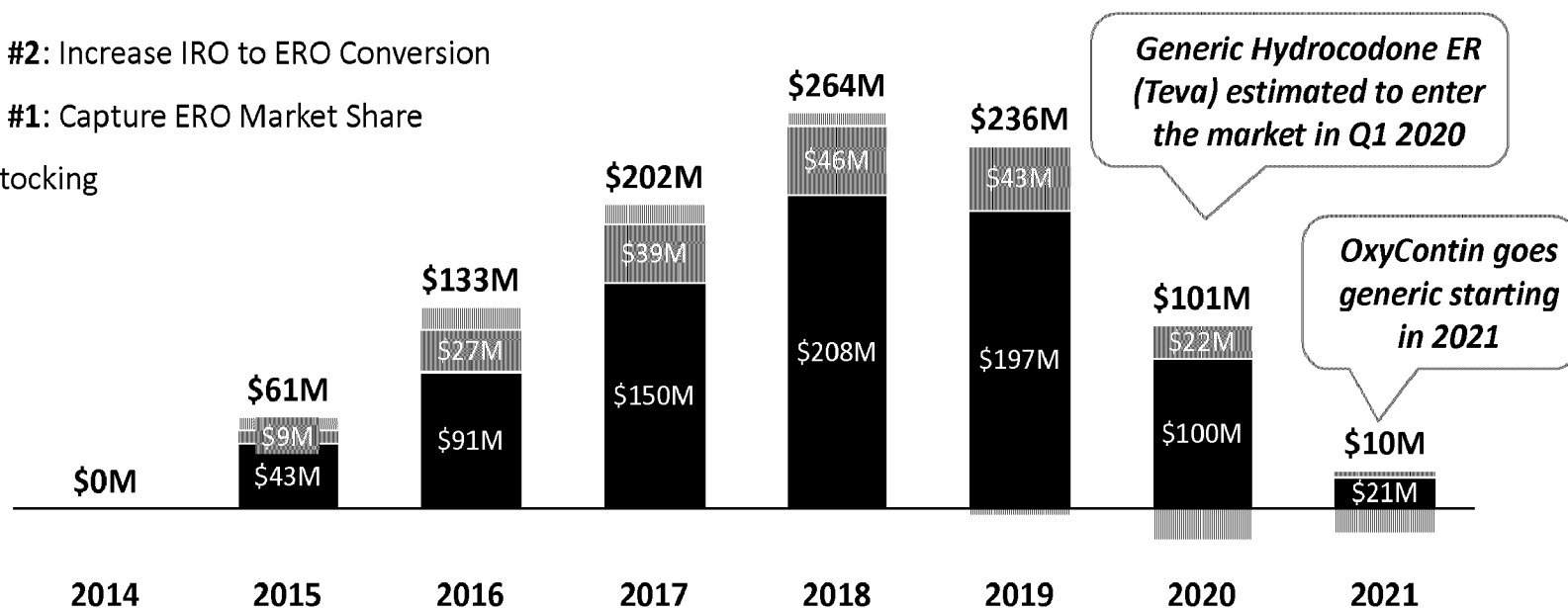
- a) Leverage Purdue's existing, experienced sales force to drive uptake with target HCPs, with Hysingla ER at priority position at launch
- b) Leverage real-world data to address payer and policy-maker concerns on Hysingla ER use
- c) Pursue favorable public policy and regulatory status for Hysingla ER (e.g., ADF special tier status)



# Hysingla ER Financial Opportunity

## Hysingla ER Net Revenue

- Strategic Pillar #2: Increase IRO to ERO Conversion
- Strategic Pillar #1: Capture ERO Market Share
- Attributed to Stocking



	2014	2015	2016	2017	2018	2019	2020	2021
Hysingla ER share of hydrocodone ERs	0%	62%	66%	57%	53%	45%	22%	4%
Hysingla ER TRxs	0K	224K	491K	793K	928K	820K	407K	88K
Gross Revenue	\$0M	\$86M	\$192M	\$312M	\$382M	\$344M	\$148M	\$15M

Note: Gross sales include demand and stocking; analysis assumes competitor rebates match Hysingla ER rebates, 43% of total IRO to ERO conversions are hydrocodone familiar, 39% of these conversions go to a branded ERO treatment, the hydrocodone ERO market captures 40% of this branded & familiar opportunity. Price: \$327/ avg. Rx in 2015 with annual +3% price increases; Assumes 90% of Hysingla ER market goes generic once either generic OxyContin or Hysingla ER is available; Sources: Butrans Market by Specialty, February OxyContin LRx Report, Peak brand share of new entrants from Source of Business Data (IMS); Monitor Deloitte Analysis

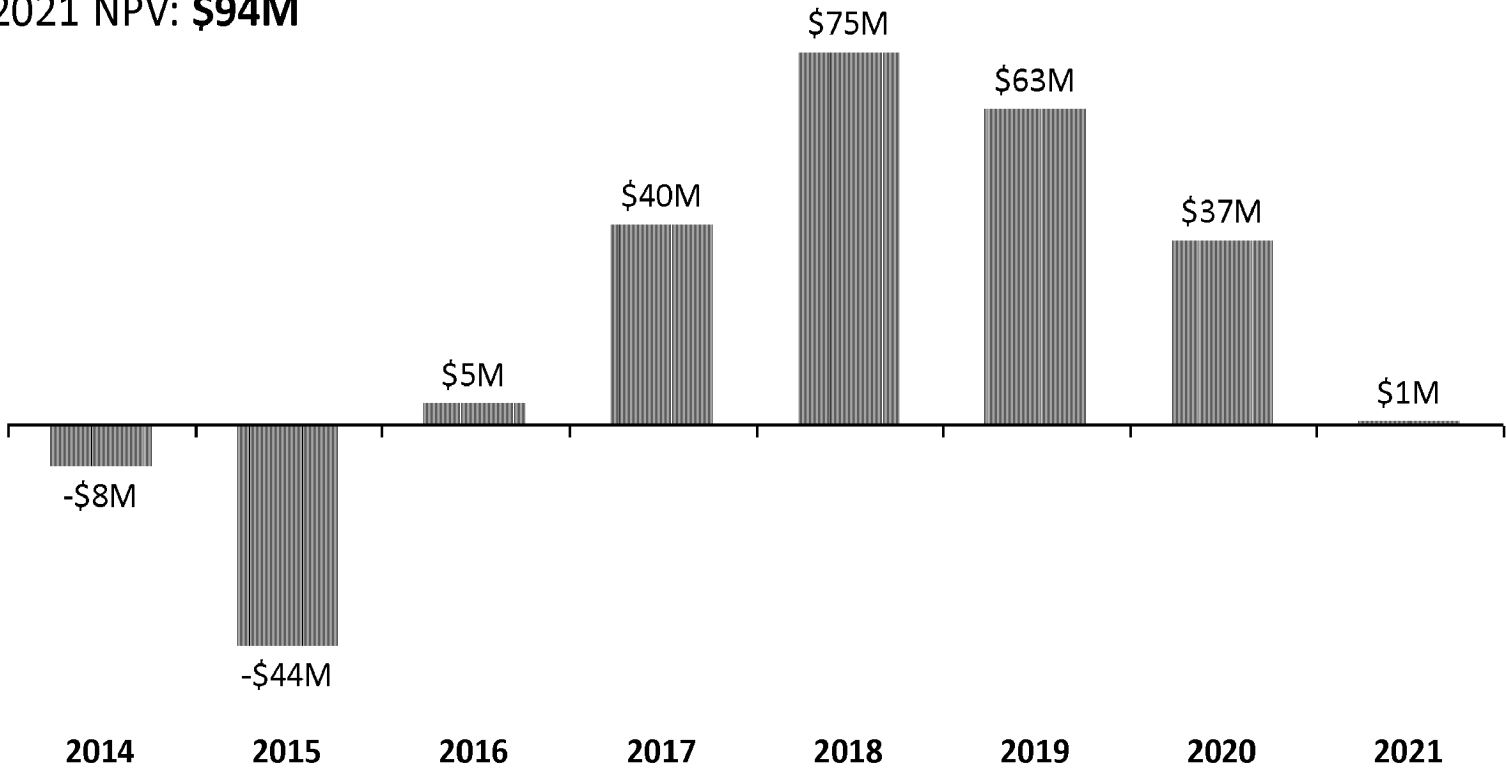
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# Hysingla ER Profitability

## Hysingla ER Net Income (2014-2021)

2014-2021 NPV: **\$94M**



Profit Margin	2014	2015	2016	2017	2018	2019	2020	2021
	N/A	-72%	3%	20%	28%	27%	37%	10%

Notes: Gross sales include demand and stocking; includes cannibalization attributed to Hysingla ER market entry from 2015-2019; Key costs (i.e., marketing, sales force) reduced in 2020 when generic hydrocodone ER (Teva) expected in market; NPV based on 9% discount rate; Sources: 2013 10-Year Plan; Butrans Market by Specialty, Combo and Chronic TRx; February OxyContin LRx Report, Peak brand share of new entrants from Source of Business Data (IMS); Monitor Deloitte Analysis

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# Hysingla ER P&L

<i>(000s)</i>	2014	2015	2016	2017	2018	2019	2020	2021	Total
Gross Sales	-	85,990	191,882	312,098	381,730	344,094	148,383	15,382	\$1,479,559
Net Sales	-	61,257	133,195	201,620	263,542	236,448	101,498	9,877	\$1,007,436
Gross Profit	-	52,917	114,922	176,146	235,247	210,994	90,614	8,835	\$889,676
Selling & Promotion <i>% of net sales</i>	11,600	81,333 133%	77,699 58%	75,793 38%	73,930 28%	72,113 31%	22,114 22%	-	\$414,582 41%
Other Expenses (R&D, Legal, G&A, Health Care Reform Fees)	1,400	20,227	19,256	22,291	25,236	19,524	11,314	7,367	\$126,614
Product Contribution <i>% net sales</i>	\$(13,000)	\$(48,643) -79%	\$17,967 13%	\$78,062 39%	\$136,081 52%	\$119,357 50%	\$57,186 56%	\$1,469 15%	\$348,479 35%
Cannibalization Impact	-	19,603	11,022	16,029	21,201	21,960	-	-	\$89,814
Product Contribution Post Cannibalization <i>% of net sales</i>	\$(13,000)	\$(68,246) -111%	\$6,946 5%	\$62,033 31%	\$114,880 44%	\$97,397 41%	\$57,186 56%	\$1,469 15%	\$258,665 26%

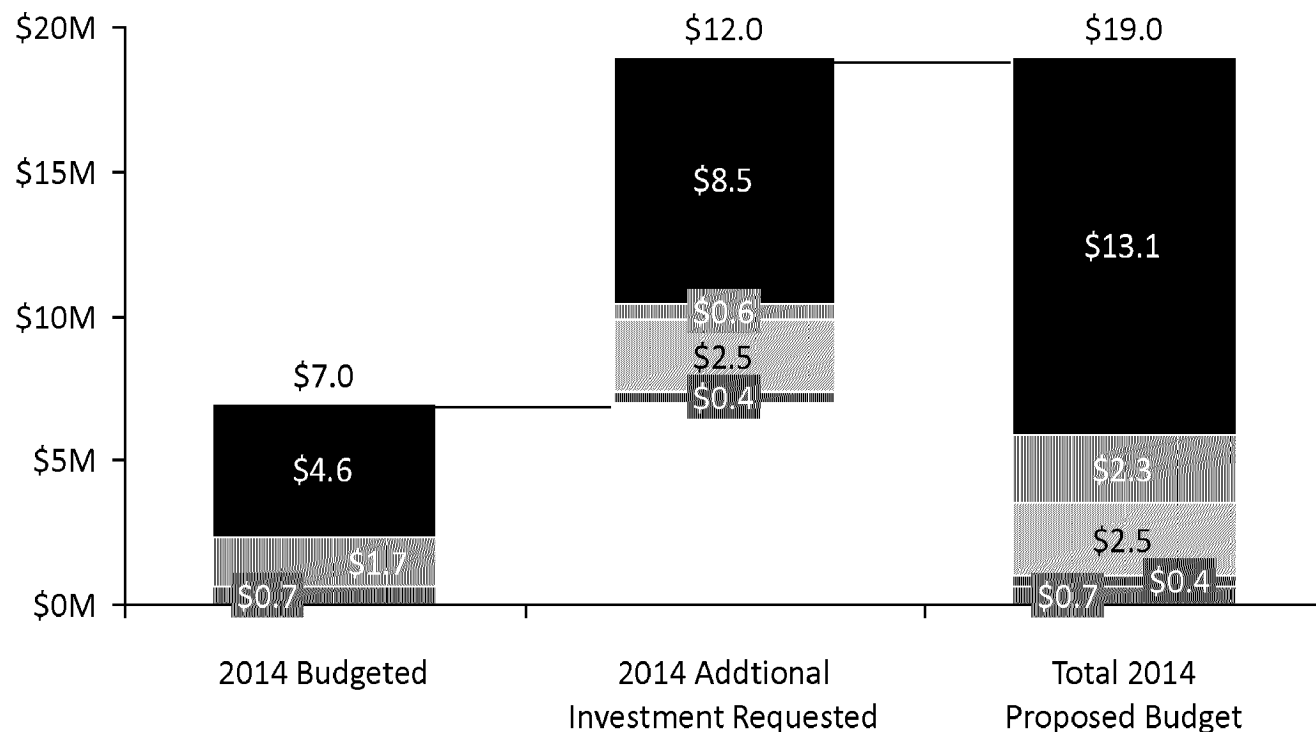
NPV: \$94M

Note: Gross sales include demand and stocking; includes cannibalization attributed to Hysingla ER market entry from 2015-2019; Key costs (i.e., marketing, sales force) reduced in 2020 when generic hydrocodone ER (Teva) expected in market; Selling & Promotion includes ~\$48M per year of sales expense (1/3 cost of the current 525 sales reps)





# 2014 Investment Request



Marketing / Agency	Launch Strategy / Brand Planning	\$1.7	\$5.0	\$6.7
	Creative, Sales Aids, Advertising, Conventions	\$1.4	\$1.0	\$2.4
	Managed Markets, Fulfillment, REMS	\$0.6	\$1.5	\$2.1
	Other Promotional Support	\$0.9	\$1.0	\$1.9
FAMR	Market Research	\$1.7	\$0.6	\$2.3
Education	Unbranded Education Campaign	-	\$2.5	\$2.5
HOPE	Cost and Time Series Analyses	-	\$0.4	\$0.4
Publications	Publication Plan	\$0.7	-	\$0.7

Note: Does not include \$1M in amortization of milestones in 2014 in P&L



## 2015 S&P Investment Request

### 1. Establish Hysingla ER as Brand of Choice for Proactive Converters

Name	\$M
KOL Program	\$7.6M
Ads, Print, Direct Mail, PTN	\$4.1M
eMarketing	\$3.5M
Agency Fee (half)	\$1.8M
Virtual Rep Call Cntr.	\$0.3M
Other (e.g., analytics)	\$1.5M
Publications Plan	\$0.7M
<b>Total</b>	<b>\$19.5M</b>

### 2. Increase Hydrocodone IR to ER Conversion with Focus on Delayers

Name	\$M
Unbranded HCP, Patient	\$5.0M
Agency Fee (half)	\$1.8M
Physicians Interactive	\$1.7M
Patient Identification	\$0.8M
Telemarketing	\$0.5M
Other (e.g., analytics)	\$1.5M
<b>Total</b>	<b>\$11.3M</b>

### 3. Align Access Strategy and Targeting to Maximize Profitable Growth

Name	\$M
Savings Card Admin	\$2.3M
Adherence Prog.	\$1.1M
H.O.P.E.	\$2.8M
<b>Total</b>	<b>\$6.2M</b>

### 4. Optimize Purdue Pain Assets to Accelerate Hysingla ER Uptake

Name	\$M
Conventions	\$2.0M
Special Promotions	\$1.5M
Sales Force (share of existing team)	\$47.4M
<b>Total</b>	<b>\$50.9M</b>

Cost Center	Marketing	Sales	Other Launch Support	Overall
<b>Total \$M</b>	<b>\$34M</b>	<b>\$47M</b>	<b>\$7M</b>	<b>\$88M</b>

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## Recommendations

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Launch Hysingla ER with a focus on driving share within two priority HCP segments

Fund additional investment (\$12M incremental in 2014) to build foundation for Hysingla ER launch and to generate momentum in the limited timeframe as the first-to-market hydrocodone ER with ADF



# Appendix

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# Hysingla ER P&L – Detailed

(000s)		2014	2015	2016	2017	2018	2019	2020	2021
<b>Gross Sales</b>			<b>\$85,990</b>	<b>\$191,882</b>	<b>\$312,098</b>	<b>\$381,730</b>	<b>\$344,094</b>	<b>\$148,383</b>	<b>\$15,382</b>
Fee for Service	% gross		1,720 2%	3,838 2%	6,242 2%	7,635 2%	6,882 2%	2,968 2%	308 2%
Sales Discounts & Allowances	% gross		7,019 8%	9,594 5%	12,484 4%	11,452 3%	10,323 3%	4,451 3%	461 3%
Patient Savings Cards Disc.	% gross		6,019 7%	8,535 4%	11,705 4%	- 0%	- 0%	- 0%	- 0%
Rebates on Factory Sales	% gross		9,975 12%	36,720 19%	80,047 26%	99,102 26%	90,442 26%	39,466 27%	4,735 31%
<b>Net Sales</b>			<b>61,257</b>	<b>133,195</b>	<b>201,620</b>	<b>263,542</b>	<b>236,448</b>	<b>101,498</b>	<b>9,877</b>
COGS/Shipping & Warehsg	% gross		3,440 4%	7,675 4%	12,484 4%	15,269 4%	13,764 4%	5,935 4%	615 4%
Royalty	% net		4,901 8%	10,597 8%	12,990 6%	13,025 5%	11,689 5%	4,949 5%	427 4%
<b>Gross Profit</b>			<b>52,917 62%</b>	<b>114,922 60%</b>	<b>176,146 56%</b>	<b>235,247 62%</b>	<b>210,994 61%</b>	<b>90,614 61%</b>	<b>8,835 57%</b>
Selling & Promotion	% net	11,600	81,333 133%	77,699 58%	75,793 38%	73,930 28%	72,113 31%	22,114 22%	-
Marketing Expense		11,600	33,933	28,877	25,506	22,135	18,764	5,629	-
Sales Force Expense			47,400	48,822	50,287	51,795	53,349	16,485	-
Other Expenses		1,400	20,227	19,256	22,291	25,236	19,524	11,314	7,367
Amort. of Milestones		1,000	1,600	1,600	1,600	1,600	1,600		
Health Care Reform Fee			-	727	1,773	3,038	2,659	2,518	1,343
Legal Fees			2,500	2,625	2,756	2,894	3,039	-	-
General & Admin	% net		1,907 3%	3,552 3%	5,781 3%	7,685 3%	7,256 3%	3,689 4%	773 8%
R&D		400	14,220	10,752	10,381	10,018	4,970	5,107	5,251
<b>Product Contribution</b>	% net	<b>\$(13,000)</b>	<b>\$(48,643) -79%</b>	<b>\$17,967 13%</b>	<b>\$78,062 39%</b>	<b>\$136,081 52%</b>	<b>\$119,357 50%</b>	<b>\$57,186 56%</b>	<b>\$1,469 15%</b>
Cannibalization			19,603	11,022	16,029	21,201	21,960		
OxyContin Impact			17,158	9,178	13,393	17,912	18,645		
Butrans Impact			2,445	1,844	2,637	3,289	3,315		
<b>Net Product Contribution</b>	% net	<b>\$(13,000)</b>	<b>\$(68,246) -111%</b>	<b>\$6,946 5%</b>	<b>\$62,033 31%</b>	<b>\$114,880 44%</b>	<b>\$97,397 41%</b>	<b>\$57,186 56%</b>	<b>\$1,469 15%</b>
<b>Net Income</b>	% net	<b>\$(8,450)</b>	<b>\$(44,360) -72%</b>	<b>\$4,515 3%</b>	<b>\$40,321 20%</b>	<b>\$74,672 28%</b>	<b>\$63,308 27%</b>	<b>\$37,171 37%</b>	<b>\$955 10%</b>
<b>NPV: \$94M</b>									

Note: Gross sales include demand and stocking; includes cannibalization attributed to Hysingla ER market entry from 2015-2019; Key costs (i.e., marketing, sales force) reduced in 2020 when generic hydrocodone ER (Teva) expected in market



# Framework for Hysingla ER Launch Readiness

## Positioning

### Positioning statement

#### TO

- Chronic pain patients who require uninterrupted pain relief and are on or have used hydrocodone opioids to manage their condition

#### HYD IS THE BRAND OF

- Extended release opioid

#### THAT

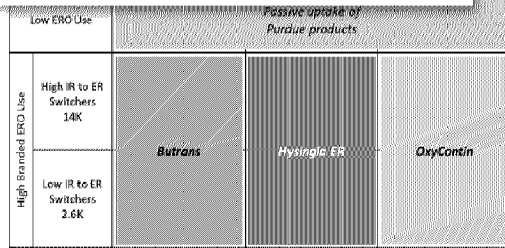
- Is the optimal<sup>TM</sup> hydrocodone formulation for consistent and seamless transition from IR to ER

#### BECAUSE

- The only Q24h formulation of hydrocodone with abuse-deterrent properties
- The familiarity of hydrocodone, a commonly used opioid
- The flexibility of a single entity opioid, avoiding the dosing ceiling caused by acetaminophen
- A range of seven dosage strengths to allow for tailoring to individual patients

#### SO THAT

- Physicians have the ability to provide opioid pain relief with a greater degree of certainty



Market Map

## Hysingla ER Strategies

### Strategic Pillars

1. Establish Hysingla ER as Brand of Choice for Proactive Converters
2. Increase Hydrocodone IR to ER Conversion with Focus on Delayers
3. Align Access Strategy and Targeting to Maximize Profitable Growth
4. Optimize Purdue Pain Assets to Accelerate Hysingla ER Uptake

## Value Proposition



Payor / Policy



Patient



Provider



IDN

- Positioning serves as the foundation for brand strategy

- Brand strategy consists of four strategic pillars for Hysingla ER that will bring the positioning to life

- Strategic pillars outline how Hysingla ER's value proposition will be made clear to all stakeholders



# Positioning for Purdue's Pain Portfolio

<div>Patient Characteristics</div> <div>Prescriber Characteristics</div>		Chronic Pain Patients Not Using Opioids, Using Low-dose Hydrocodone IR or Using Tramadol IR	Hydrocodone IR patients (≥20mg/day)	Oxycodone IR patients
Low ERO Use		Passive uptake of Purdue products		
High Branded ERO Use	High IR to ER Switchers 14K	Butrans	Hysingla ER	OxyContin
	Low IR to ER Switchers 2.6K			

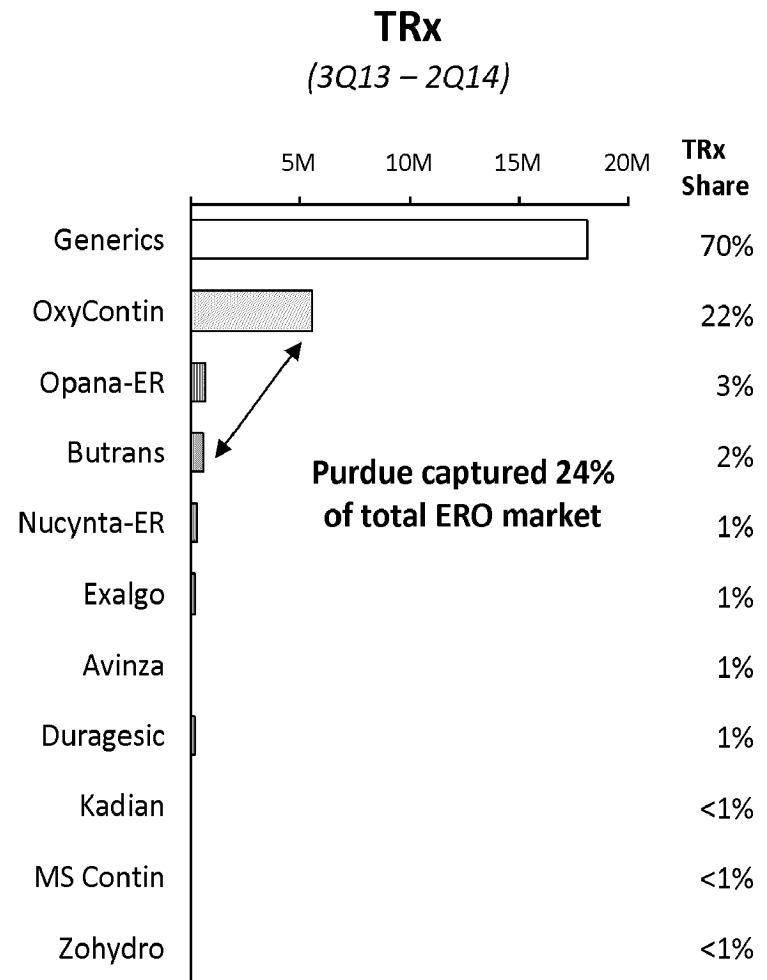
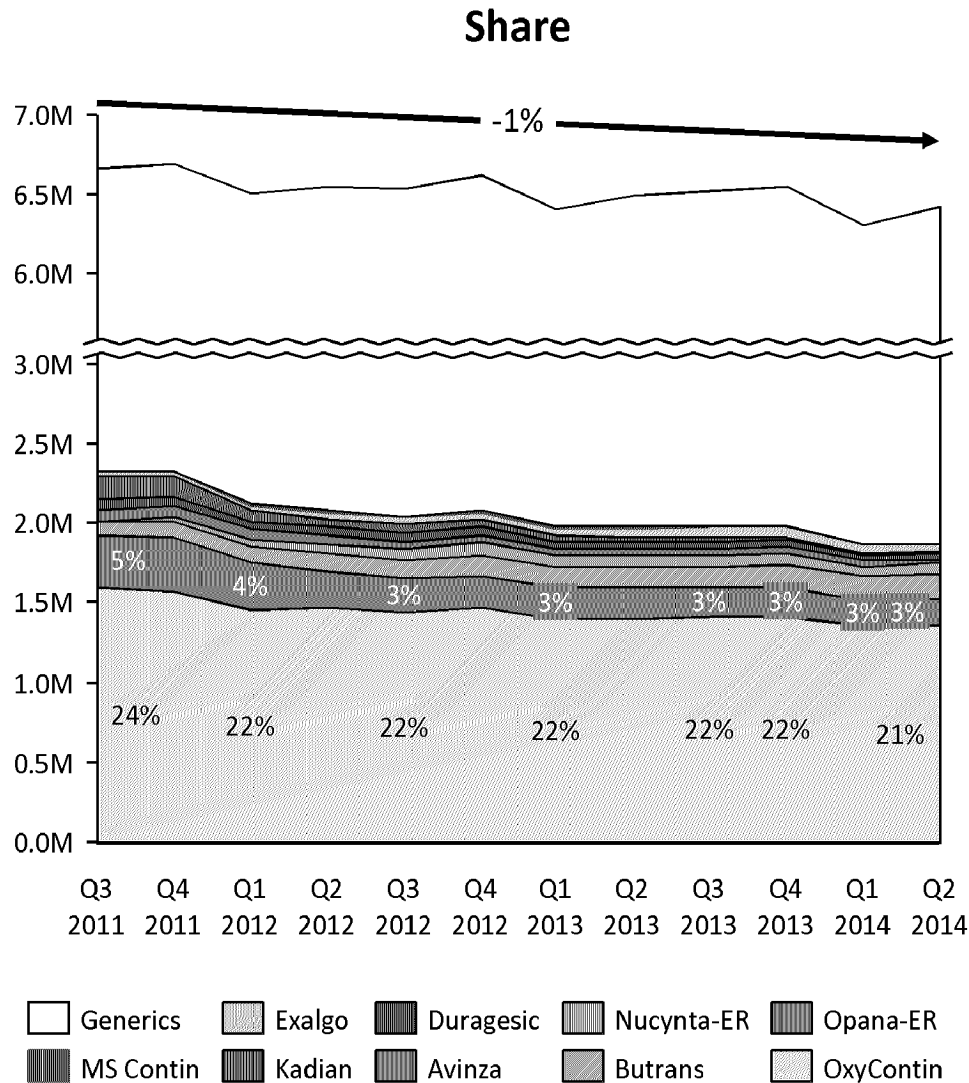
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Source: IMS Health, Purdue Pharma analysis, Monitor Deloitte analysis





# Current Branded ERO Market Environment





# Hydrocodone ER Competition

	2014		2015	
	Zohydro	Hysingla ER	MNK-155	CEP-33237
	Zogenix	PURDUE	Mallinckrodt Pharmaceuticals	TEVA
Launch	March 2014	Q1 2015	Q2 2015	Q4 2015
Abuse Deterrence	None (ADF to launch Q4 2016 <sup>1</sup> )	Physical abuse deterrence (ADF label pending)		
Label / Product Properties	<ul style="list-style-type: none"> <li>Q12 dosing</li> <li>6 dose strengths</li> <li>No APAP</li> </ul>	<ul style="list-style-type: none"> <li><b>Q24 dosing</b></li> <li>7 dose strengths</li> <li>No APAP</li> </ul>	<ul style="list-style-type: none"> <li>Likely indicated for acute post-op pain</li> <li>Combined IR and ER pharmacokinetics</li> <li>Contains APAP</li> </ul>	<ul style="list-style-type: none"> <li>Q12 dosing</li> <li>4-5 dose strengths</li> <li>No APAP</li> </ul>
Loss of Exclusivity	ADF version post Q4 2021	Q4 2022	No exclusivity / patent overlap with competitors	Q1 2020 (if launched in 2015)

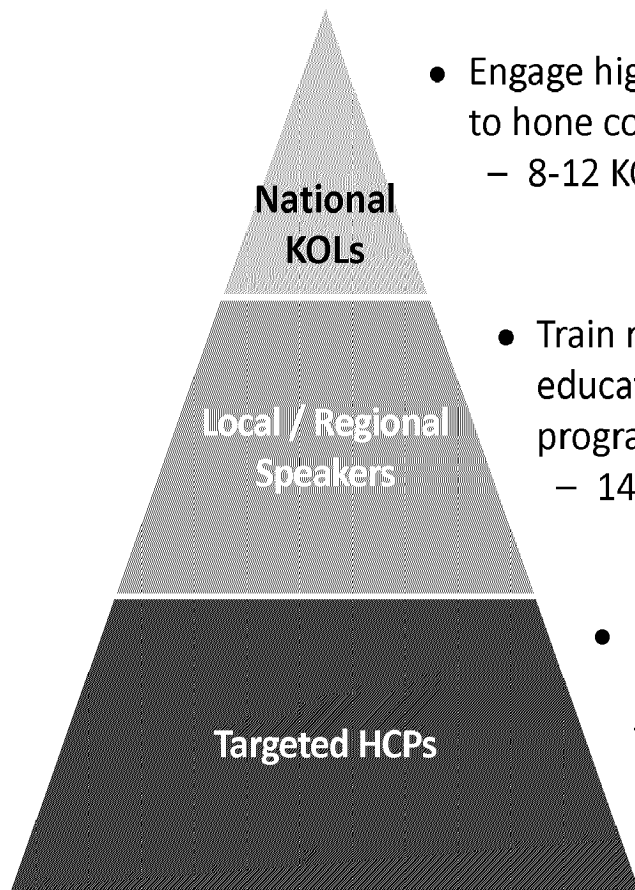
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Note: 1) An abuse deterrent formulation of Zohydro will likely launch in 2015 but without an ADF indication



## b) KOL Engagement Strategy

### *Description*



- Engage high-profile KOLs at regular advisory boards to hone commercial strategies for the brand
  - 8-12 KOLs
- Train regional thought leaders to provide education on Hysingla ER at in-person speaker programs
  - 140-150 Speakers
- Engage select HCPs through local speakers program and web conferences / teleconferences
  - 9,900 HCPs through speakers program
  - 1,000 HCPs through web conferences



**Total Reach**  
**~11,000 HCPs**  
*(70% of target HCPs)*

## b) Publication Plan (for Publications and Presentations)

### Phase 1: Pre-Launch (2013-2014)

- Public health and economic value of abuse-deterrent opioid formulations
  - Costs to employers
  - Use of opioids with ADF to address opioid abuse
- Hydrocodone / APAP products – some patients prescribed high doses, long-term treatment, risks of toxicity
  - Exposure to high doses of acetaminophen is common despite risks of toxicity
- Introduce Hysingla ER as a drug in development to the scientific community

### Phase 2: Peri-Launch (1Q-2Q 2015)

- Efficacy, effectiveness, tolerability, and safety
  - Double-blind pivotal trial
  - Open-label 12-month trial
  - Incoming Vicodin users
  - Hysingla ER's ADF
  - Doing guidelines
  - Once-daily pharmacologic profile
  - Information for payers

### Phase 3: Post-Launch (3Q 2015-2016)

- Long-term effectiveness and safety
  - Open-label 18-month data
- No signal of hearing disturbances
- Tolerability and effective analgesia in multiple patient populations
- Comprehensive pharmacologic profile
  - Lack of PK effect with food
  - PK in special populations
  - Review of clinical pharmacology program
- Abuse deterrence in community settings
- Pharmacoeconomics (HOPE)

#### Target Groups for Presentations and Publications

#### Pain medicine specialists

- American Acad. of Pain Mgmt.
- American Acad. of Pain Med.
- American Pain Society
- Etc.

#### Primary care / supportive care

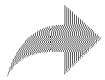
- American Academy of Family Practitioners
- American Assoc. of NPs
- American Academy of PAs

#### Managed care / payers

- American Acad. of Managed Care Pharmacy
- CPDD
- ISPOR



## a) IRO to ERO Switching Triggers



### Primary Triggers for Switching

- Too many pills per day (limit for most physicians of 6-8)
- Dose too high and pain not managed sufficiently
- Break-through pain or “highs and lows”
- Running out of pills prior to the end of the prescription
- Acute pain becomes chronic (lasts longer than 3 months)



### Primary Triggers for NOT Switching

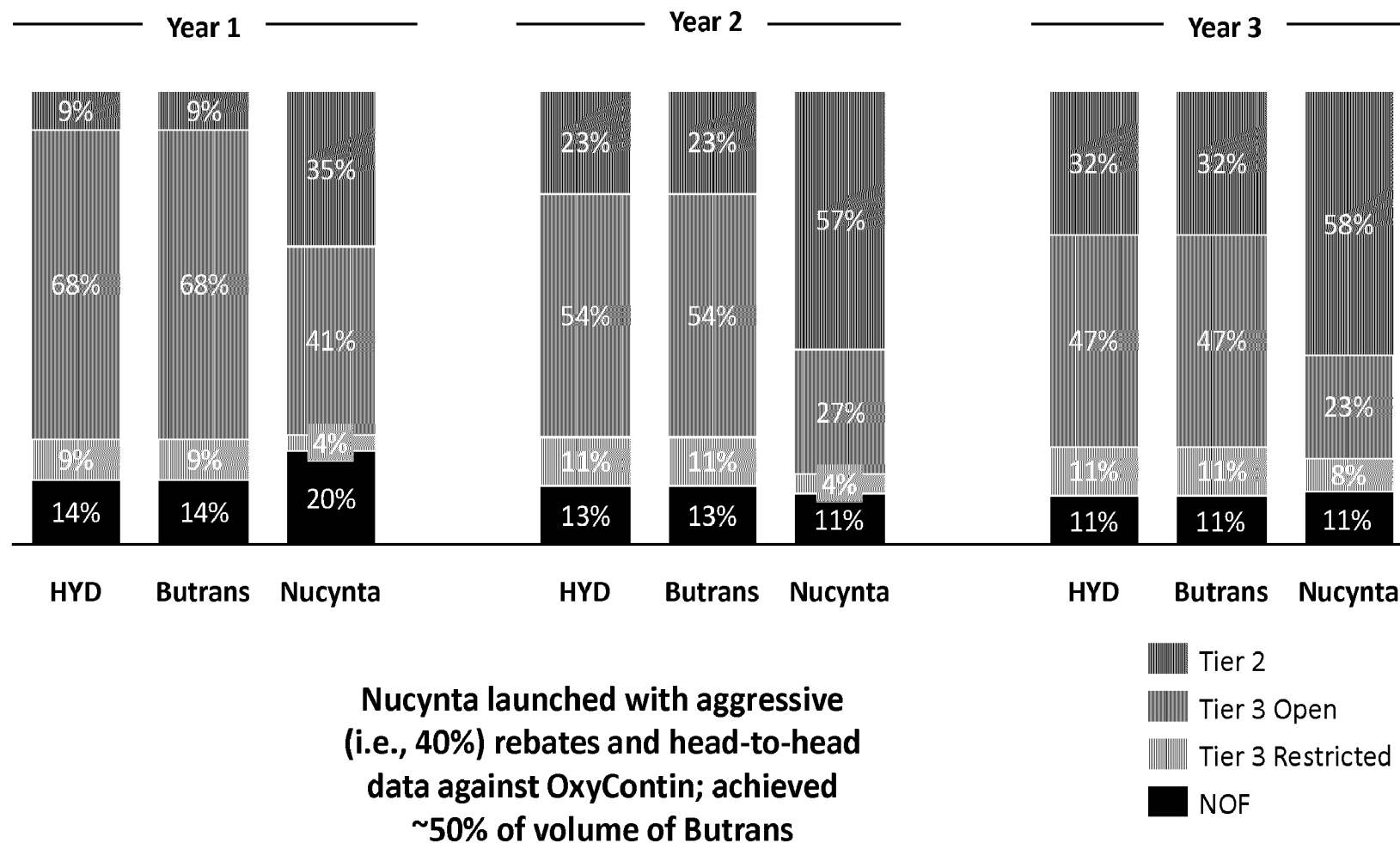
- Provider unwilling to initiate ERO (unfamiliarity with EROs, pain not deemed “severe enough,” higher scrutiny of CII vs. CIII)
- Inconsistent process for reassessing pain
- Patient viewed as well-controlled / not complaining
- Prohibitive insurance (e.g., branded ERO is NOF)
- Previous ERO failure (e.g., inadequate pain relief, adverse drug event)

### Who switches and when?

- **HCPs who are comfortable prescribing EROs** are most likely to switch to an ERO **once an IRO has been proven ineffective**
- **Pain Management specialists** (i.e., pain management, anesthesiologist, PM&R, Rehabilitation Medicine) frequently modify opioid usage to a combination of immediate and extended release opioids **upon referral from inappropriately-dosed IROs**
- **Neurologists switch as a last resort**, after other agents (e.g., Lyrica, gabapentin) have been tried. Extended release opioids are frequently viewed as an **add-on therapy**



## a) Post-launch Commercial Formulary Coverage Comparison



Note: 1) Tier 3 Open includes 30-day quantity limits and step edits through hydrocodone IR; 2) Coverage is an average of rates during Q1-Q4 of each year post launch  
 Sources: Fingertip Formulary as of 7/3/14; Formulary Data Trend Report 2010 forward for Butrans, Exalgo, and Nucynta ER; HYD forecast based on Managed Markets team projections

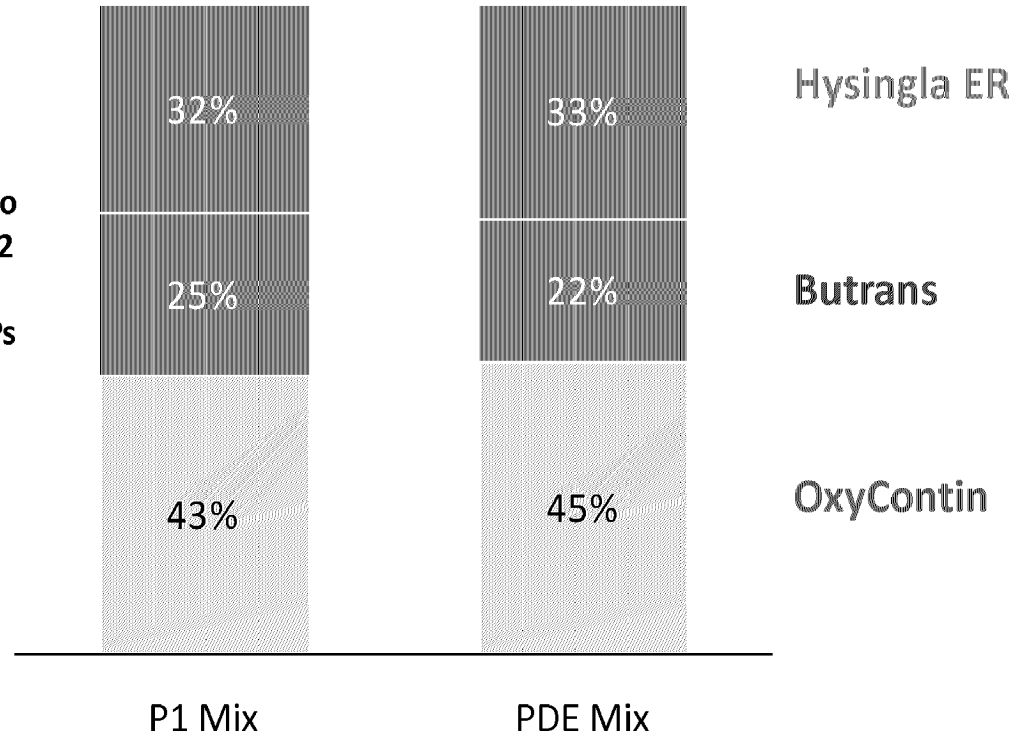
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## a) Current Sales Force Supports Full Portfolio

80K target HCPs overall

Hysingla ER to  
be in P1 or P2  
with 16K  
targeted HCPs



Hysingla ER	255K	384K
Butrans	205K	254K
OxyContin	346K	538K





## b) Post-Marketing Studies to Support Payer Strategy

	Key Message	Data	Barriers Addressed
Real-world/Epidemiology	Purdue's PEO-based formulation deters abuse of opioids with abuse-deterrent characteristics	<ul style="list-style-type: none"> <li>Postmarketing epidemiology studies for reformulated OxyContin demonstrating decreases in abuse</li> </ul>	<ul style="list-style-type: none"> <li>Concern that large dosage strength tablets of hydrocodone may become widely abused or diverted if Hysingla ER use increases</li> </ul>
	Purdue's PEO-based formulation decreases resource utilization associated with abuse	<ul style="list-style-type: none"> <li>Postmarketing epidemiology studies for reformulated OxyContin demonstrating decreases in diagnosed abuse / addiction / overdose</li> </ul>	<ul style="list-style-type: none"> <li>Concern that Hysingla ER will increase resource utilization for payers due to increased abuse/addiction</li> </ul>
	A large number of patients remain on IR hydrocodone-acetaminophen for longer than 90 days and chronically consume unsafe levels of acetaminophen from IR hydrocodone-acetaminophen	<ul style="list-style-type: none"> <li>MarketScan commercial and Medicaid insurance claims analyzed within Purdue</li> </ul>	<ul style="list-style-type: none"> <li>Opinion that ER hydrocodone is not needed because IR hydrocodone is used short term and is generally safe</li> </ul>
Risk Management	Patients who use long-term ER opioids can be predicted so that patient segments/pricing can be determined	<ul style="list-style-type: none"> <li>MarketScan commercial and Medicaid insurance claims analyzed within Purdue</li> </ul>	<ul style="list-style-type: none"> <li>Confusion about which patients would be suitable for Hysingla ER and budget impact</li> </ul>
	Abuse rates of Hysingla ER in the community compare favorably with comparator opioid products and are lower than Zohydro	<ul style="list-style-type: none"> <li>FDA-required postmarketing epidemiology studies for Hysingla ER assessing abuse versus other opioids</li> </ul>	<ul style="list-style-type: none"> <li>Concern that Hysingla ER use will exacerbate the problem of abuse, overdose &amp; death associated with opioids</li> </ul>
	Prescribers and patients are educated about safe and appropriate use of Hysingla ER by the ER/LA REMS	<ul style="list-style-type: none"> <li>REMS Assessments indicating EMS-compliant continuing education courses are widely available and effective</li> </ul>	<ul style="list-style-type: none"> <li>Concern that Hysingla ER will be prescribed inappropriately or used unsafely by patients</li> </ul>

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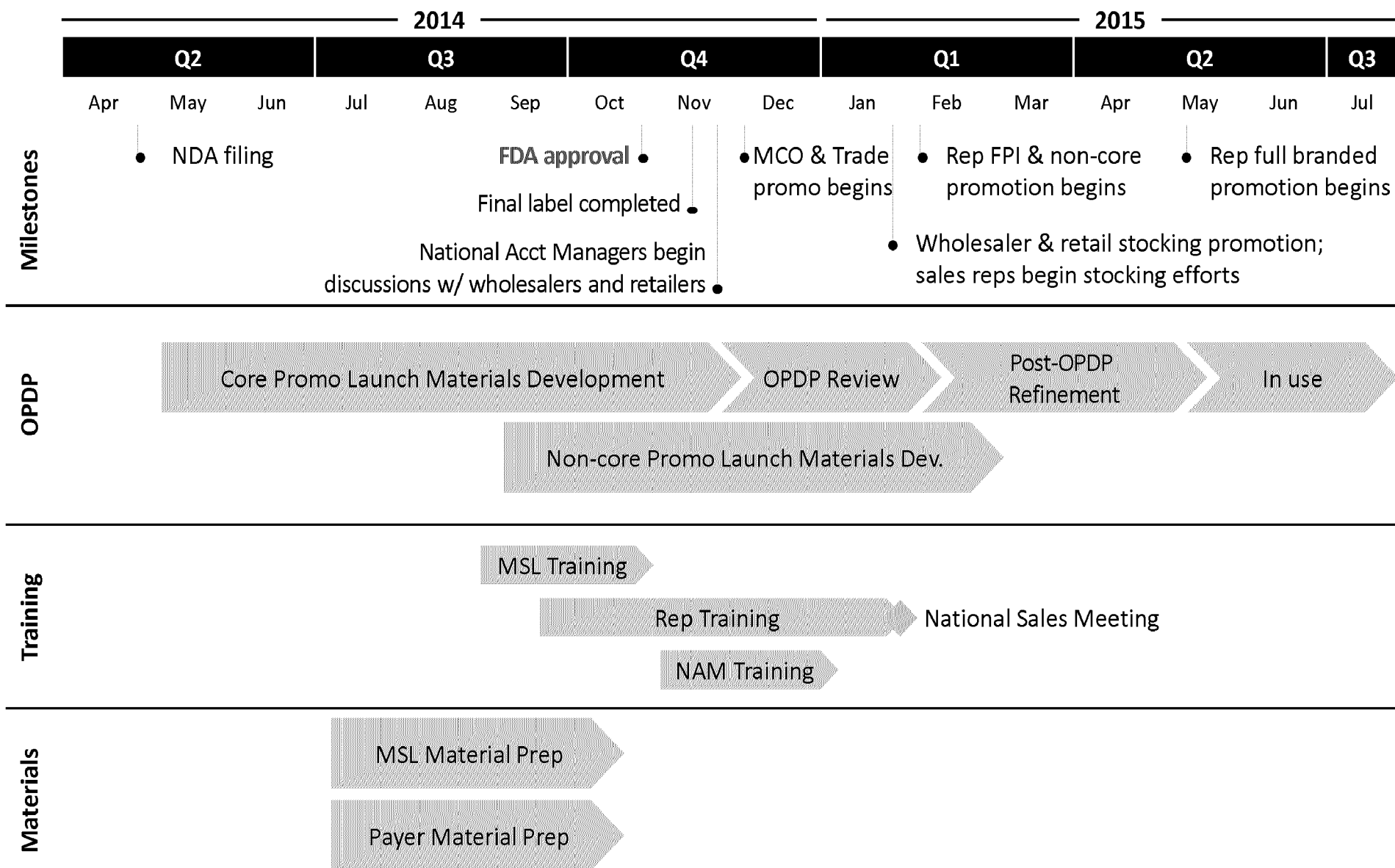


## c) Corporate Affairs Support for Hysingla ER

Function	Strategy	Tactical Details
<b>Government Relations</b>	Drive policy initiatives at the federal and state level to support access for Hysingla ER and remove hydrocodone formulations without ADF from the market, if desired	<ul style="list-style-type: none"> <li>• Introduce and advance state-level legislation that prohibits prescribing of non-ADF medication when an ADF is prescribed</li> <li>• Continue informing FDA regulatory policymaking process with respect to value of ADFs and risk of non-ADF generics</li> </ul>
<b>Communications</b>	Conduct outreach through the media and other communications channels to promote the value of Hysingla ER as a new therapeutic agent with abuse-deterrent properties	<ul style="list-style-type: none"> <li>• Generate mass-market, trade outlet and social media publicity around product milestones</li> <li>• Conduct regular informational briefings to select reporters, increasing their knowledge of the product class; Hysingla ER specifically, new research data, and related medical and policy issues</li> <li>• Leverage paid media to generate awareness of and support for Hysingla ER as a tool for appropriate pain management with abuse deterrent properties</li> </ul>
<b>Policy / Alliance Development</b>	Communicate the value of Hysingla ER to key opinion leaders, HCP organizations, and patient advocacy groups; mobilize these groups to support product commercialization	<ul style="list-style-type: none"> <li>• Develop tools to enable Purdue and its external stakeholders to appropriately and effectively convey the value of ADFs</li> <li>• In alignment with the Communications function, rapidly correct misinformation regarding Hysingla ER, its product class and/or the broader area of pain management medication</li> </ul>



# Hysingla ER Launch Rollout Timeline

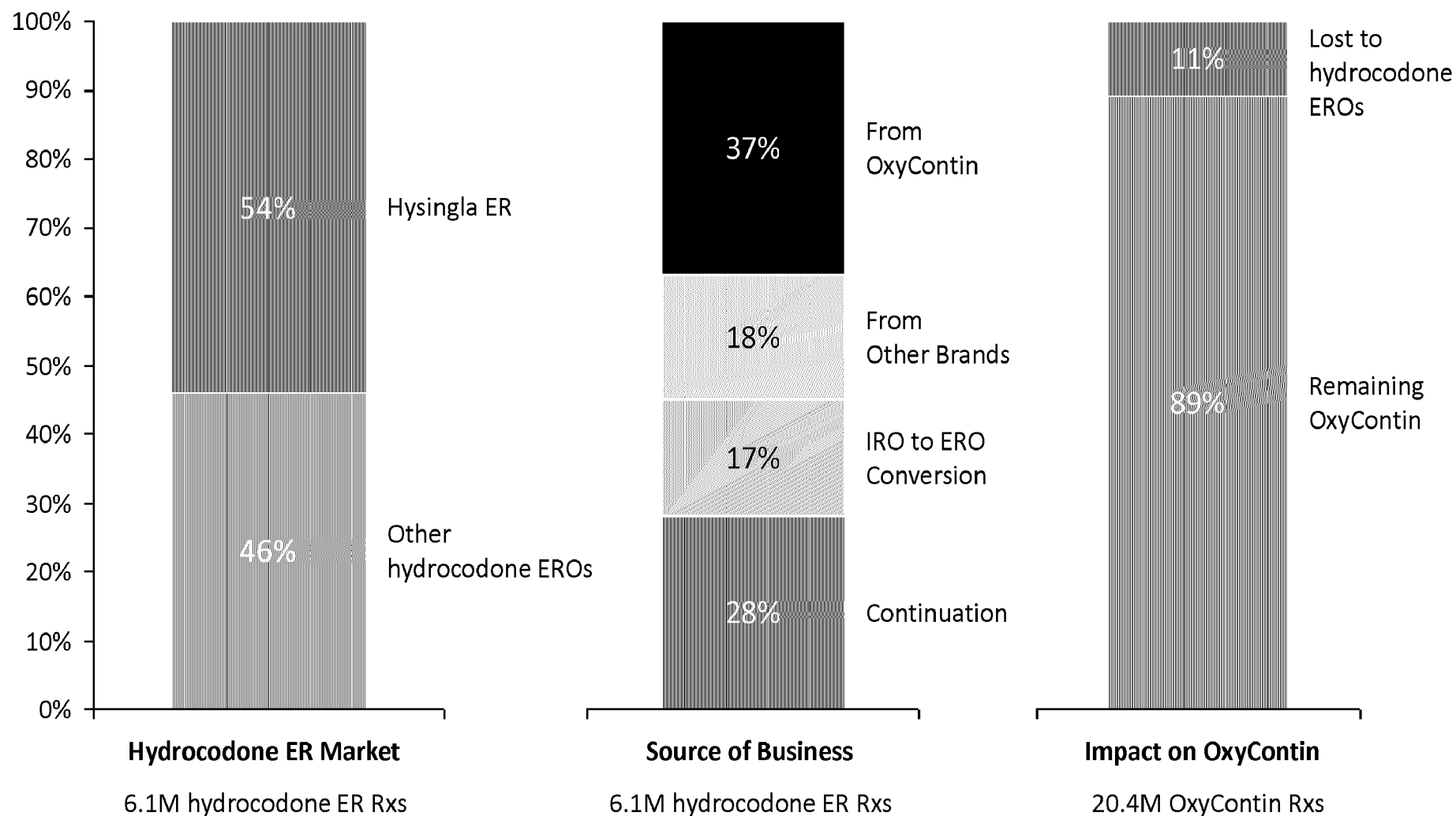


Note: Currently evaluating accelerated launch in Q4 2014



# Sources of Business of Hydrocodone EROs – 2015 - 2019

2015 - 2019 TRxs



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## Key Risks

Risk	Downside Potential	Risk Level
Lower Managed Care Coverage	Managed care requires higher rebates and / or lower formulary status Teva achieves better access than Hysingla ER	
Earlier Generic Entry	Generic non-ADF Zohydro launches before 2020 and gains share Teva product goes generic at Hatch Waxman expiry (2018 vs. 2020)	
Lower ERO Market Growth	Hydrocodone ER entry does not increase switching rate from IRO to ERO Hydrocodone products not rescheduled	
No 100mg/120mg Dose Approval	100mg and 120mg dosing not approved	
Higher Competitive Intensity	MNK product receives indication broader than post-op pain Zohydro able to overcome negative press; gains in market share Additional competitive products (e.g., Collegium) enter the market and shift Purdue's focus away from Hysingla ER	



Low Risk



Medium Risk



High Risk

Note: Risk level is a qualitative assessment of probability and likely impact

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PURDUE-COR-00017566

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# TAB 6

# **Quarterly Compliance Report to Board of Directors 2Q2014**

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Bert Weinstein

Vice President, Corporate Compliance

August 14, 2014





# Compliance Summary for 2Q2014

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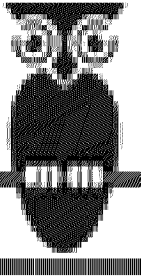


Purdue continues to have strong systems and processes in place to prevent and detect violations of law, regulations and company policies, and to remediate issues before they become significant problems.

***No significant compliance issues in the 2<sup>nd</sup> quarter, or to date in 2014***

The following pages report on Purdue's Sunshine Act reporting and on Compliance audits during 2Q2014





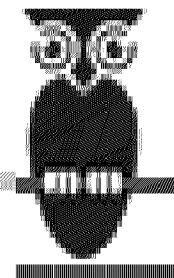
# Sunshine Act



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PURDUE-COR-00017570

# 2014 Sunshine Act filing (2013 data)



- Sunshine filing timely made in June for six Purdue “Applicable Manufacturer” entities - - see below
- The “General Dollar” amount of \$3,774,933 will be the reported spend on the CMS website in September; “Research Dollars” will be reported on a delayed basis in the future to protect confidential R&D information

Applicable Manufacturer	General (# transactions)	Research (# Transactions)	Total Transactions	General Dollars	Research Dollars *	Total Dollars
Purdue Pharma L.P.	22,892	953	23,845	2,732,705.04	6,263,169.61	\$8,995,874.65
Rhodes Pharmaceuticals L.P.	1	13	14	87.56	646,708.70	\$646,796.26
Purdue Products L.P.	4	0	4	5,669.96	0	\$5,669.96
Purdue Neuroscience Company	0	77	77	0	361,266.46	\$361,266.46
Purdue Transdermal Technologies L.P.	2420	4	2424	1,036,125.59	9,349.54	\$1,045,475.13
Purdue Pharma of Puerto Rico	17	0	17	345.19	0	\$345.19
<b>TOTAL</b>	<b>25,334</b>	<b>1,047</b>	<b>26,381</b>	<b>3,774,933.34</b>	<b>7,280,494.31</b>	<b>\$11,055,427.65</b>

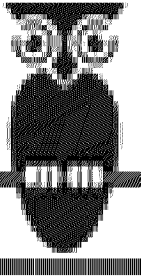


# “Dispute” period for HCPs/Teaching Hospitals



- During the period July 14<sup>th</sup> - August 27<sup>th</sup>, HCPs and Teaching Hospitals may view data and raise disputes with CMS as to spend reported by Applicable Manufacturers
- To date, no disputes have been received (perhaps, because, in order to dispute spend, recipients must first register on the CMS website, requiring personal data and a complicated process?)
- Corporate Compliance will manage any disputes with relevant business areas affected to preserve customer relations
- CMS plans to make all Applicable Manufacturers' data public September 30<sup>th</sup>





# Compliance Audits



# Compliance Audits Completed – 2Q2014



## Managed Care

- To provide a level of assurance that Purdue Managed Care Account Executives and Area Managers were performing activities in compliance to the Managed Care SOP.
- No Critical Findings; Findings concerning documentation of issues on FCRs, submission timing of FCRs, accuracy / timing of expense submissions, timing of call note entries, and call note reviews by managers. Remediation is underway

## Aggregate Spend - Commercial

- To verify that Sales Representatives were properly documenting expenses related to Health Care Professionals
- No Critical Findings; Findings concerning data and documentation accuracy and manager oversight. This was a follow up audit from 2013, to assure accurate state and federal spend reports.



# Compliance Audits In Progress – 2Q2014



## Speaker Programs

- To assess compliance with speaker program procedures and company guidelines
- Report pending – preliminary findings include: size of speaker bureau may be too large for the number of programs; but significant improvements from 2011 Compliance audit

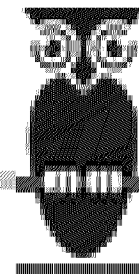
## Contracts with HCPs and payment at FMV

- To assess compliance with contracting and fair market value procedures
- Report pending - No Critical Findings; found a small percentage of transactions did not have a Statement of Work associated with the HCP's contract



# Questions?

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If there are any questions or comments, please  
contact Bert Weinstein at

@pharma.com, or at

**Redacted**





**To:** Sackler, Dr Raymond R [REDACTED]@pharma.com]; Sackler, Beverly [REDACTED]@pharma.com]; Sackler, Dame Theresa [REDACTED]@mdsackler.co.uk]; Sackler, Dr Richard [REDACTED]@pharma.com]; Sackler Lefcourt, Ilene [REDACTED]@pharma.com]; Sackler, Dr Kathe [REDACTED]@pharma.com]; Sackler, Jonathan [REDACTED]@pharma.com]; Sackler, Mortimer D.A. [REDACTED]@pharma.com]; Sackler, David A. [REDACTED]@srllc.com]; Boer, Peter [REDACTED]@pharma.com]; Boer, Peter [REDACTED]@boer.org]; Judy Lewent ([REDACTED]@msn.com) [REDACTED]@msn.com]; Lewent, Judy [REDACTED]@pharma.com]; Pickett, Cecil [REDACTED]@pharma.com]; Costa, Paulo [REDACTED]@pharma.com]; Snyderman, Ralph [REDACTED]@pharma.com]  
**Cc:** Baker, Stuart [REDACTED]@chadbourne.com]; Timney, Mark [REDACTED]@pharma.com]; Mahony, Edward [REDACTED]@pharma.com]; Strassburger, Philip [REDACTED]@pharma.com]; Wikström, Åke [REDACTED]@mundipharma.co.uk]; Landau, Dr. Craig [REDACTED]@purdue.ca]; [REDACTED]@mundipharma.co.uk]; Singh, Raman [REDACTED]@mundipharma.com.sg]; [REDACTED]@cbmitchell.co.uk]; Roncalli, Anthony [REDACTED]@chadbourne.com]; [REDACTED]@chadbourne.com]  
**From:** Baker, Stuart  
**Sent:** Tue 8/12/2014 7:24:37 PM  
**Subject:** Final Agenda and Board Book - Meetings of the Boards of Directors (U.S. Companies) U.S. Board Book (Final - August 13-14, 2014) .pdf

Tuesday, August 12, 2014

Dear All,

Attached is the final Agenda and Board Book for the meetings of the Boards of Directors (U.S. Companies) to be held on Thursday, August 14, 2014 in the Stamford Board room. The meetings of the Boards of Directors (U.S. Companies) will commence on Thursday following the meetings of the Board of Directors of MNP Consulting Limited.

Directors are encouraged to attend the meetings in person.

For those persons joining the meetings telephonically, please note the **new call-in details** for these meetings as follows:

From the United States: [REDACTED]  
Outside the United States: [REDACTED]  
Passcode: [REDACTED]

The attached materials have been uploaded to BoardVantage.

Stuart

This e-mail, and any attachments thereto, is intended only for use by the addressee(s) named herein and may contain legally privileged and/or confidential information. If you are not the intended recipient of this e-mail, you are hereby notified that any dissemination, distribution or copying of this e-mail, and any attachments thereto, is strictly prohibited. If you have received this e-mail in error, please notify me by replying to this message and permanently delete the original and any copy of this e-mail and any printout thereof.

For additional information about Chadbourne & Parke LLP and Chadbourne & Parke, a multinational partnership, including a list of attorneys, please see our website at <http://www.chadbourne.com>

**BOARDS OF DIRECTORS MEETINGS  
(U.S. Companies)**

**AGENDA**

**Thursday, August 14, 2014 (10:00 a.m. – 4:00 p.m.)**

**(Total Time: 145 Minutes or 2 Hours and 25 Minutes)**

1. Interim Decisions
  - None
2. Pending Decisions
  - None
3. HYD Launch Preview (60 Minutes) (U.S. - 3 through U.S. - 41)
4. 2014 Financial Update and 2015 Budget Preview (30 Minutes) (U.S. - 43)
5. U.S. 2Q2014 Written Compliance Report (U.S. - 45 through U.S. - 53)
6. Update - Targiniq® (15 Minutes)
7. Talent Development and Compensation Committee Report on U.S. Candidates, Recommendations and Consideration by the Board of Directors (30 Minutes) (U.S. - 55)
  - A. Vice President, Sales
  - B. Vice President, Licensing and Business Development
  - C. Vice President, Human Resources
  - D. Vice President, Marketing and Managed Markets
8. Celltrion (10 Minutes)
9. Other

# TAB 3

## PROPOSED DECISION

August 14, 2014

### Additional Investment – Hysingla<sup>®</sup> ER (HYD)

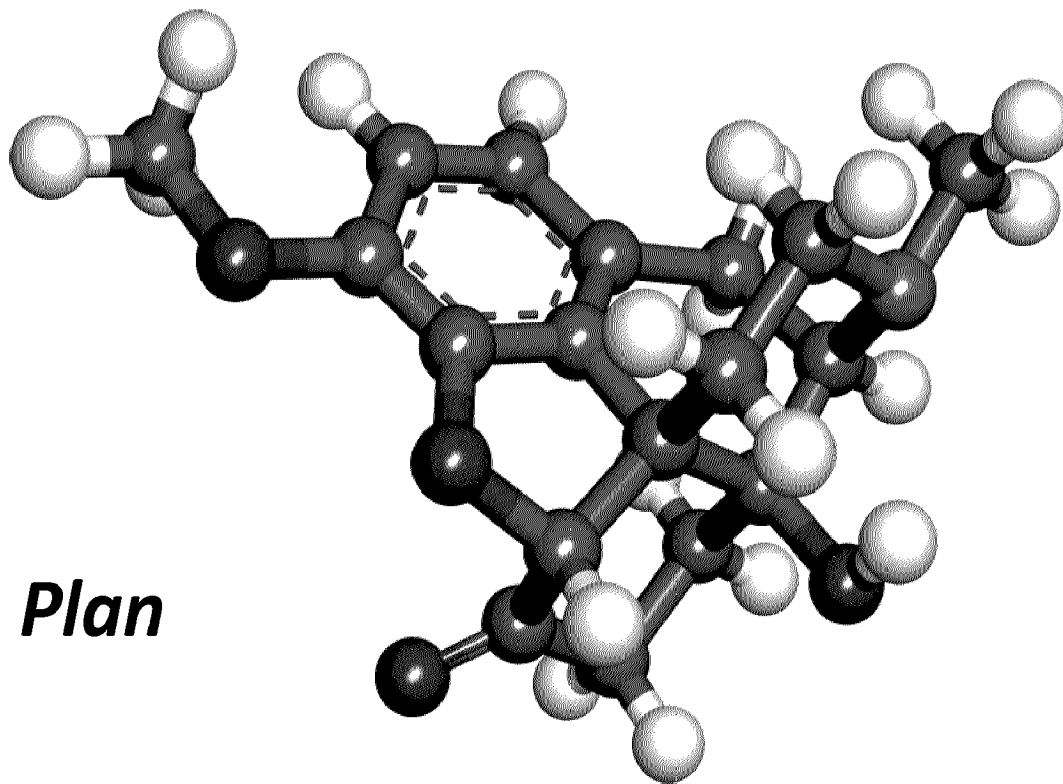
It is recommended to approve an additional investment in 2014 in the amount of \$12 million in support of the launch of Hysingla<sup>®</sup> ER (HYD). This investment is in addition to the \$7 million already funded for pre-filing work. With the NDA filed, additional pre-launch work is recommended as follows:

		2014 Additional Investment Requested
Marketing / Agency	Launch Strategy / Branding	\$5.0 million
	Creative, Sales Aids, Advertising, Conventions	\$1.0 million
	Managed Markets, Fulfillment, REMS	\$1.5 million
	Other Promotional Support	\$1.0 million
FAMR	Market Research	\$0.6 million
Education	Unbranded Education Campaign	\$2.5 million
HOPE	Cost and Time Series Analyses	\$0.4 million
Publications	Publication Plan	-
TOTAL:		\$12.0 million

(Recommendation of the Board of Directors of MNP Consulting Limited)

# ***PURDUE***

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## ***Hysingla ER Launch Plan***

August 1, 2014

**U.S. - 4**



## Agenda

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- Executive Summary
- Market Context and Opportunity
- Hysingla ER Strategies
- Hysingla ER Forecast
- Recommendations



## Executive Summary

---

- Hysingla ER **fills a current unmet need** for a hydrocodone ER with abuse deterrent formulation (ADF)
  - Despite Zohydro's recent approval, limited uptake due to lack of ADF and minimal market presence leave a considerable opportunity for Hysingla ER
  - While Hysingla ER will be the **first-to-market hydrocodone ER with ADF**, Teva's expected launch (Q4 2015) will limit Hysingla ER's key competitive advantage
- To capitalize on the limited window of opportunity, **Hysingla ER will launch a selective go-to-market strategy targeting two key prescriber segments:**
  - **Proactives:** Opportunity for Hysingla ER to capture share of branded ERO prescriptions, driven by molecule-to-molecule preferences, and reinforce IRO to ERO conversion
  - **Delayers:** Potential to increase low rate of ERO conversion for chronic IRO patients and capture share for Hysingla ER
- Four key strategies will drive Hysingla ER's success:
  - **Establish Hysingla ER as the Brand of Choice for Proactive Converters**
  - **Increase Hydrocodone IR to ER Conversion with Focus on Delayers**
  - **Align Access Strategy and Targeting to Maximize Profitable Growth**
  - **Optimize Purdue Pain Assets to Accelerate Hysingla ER Uptake** including leveraging the existing sales force
- The current forecast projects an **NPV of \$94M with 2018 peak net sales of \$264M (profitable in 2016)**
- **We recommend launching Hysingla ER** given the strong financial opportunity and market / patient need
  - Request **incremental \$12M in cross-functional investment in 2014** to maximize our launch opportunity



# Brand Vision and Goals



**Vision:** Be the leading hydrocodone ER—complementing a portfolio of pain medications for chronic pain patients



## Objectives:

### Launch (2015)

- \$86M Gross Sales
- \$61M Net Sales
- 224K Rxs
- 45K Patients
- 9% Tier 2 Commercial
- 68% Tier 3 Commercial
- 13% Tier 3 Med-D

### Peak (2018)

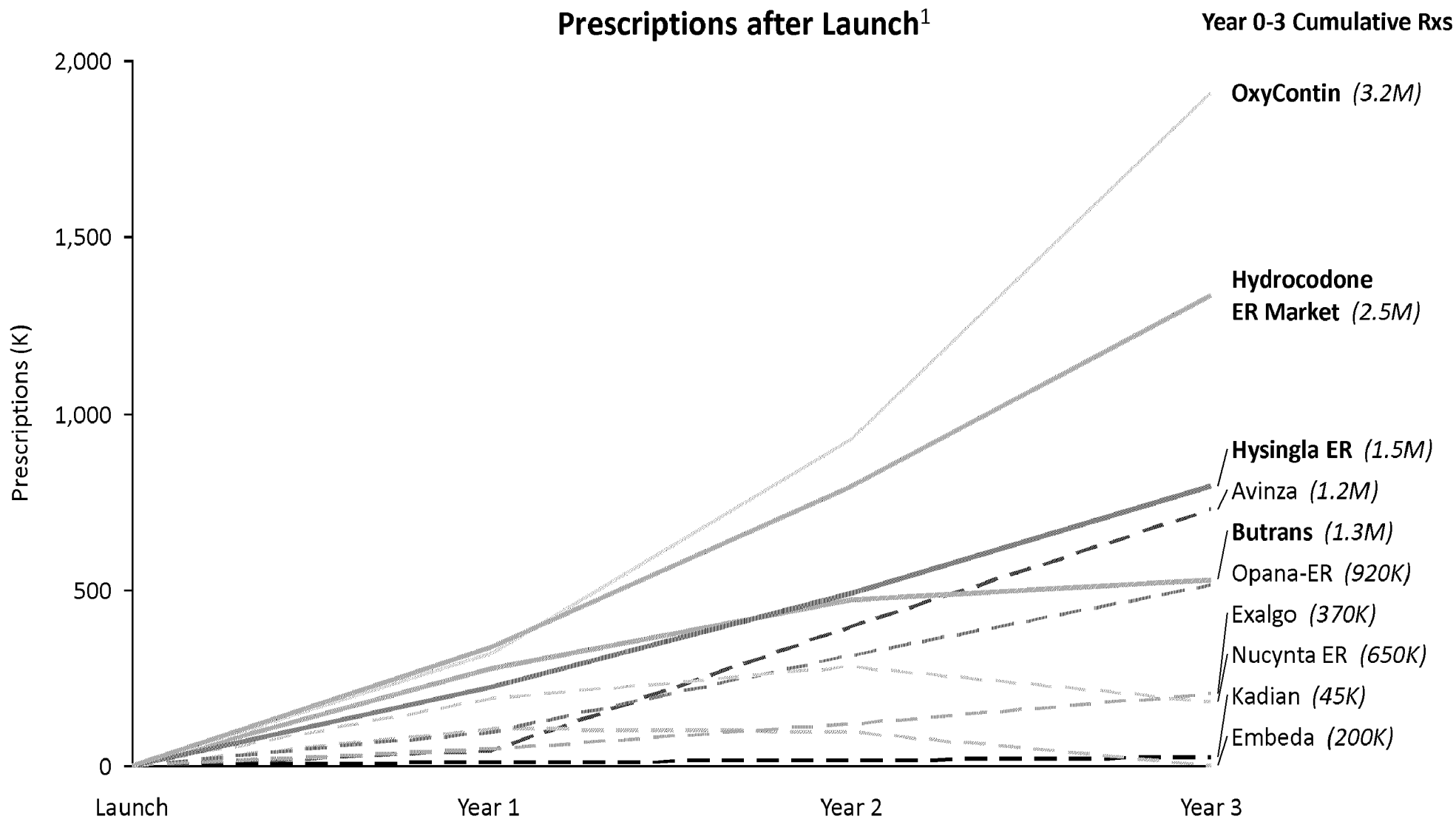
- \$382M Gross Sales
- \$264M Net Sales
- 928K Rxs
- 186K Patients
- 32% Tier 2 Commercial
- 16% Tier 2 Med-D
- 47% Tier 3 Commercial
- 24% Tier 3 Med-D

Note: 1) Gross sales include demand and stocking 2) Assumes 5 Rxs per patient, based on basket of EROs  
Source: IMS Health; Monitor Deloitte Analysis





# Hysingla ER Forecasted Performance Relative to Other Launches



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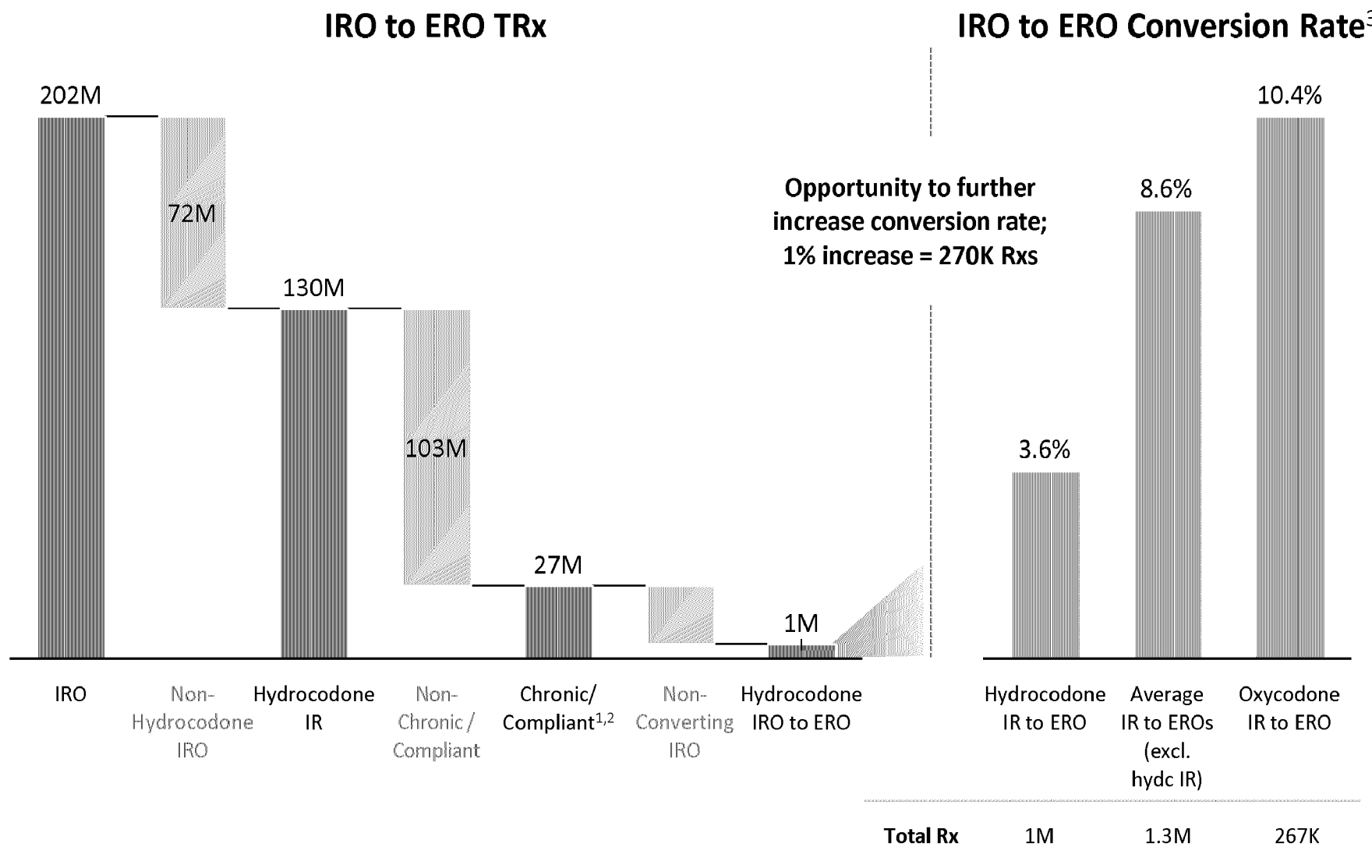
Source: Long-acting SEO Launch Comparison

Note: 1) FDA Approval dates: Kadian 3Q96; Avinza 1Q02; Embeda 3Q09; Opana-ER 2Q06; Exalgo 1Q10; Nucynta ER 3Q11; Butrans 2Q10; OxyContin 4Q95

**U.S. - 8**



# Hysingla ER Market Opportunity



Notes: 1) Chronic, compliant based on 90+ days on therapy and >80% compliance by fulfillment; 2) Chronic definition allows for a 15-day fulfillment gap; 3) Of Rx to chronic and compliant patients

Sources: Butrans Market by Specialty, 2013; ERO TRx, 2014

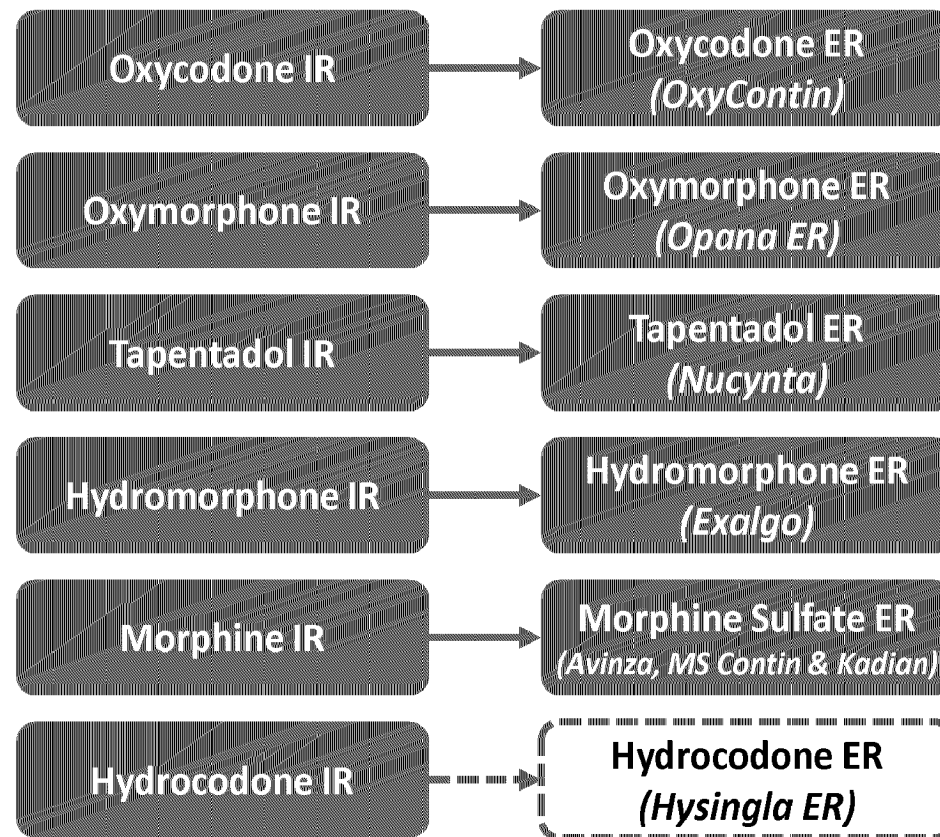
**U.S. - 9**



# Benefits of Keeping Patient on Same Molecule

Surveyed HCPs <sup>1</sup>	
Patient was able to <b>tolerate</b> it	75%
Anticipate sustained <b>efficacy</b>	69%
Easier to explain / patient is more likely to accept or be <b>compliant</b>	46%
More likely to be <b>covered by insurance</b>	37%
<b>Patient is familiar</b> with it	36%
<b>Physician is familiar</b> with it	30%

## Current Molecule-to-Molecule IRO-to-ERO Options



Other than Zohydro, there is currently no molecule-to-molecule switch available for hydrocodone IR patients

Note: 1) Based on PCPs (n=98), NP/PAs (n=48), Pain Specialists (n=95), Oncologists (n=45)

Sources: Hydrocodone ER Exploratory, April 2013; HYD Drivers of Choice Report, December 2013; Chronic Pain Patient Flow Study Update, November 2013

U.S. - 10



## Strategic Pillar #1

1.

**Establish  
Hysingla ER as  
Brand of Choice for  
Proactive  
Converters**

2.

**Increase  
Hydrocodone IR to  
ER Conversion with  
Focus on Delayers**

3.

**Align  
Access Strategy  
and Targeting to  
Maximize  
Profitable Growth**

4.

**Optimize  
Purdue Pain Assets  
to Accelerate  
Hysingla ER  
Uptake**

- a) Disproportionately invest resources – including sales force – in ‘Proactives’ for first 6 months post-launch to establish Hysingla ER as the brand of choice for hydrocodone IR-exposed patients over other EROs
  - Promote Hysingla ER as the first and only opioid with ADF and Q24h hydrocodone ER without APAP
- b) Cultivate relationships with existing KOLs / speakers during initial early-start program and leverage publications to support Hysingla ER differentiation

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## a) Hysingla ER Proactives Profile (14K HCPs)

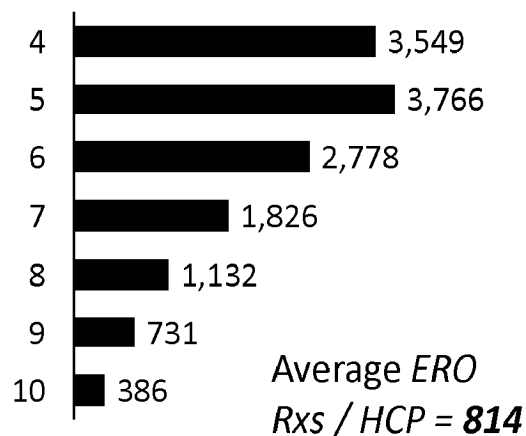
### Key Insights

- Proactives believe that **EROs provide better pain management** for eligible patients
- Specialists, PCPs see the advantages of **molecule-to-molecule switches**, but to varying degrees
- Ability to **add Hysingla ER into opioid options and rotation schedule** is attractive
- QD dosing is advantageous, although some concerned **will not last as indicated**
- ADF** and lack of APAP offer **moderate appeal**

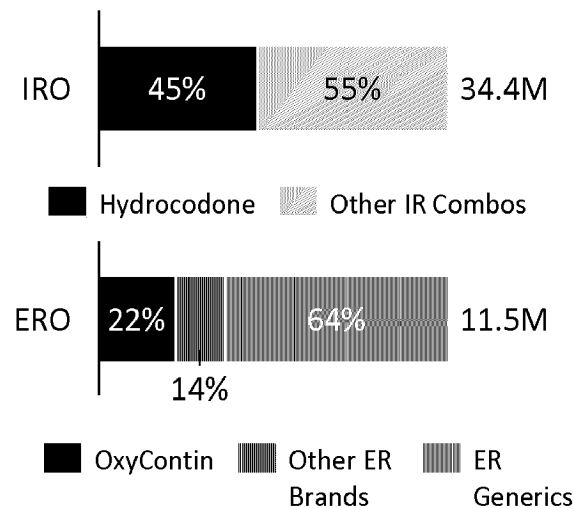
### Key Data Points

# of HCPs	~14K
Branded ERO prescriptions	4.1M
% Current OxyContin targets	79%
Average IRO to ERO conversion rate	4.6%
% Specialists / PCPs	62%/38%
% Outpatient	61%
% No-see HCPs	15%

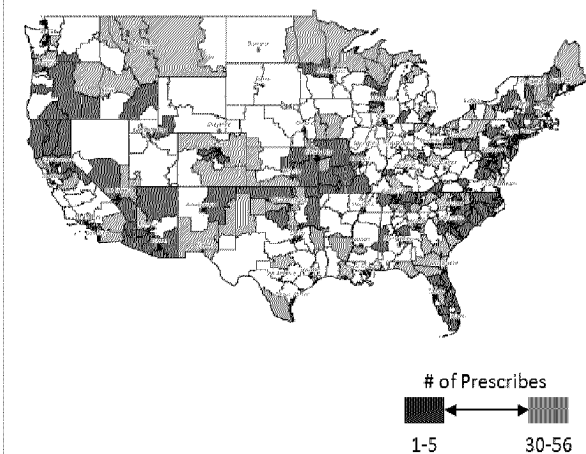
### HCPs by ERO Decile



### Opioid TRx

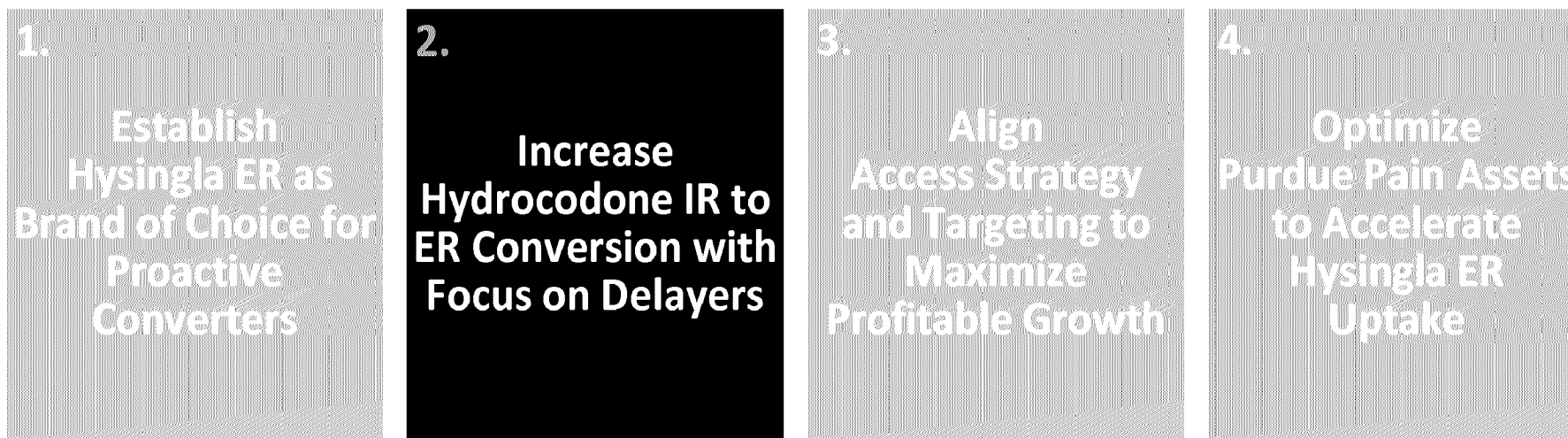


### Geographic Distribution





## Strategic Pillar #2



- a) Develop scientific data and messages supporting the value of converting appropriate hydrocodone IR patients to EROs
  - Identify appropriate patient populations for conversion
  - Define treatment algorithms for conversion and monitoring of patients from hydrocodone IR to an ERO
- b) Launch unbranded and branded campaigns to increase Delayer and Proactive conversion rates
  - Leverage tech-driven solutions and longitudinal patient data to help HCPs identify appropriate chronic IRO patients for EROs
  - Launch unbranded patient educational campaign to highlight the advantages of EROs for around-the-clock pain relief

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## b) Hysingla ER Delayers Profile (2.4K HCPs)

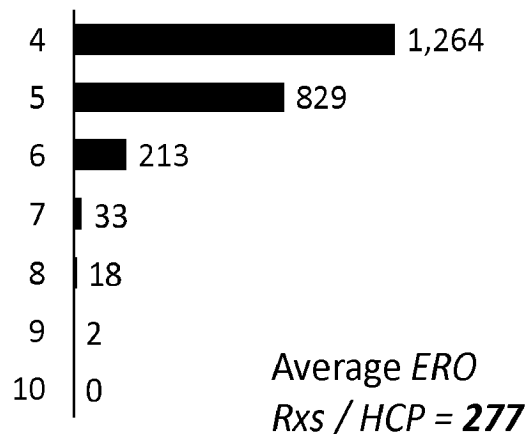
## Key Insights

- Delayers use EROs as escalation when other pain management approaches fail
- Delayers are **more likely to respond to patient requests** to switch to ER or stay on IR
- Some believe molecule-to-molecule conversion will accelerate **dependence and desensitization**
- **Good coverage** and **comparable costs** are crucial for uptake
- QD dosing is beneficial; **ADF is less relevant**

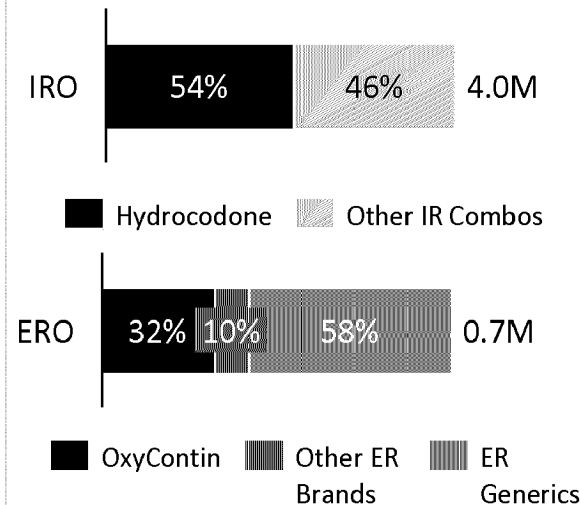
## Key Data Points

# of HCPs	~2.4K
Branded ERO prescriptions	274K
% Current OxyContin targets	70%
Average IRO to ERO conversion rate	0.8%
% Specialists / PCPs	28%/72%
% Outpatient	70%
% No-see HCPs	20%

## HCPs by ERO Decile



## Opioid TRx



## Geographic Distribution

