

**From:** Jeffrey Dierks </O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JDIERKS>  
**To:** Matthew Day  
**Sent:** 9/2/2016 8:40:35 PM  
**Subject:** RE: Managers Meeting slides, DRAFT  
**Attachments:** 2016 8-9 Fall Mgrs Mtg VERv3 MD-JD.pptx



Matt-  
I added 5 slides up front to tell the Pain Care story – welcome your thoughts.  
I need to build the animation for slide 3 and 4 but wanted to get your thoughts first.  
Thanks in advance-  
Jeff



**Jeffrey Dierks** Senior Director, Pain Care Marketing  
Tel: +1-610-786-7899  
[Jeffrey.Dierks@tevapharm.com](mailto:Jeffrey.Dierks@tevapharm.com) [www.tevapharm.com](http://www.tevapharm.com)



#### OUR PURPOSE & VALUES

**From:** Matthew Day  
**Sent:** Thursday, September 01, 2016 3:53 PM  
**To:** Jeffrey Dierks  
**Subject:** Managers Meeting slides, DRAFT



**Matt Day**  
Director of Marketing – CNS/ Pain Care  
Tel: 610-727-6573 / [matthew.day@tevapharm.com](mailto:matthew.day@tevapharm.com)



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# Pain Care Vision

Jeffrey Dierks

Senior Director, Pain Care Marketing

# Teva will be a Leader in Pain Care by 2020

*Teva's **Global Specialty Medicines** business has a world-leading position in innovative treatments for disorders of the central nervous system (CNS), including neurological and neurodegenerative diseases, pain, and movement disorders*

*Teva has identified three therapeutic areas of focus for the future  
Pain Care is one of them*

# Building a Pain Care Franchise from a Position of Strength

TEVA

Pain  
Care

In-line Pain Care brands  
generating \$300M gross  
sales in 2015

#1 or #2 In Market

Once-Daily

amrix®

(Cyclobenzaprine Hydrochloride  
Extended-Release Capsules)

 **FENTORA.**  
(fentanyl buccal tablet)®

2015

2016

2017

2018

2019

2020+

**Vantrela™ ER**  
(hydrocodone bitartrate)®  
extended-release tablets

AD IR Hydrocodone with APAP

AD IR Oxycodone with APAP

Funapide NaV 1.7

AD Fentanyl Patch

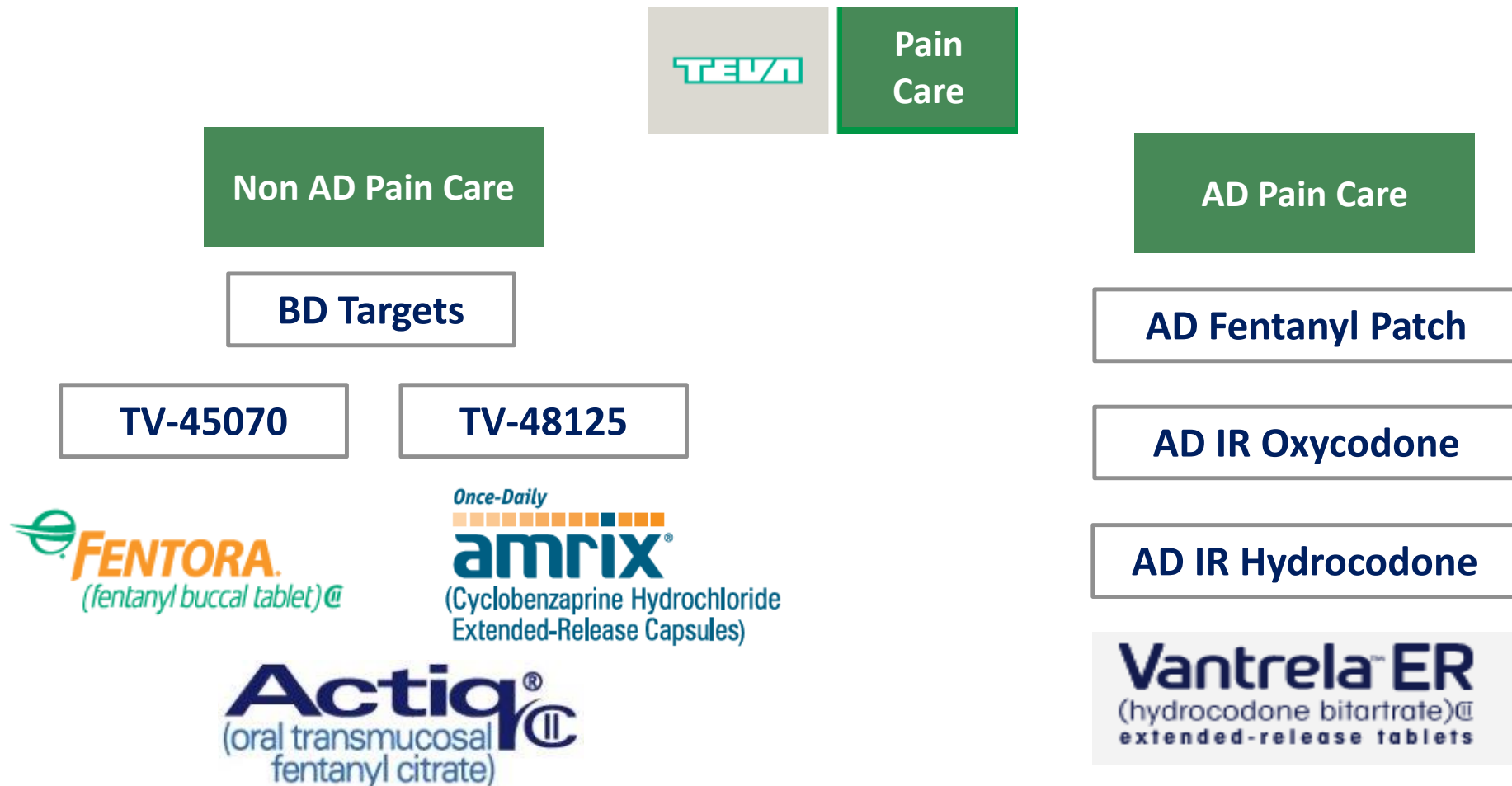
Multiple NTEs and BD Targets Under Assessment

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**Vantrela™ ER**  
(hydrocodone bitartrate)®  
extended-release tablets

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# Building a Diversified Pain Care Franchise

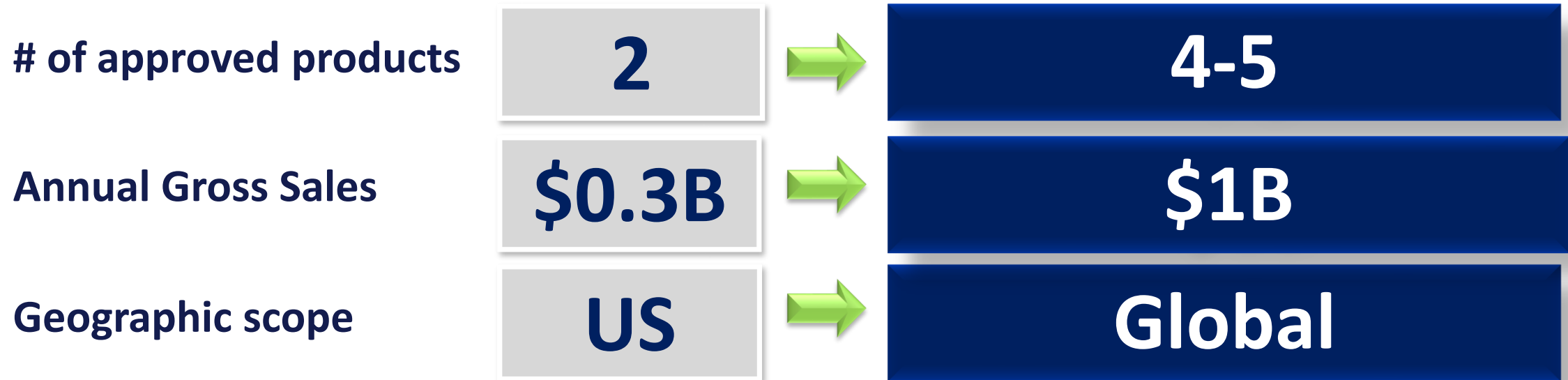


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# Our goal: become a leader in pain by 2020



*Build a sustainable leadership position in the Pain Care space  
by redefining the opioid market*

- Launch VANTRELA™ ER to become the foundation of our AD pain portfolio
- Continue development of additional pipeline products to bolster both AD and non-AD pain portfolios
- Extend beyond the ‘pill in a bottle’



# VANTRELA™ ER

Fall Managers Meeting

September 20, 2016

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**Vantrela™ ER**  
(hydrocodone bitartrate)   
extended-release tablets

## FOR INTERNAL PURPOSES ONLY – NOT FOR USE IN PROMOTION

This presentation contains proposed confidential and proprietary marketing and promotional strategies, tactics, and programs, as well as market research and other similar programs, all of which will only be developed and implemented after appropriate review and approval has been obtained in accordance with applicable policies (e.g., CARE, PARC, or Legal/Compliance review). All sales and marketing activity shall be strictly limited to the indications currently listed in a product's approved package insert. This document may also contain forecasts regarding Teva products that have been prepared for confidential business contingency analysis and planning purposes only to consider various business scenarios. Such forecasts and the assumptions used do not reflect or constitute a legal analysis or opinion regarding the merits of pending or anticipated litigation or a legal assessment as to which scenario(s) is/are more likely. Nor do they represent a final agreed course of action and any inference to that effect is not intended and is hereby expressly disclaimed.

# AGENDA

Vantrela ER Marketing Team

Market Overview & Product Insights

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Launch Phases & Timeline

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Activities by Launch Phase

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Workshop Overview

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Q&A

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# Vantrela ER Marketing Team

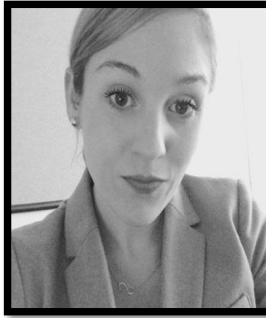
Jeff



**Healthcare  
Professional**



**Reimbursement  
& Patient**



**Media**



**ISR & Analytics**



**PR & Advocacy**

Sales  
Sales Training  
Marketing  
Medical  
PARC  
Market Access



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**Vantrela™ ER**  
(hydrocodone bitartrate)@  
extended-release tablets

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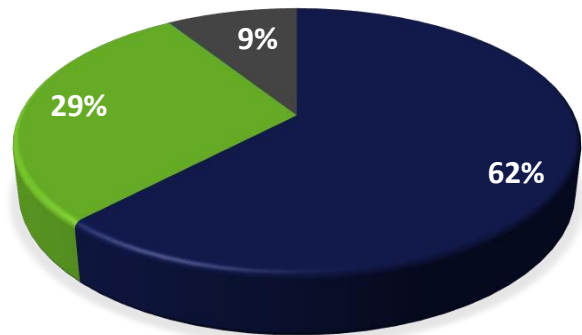
# Hydrocodone Is The # 1 Prescribed Molecule

## US Opioid Market

Sales: \$8.5B

Volume: 240M TRx

■ SAO COMBO ■ SAO PURE ■ TIRF ■ LAO



SAOs dominate TRxs (220M TRx)  
LAOs dominate dollars (\$5B)

Source: IMS NPA, extracted July 2016

## Key Insights & Opportunities

- Long-acting Opioid market is ~\$5B in sales
- 93M Hydrocodone Rx's written each year (~40%, #1 prescribed)
  - ~25% decline since CII rescheduling in October 2014
- Opioid abuse and misuse creating pressure for AD advancements

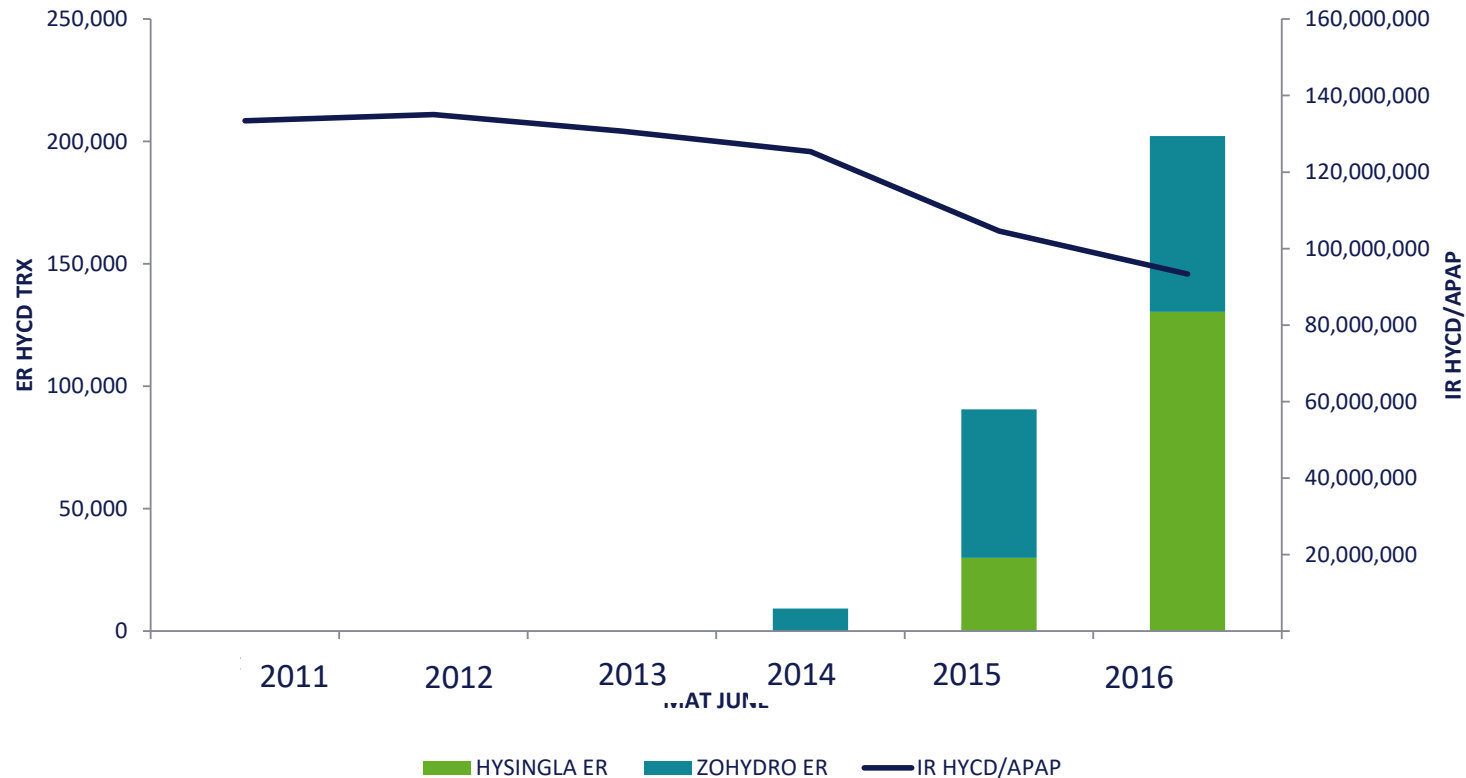
## Key Competitors

- Hysingla ER – Purdue AD QD ER Hydrocodone Q4 2014
- Zohydro ER – Pernix BID reformulation Q1 2015
- Limited uptake due to clinical profile & value proposition/access

## Payer / Access Landscape

- Payers are currently managing LAO category
- State & Federal legislation gaining traction to mandate ADT access
- Contracting and HEOR data necessary to penetrate market

# ER Hydrocodone Prescribing Is Increasing



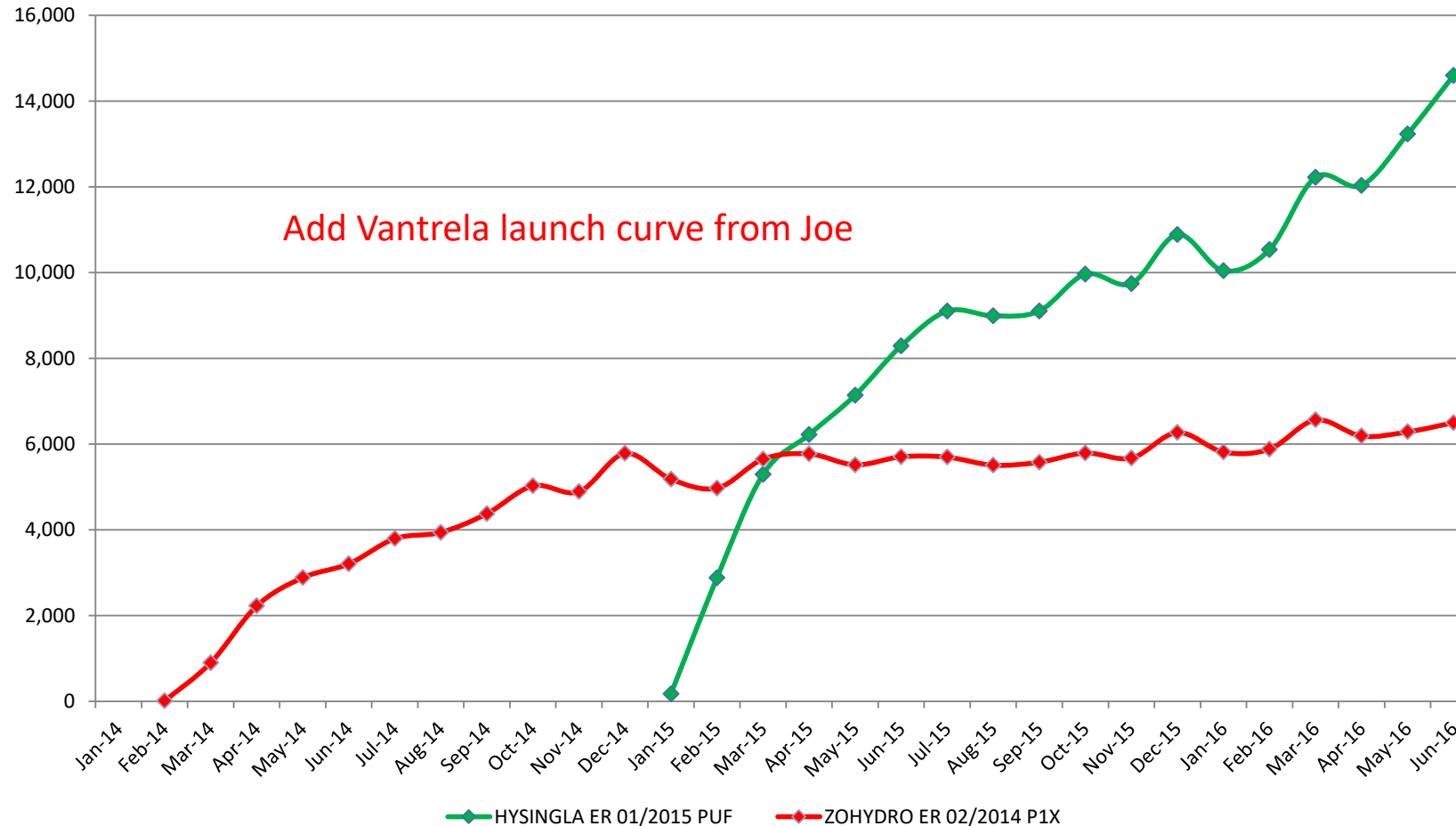
IR hydrocodone/APAP market has stabilized since the impact of DEA schedule change

No impact on prescribing when new formulation of Zohydro ER entered the market

ER Hydrocodone TRx volume more than doubled in last 12 months

Source: IMS NPA, extracted July 2016

# Abuse Deterrent Hydrocodone ER Product Launches

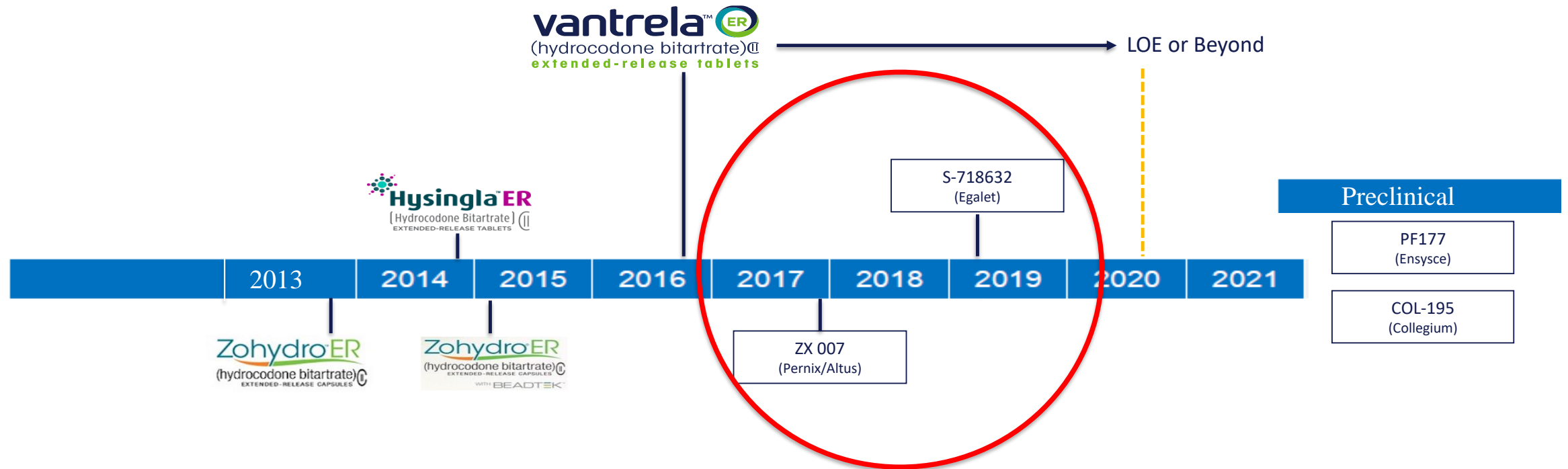


# Abuse Deterrent Labeling Properties

UPDATED SLIDE  
WITH INFO

Feature	Vantrela ER	Hysingla	Zohydro ER	Oxycontin	Xtampza
Category I (Extraction)	X (IV)	X (IV, IN)		X	X
Category II (PK) - Nasal	X				X
Category II (PK) - Oral	X				
Category III (Liking) – Nasal	X (finely milled)			X	X
Category III (Liking) - Oral	X (finely crushed)	X (chewed)		X (chewed)	
Oral	Cat II, III	Cat III		X (chewed)	
Intranasal	Cat II, III	Cat I, III		X	X
IV	Cat I	Cat I		X	X
Taken with/without Food	X	X	X	X	Empty stomach
Dosing	Q12	QD	Q12	Q12	Q12 (intact or sprinkle over applesauce)

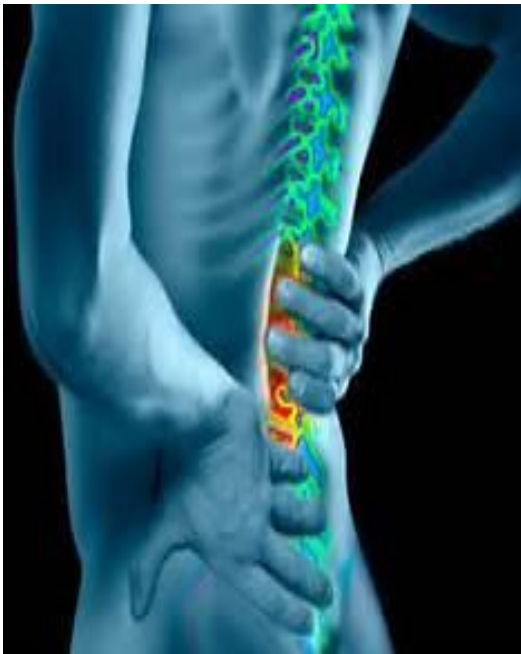
# Future ER Hydrocodone Pipeline



Source: Company Press Releases, Internal documents, Pharmaproject

# Appropriate **Patient Population** & Competitive Set is Well Defined

93M Hydrocodone Rx's written each year/ 26% of TRx's are transitioned to LOAs



## Patient Type

- Appropriate patients transitioning from IR Hydrocodone
- Back pain, neck pain... (In Trails)
- Average age from trilas

## LITERAL COMPETITIVE SET (LAOs)

**Hysingla<sup>®</sup>ER**  
[Hydrocodone Bitartrate] (II)  
EXTENDED-RELEASE TABLETS

**Zohydro<sup>®</sup>ER**  
(hydrocodone bitartrate) (II)  
EXTENDED-RELEASE CAPSULES  
WITH BEADTEK<sup>®</sup>

**OXYCONTIN<sup>®</sup> II**  
(OXYCODONE HCl EXTENDED-RELEASE TABLETS)

**Xtampza<sup>™</sup>ER**  
(oxycodone) EXTENDED-RELEASE CAPSULES (II)

# Ongoing Support for Patients & Providers

- Pain Matters
- Pain Week
- Pain Weekends
- Medical
- Paula

Jim R. request



## LIVING WITH PAIN

[www.propatient.com/pain](http://www.propatient.com/pain)

Chronic pain is a national epidemic that affects nearly 100 million Americans. Living with pain may affect every aspect of our lives. This Patient Education program is designed to help us learn from each other and from pain management experts to live the best life possible. Please join Paul Gileno, the founder of the US Pain foundation and other experts from ASiM and ProPatient to learn about:

- What are my options for care?
- How do I engage my care team when I feel they are reluctant to help?
- What are others in my situation doing on a daily basis to live a better life?
- What if I am feeling hopeless? Where can I turn? Who can help?

This program was a collaboration between ASiM & ProPatient  
Supported by an educational grant from Teva Pharmaceuticals

# Launch Phases & Timeline Overview

# Vantrela ER Update



FDA  
LABEL



3 ROUTES OF ABUSE  
—  
3 CATEGORIES

PHASED  
LAUNCH

0

FDA Approval

Clarity

1

Now Approved

Stocked

2

Now Available

OPDP

3

Full Campaign

# Current Launch Time Line



# Phase 0 – FDA Approval

# FDA Approval Tactics

“The Pink Sheet”  
Bloomberg

THE WALL STREET JOURNAL.

AP | PAIN  
LIVE



REUTERS

To: Field Sales  
From: Vantrela ER Marketing Team  
Date: To be sent day of Press Release regarding FDA approval of Vantrela ER  
Subject: Vantrela ER Approval and Customer Talking Points

Vantrela™ ER (hydrocodone bitartrate) extended release tablets, CI was approved by the FDA on XDATE, 2015. As this information is now public, your customers may ask you questions about Vantrela ER prior to you being trained. Following are approved talking points for you to reactively verbalize with your customer if asked about the product. Note that this information is not to be proactively shared and should not be sent to or left with your customers.

If you discuss Vantrela ER you must offer the PI. You will be shipped a supply of printed PIs in the near future. Should you receive any questions about Vantrela ER before you receive your printed PI, you should direct your customers to the VantrelaER.com website.

VANTRELA ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. VANTRELA ER is designed with the following features:

- 12-hour dosing
- Triple-layer abuse deterrence technology designed to resist common methods of abuse
- 3 dosage strengths (15, 30, 45, 60, and 90 mg strengths)
- No Acetaminophen

If you discuss VANTRELA ER with a customer, you have an obligation to provide fair and balanced information. Please discuss the limitations of use and important safety information described below.

#### Limitation of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release, opioid formulations, reserve VANTRELA ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- VANTRELA ER is not indicated as an as-needed (prn) analgesic.

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Website w/ label

Reactive Talking Points

- As the FDA approval of VANTRELA ER is now public information, your customers may ask you unsolicited questions about VANTRELA ER prior to you being trained on the product. Following are approved talking points for you to reactively verbalize with your customer if asked about the product. Note that this is not to be a proactive exchange with your customer.
- Approved Reactive Talking Points to HCP unsolicited questions
  - Doctor, I appreciate your question. I will be trained over the next few months and will be able to discuss more details with you after that.
  - In the interim, I can submit a Medical Information Request Form (MIRF )if you want to know more about the product now.
  - I will schedule an appointment to follow-up.



# Phase 1 - Now Approved Campaign

# Differentiating The Brand



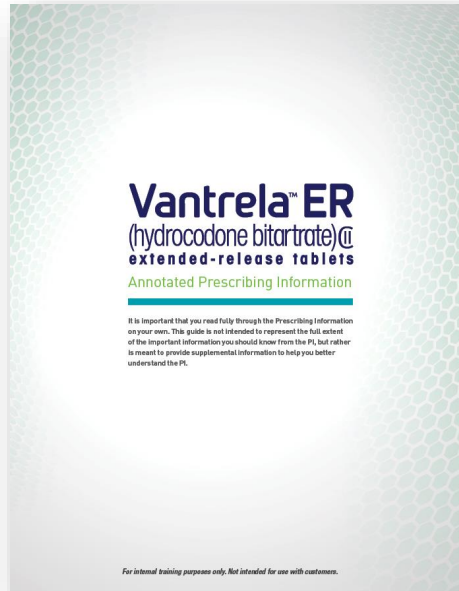
- Package Insert is the only sales aid
- Contained within the Package Insert
  - Efficacy / Safety
  - Human Abuse Liability Studies
  - 12 hour Dosing
  - 5 dosage strengths
  - No Acetaminophen
- Marketing messages not yet approved



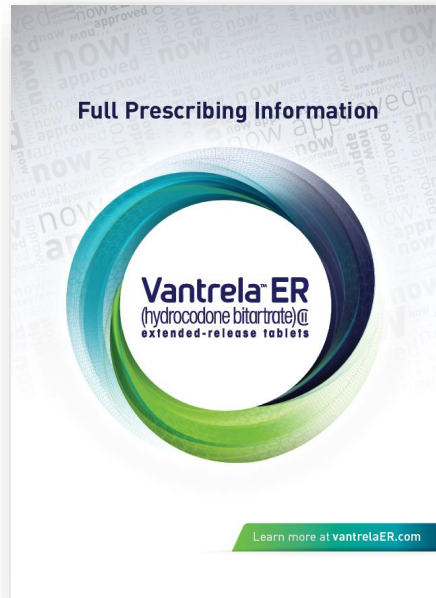
# Now Approved Resources



## Annotated PI



## Spiral Bound PI



## Digital PI on iPad



# Building The Speakers Bureau

- Purpose:
  - Quickly mobilize top speakers
- Description:
  - ~30 speakers to be identified
  - Pre-OPDP slide deck
  - Live speaker training
- Timing:
  - Contracting 1 - 2 weeks
  - Training 6 - 8 weeks post approval

Pre-Scheduled  
Webcasts

Regional Allotment  
of Venue-based  
Programs

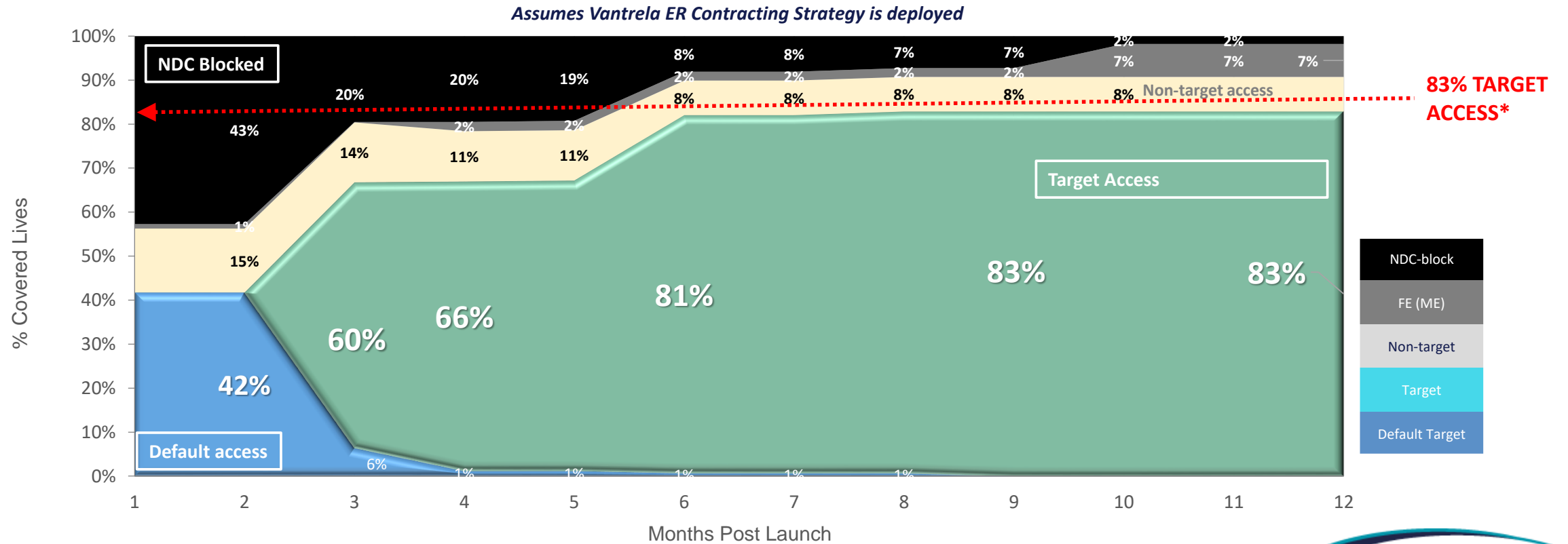


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# Phase 2: Now Available Campaign

# Vantrela ER Contracting Strategy

## Vantrela Attainable Target Access Trajectory over the first 12 months post-launch



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Source: ISA Primary Research, US Payers, August Lives Data: 139M Commercial Lives

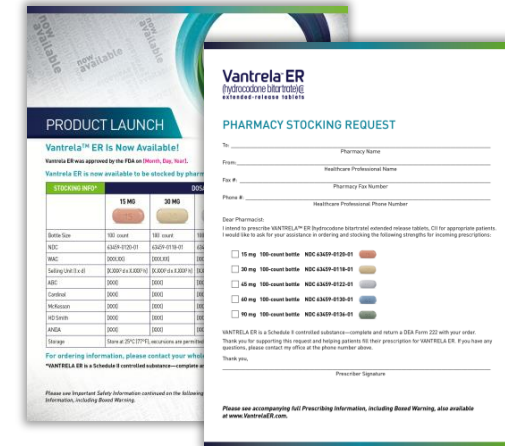
**Vantrela™ ER**  
(hydrocodone bitartrate)@  
extended-release tablets

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# Insert Heather's Updated Slides



**Verify**  
cost & coverage support



Drive pharmacy stocking  
these resources





# Phase 3: Full Campaign



## Additional Resources Available During The Full Campaign

- Verify
- Web site
- Media
- DSA
- Promotional Programming

# Field Objectives for VANTRELA™ ER

## Phase 0: FDA Approval

- Reactive talking points

## Phase 1: Now Approved – No Product Available/ Awareness

- Create brand awareness in priority target segments
- Utilize PI tools and prep build speaker bureau
- Use Appropriate Communications and Responses

## Phase 2: Now Available – Product Available/ RX Card

- Generate demand in target segments
- Introduce market access tools and co-pay program
- Continue to use PI tools & Appropriate Communications and Responses

## Phase 3: Campaign Launch

- Sell with all available tools



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(hydrocodone bitartrate)@  
extended-release tablets

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# Sale Training Overview

Wes

Wes to provide

# Question & Answer

# Back Up

# Overview

- **Marketing Review- Jeff, Matt, Heather, Wes (1 hour)**
- **PI Review – Shweta/ Jim (1 hour)**
- **PI Workshop Overview- Wes/ Helen (½ hour)**
- **Appropriate Communications Workshop Overview– Wes/ Matt/ Alex (½ hour)**
- **Access Tools Review & Workshop – Wes/ Heather (1 hour)**
- **Putting It All Together – Wes/ Helen (½ Hour)**
- **MSL Overview – Andy (½ hour)**

**TOTAL TIME= 5 hours**

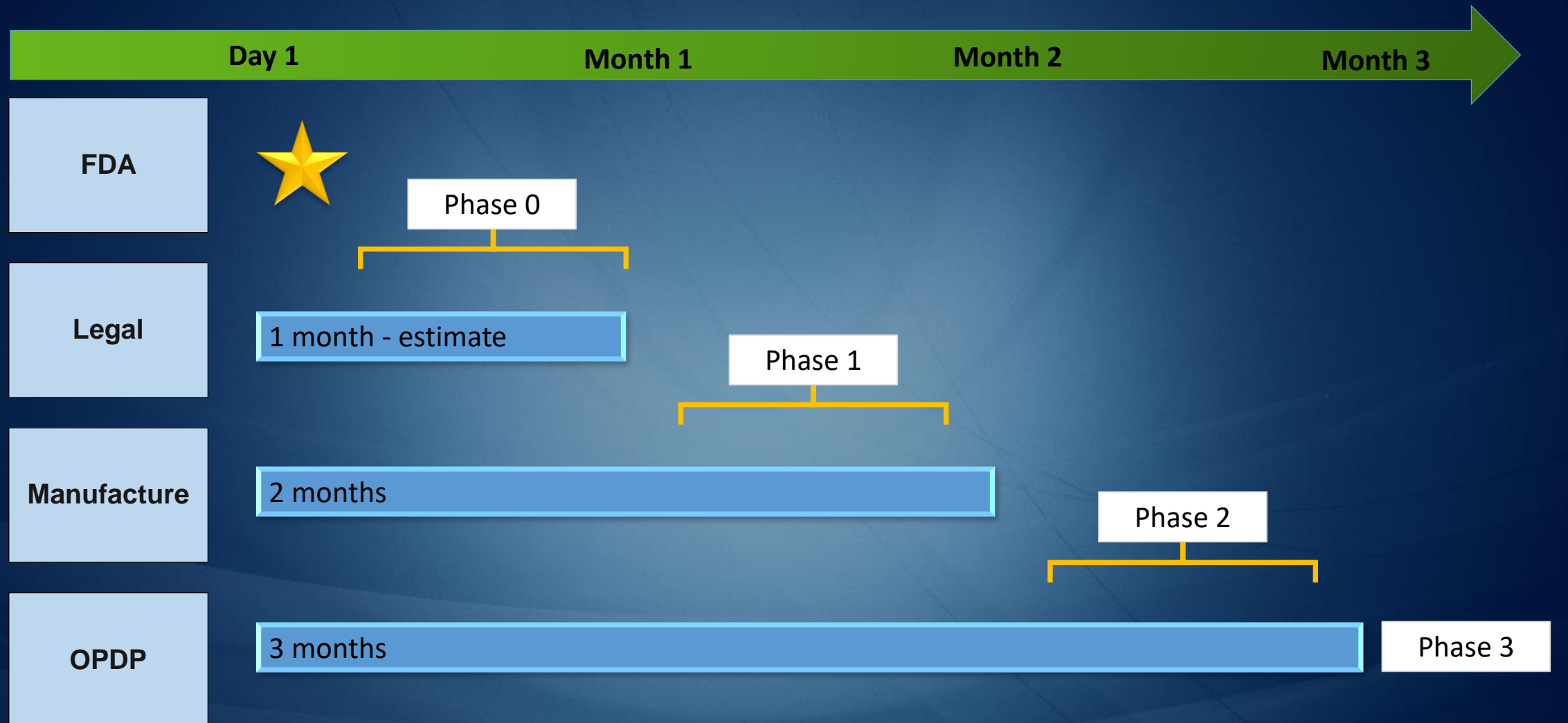


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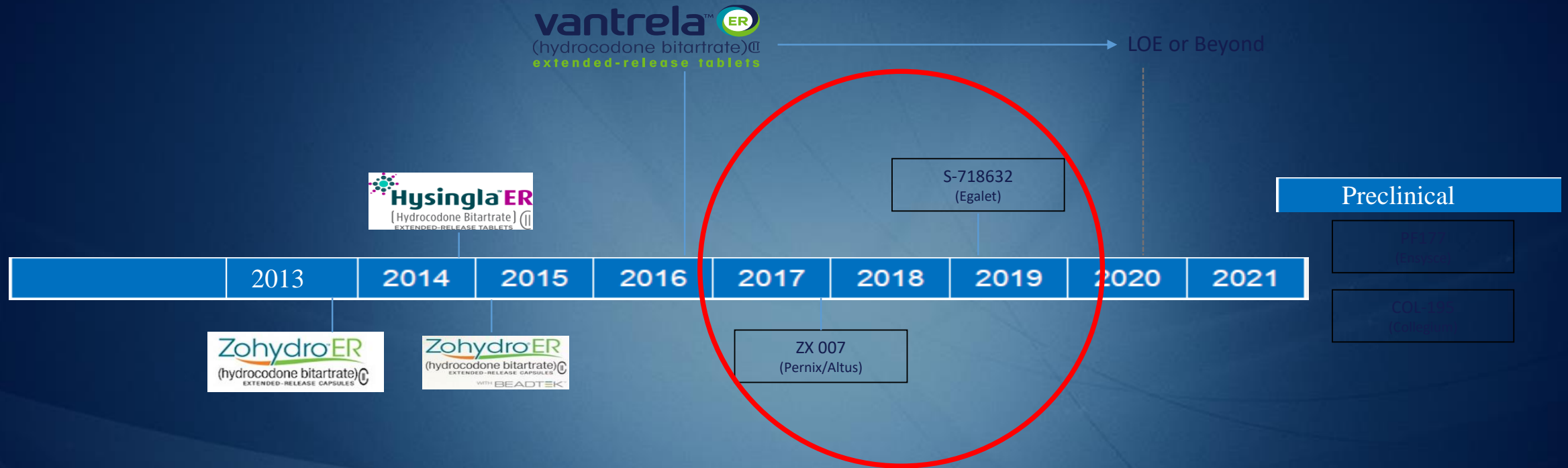
**Vantrela™ ER**  
(hydrocodone bitartrate)@  
extended-release tablets

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# Launch Variables & Timing Example



# Future ER Hydrocodone Pipeline



Source: Company Press Releases, Internal documents, Pharmaproject

# Now Available Convention Booth & Meetings



Date	Meeting
Sep 6 – 10	PainWeek - Las Vegas
Sep 22 – 25	AA of Pain Man - San Antonio

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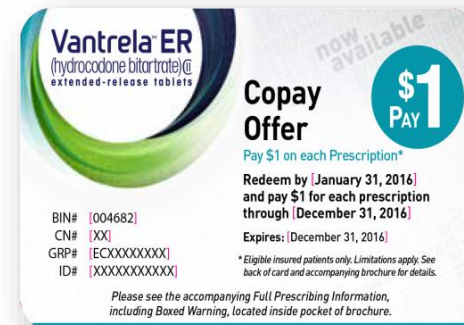
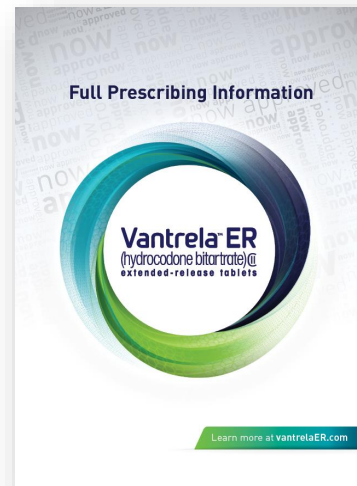
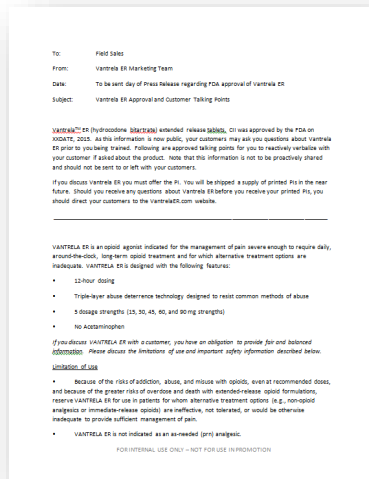


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# Vantrela ER Potential Timeline



## Reactive Talking Points





# KOL video, Learnings from Pain Week