Abuse-Deterrent Formulations of Opioids: Effectiveness and Value

Public Meeting – July 20, 2017

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

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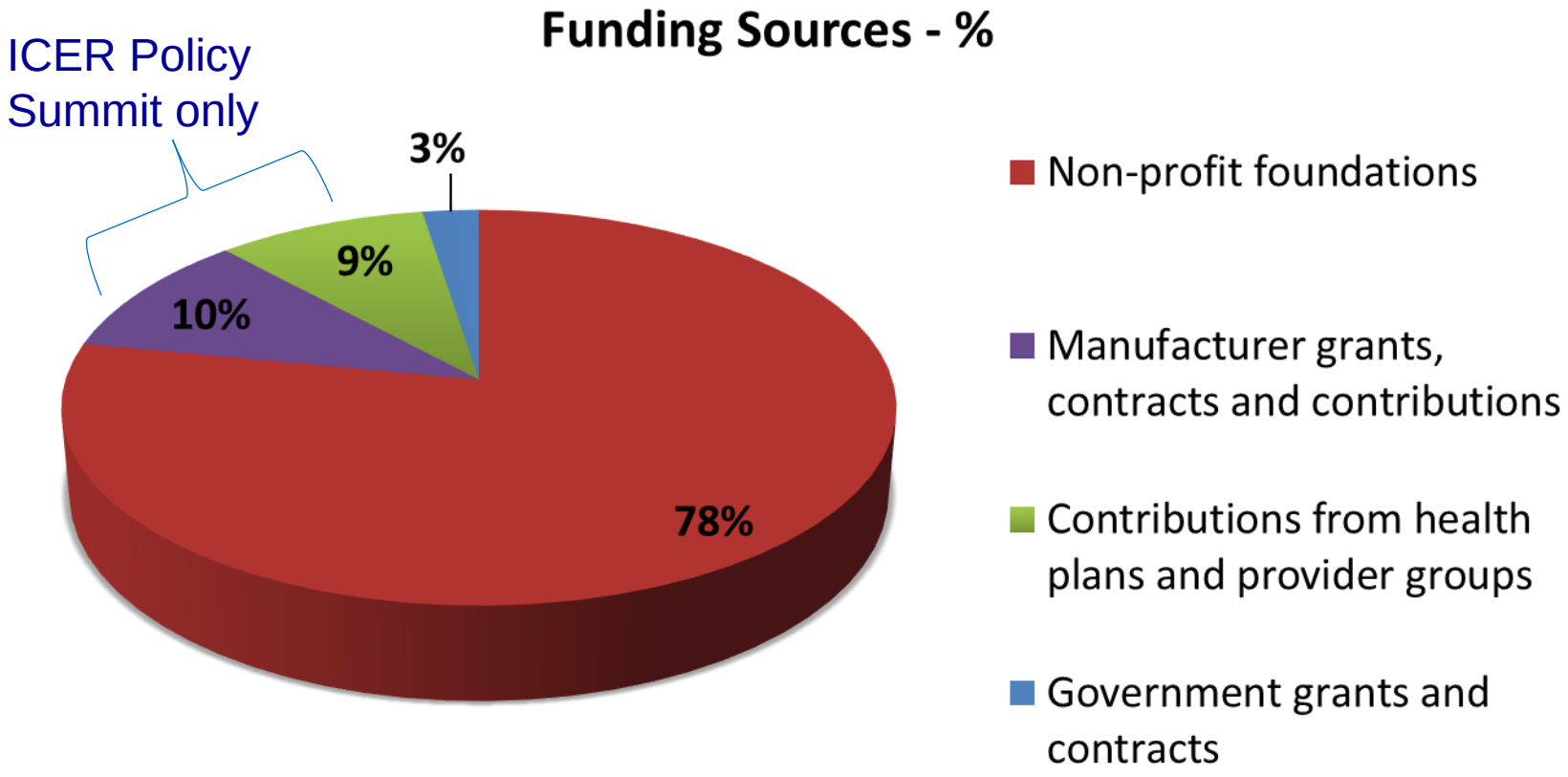
Welcome and Introduction

- New England Comparative Effectiveness Public Advisory Council (CEPAC)

- The Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2017

ICER Policy Summit only



Why are we here today?

- **Public Health and Social Crisis**

CONCORD — The number of people in New Hampshire to have died last year from drug overdoses is expected to climb to 478, 22 more than in 2015, with 70 percent of those deaths the result of fentanyl or fentanyl combined with another opiate….

-- New Hampshire Union Leader, March 9, 2017

Why are we here today?

- **Patient Need**

Pain is a significant medical problem with potentially devastating costs for patients, particularly for chronic pain patients. Opioids can be a valuable medicine for pain patients, but they also present certain risks. ADF opioids are an emerging technology that can help protect pain patients' access to necessary medications while helping to reduce costs associated with the current opioid addiction crisis.

– Institute for Patient Access

Why are we here today?

- **Questions about effectiveness, value, and affordability**

These are very expensive formulations and we don't have any evidence of direct patient effects.

-- Edward Michna, MD, Board member of the American Pain Society, Pain specialist at Brigham and Women's Hospital

…in fiscal 2016 [the VA's] opioid costs were nearly $100 million. Of this, only 1.9% were for an abuse-deterrent product…. [Switching all patients to ADF opioids] would result in approximately $1 billion yearly for these products and could represent as much as 20% of the VA pharmacy budget.

-- Manolis, et al, Health Affairs

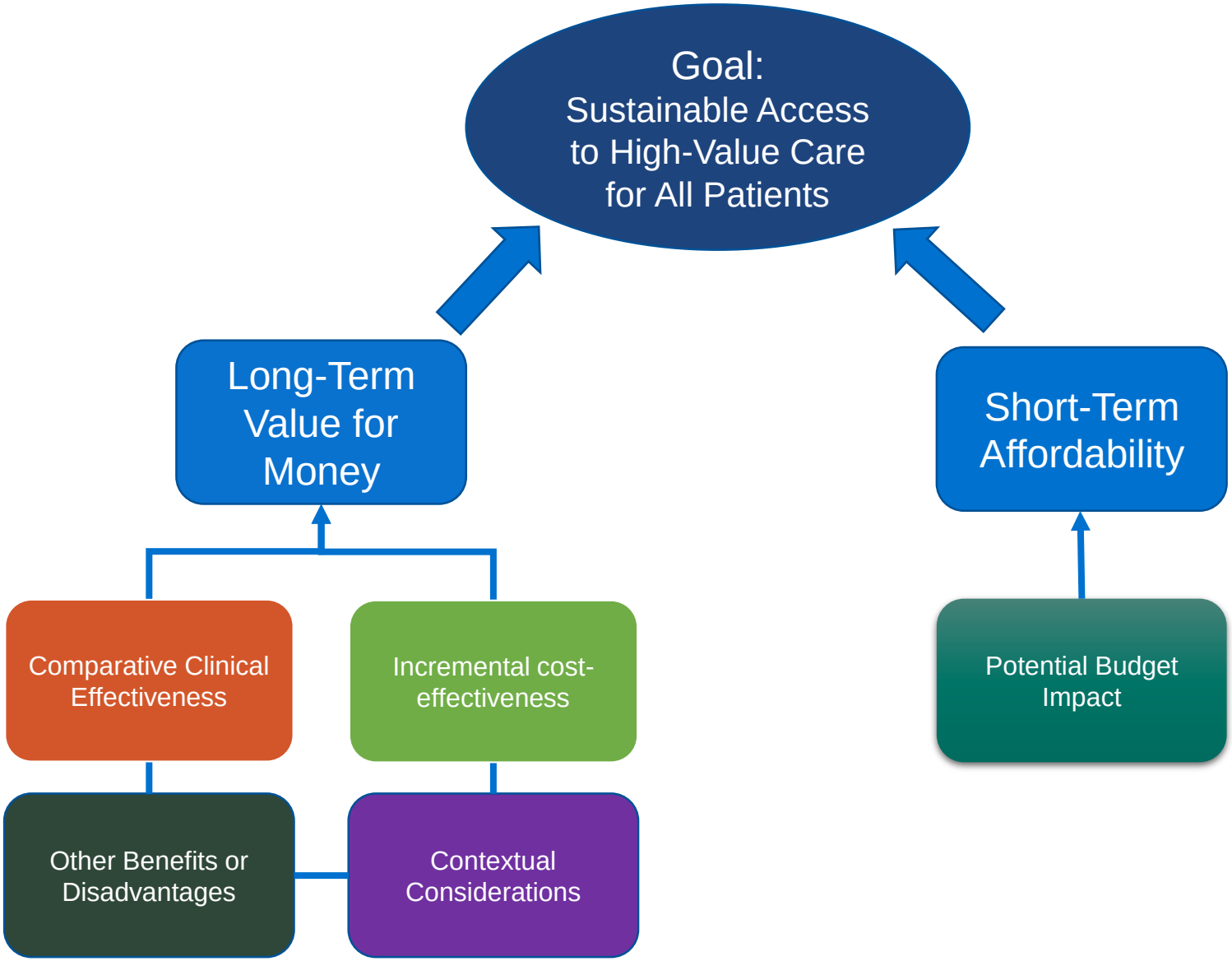
Why are we here today?

- **Public deliberation on the evidence**
- **Input from all stakeholders**
- **Discussion of policy options**

Welcome and Introduction

How was the ICER report on abuse deterrent formulations of opioids developed?

- Scoping with guidance from patient groups, clinical experts, manufacturers, and other stakeholders
- Internal ICER staff evidence analysis and cost-effectiveness modeling
- Public comment and revision
- Expert report reviewers
  - Lewis S. Nelson, MD
  - Richard C. Dart, MD, PhD
  - Alan G. White
  - Paul Gileno
- How is the evidence report structured to support CEPAC voting and policy discussion?


Goal:
Sustainable Access to High-Value Care for All Patients
Long-Term Value for Money
Short-Term Affordability
Comparative Clinical Effectiveness
Incremental cost-effectiveness
Potential Budget Impact
Other Benefits or Disadvantages
Contextual Considerations

Agenda

10:00 am	Meeting Convened and Opening Remarks
10:15 am	Presentation of the Evidence
11:15 am	Manufacturer Public Comments
11:45 am	Public Comments
12:15 pm	Break for Lunch
1:00 pm	Question 1-3 (Clinical Effectiveness): New England CEPAC Deliberation and Votes
1:25 pm	Policy Roundtable
3:20 pm	Question 4 (Policy): New England CEPAC Deliberation and Vote
3:40 pm	New England CEPAC Reflections
4:00 pm	Meeting Adjourned

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Evidence Review

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Senior Fellow
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Disclosures:
Consulting work for Celgene, Hoffman La Roche, Lundbeck

Key review team members:
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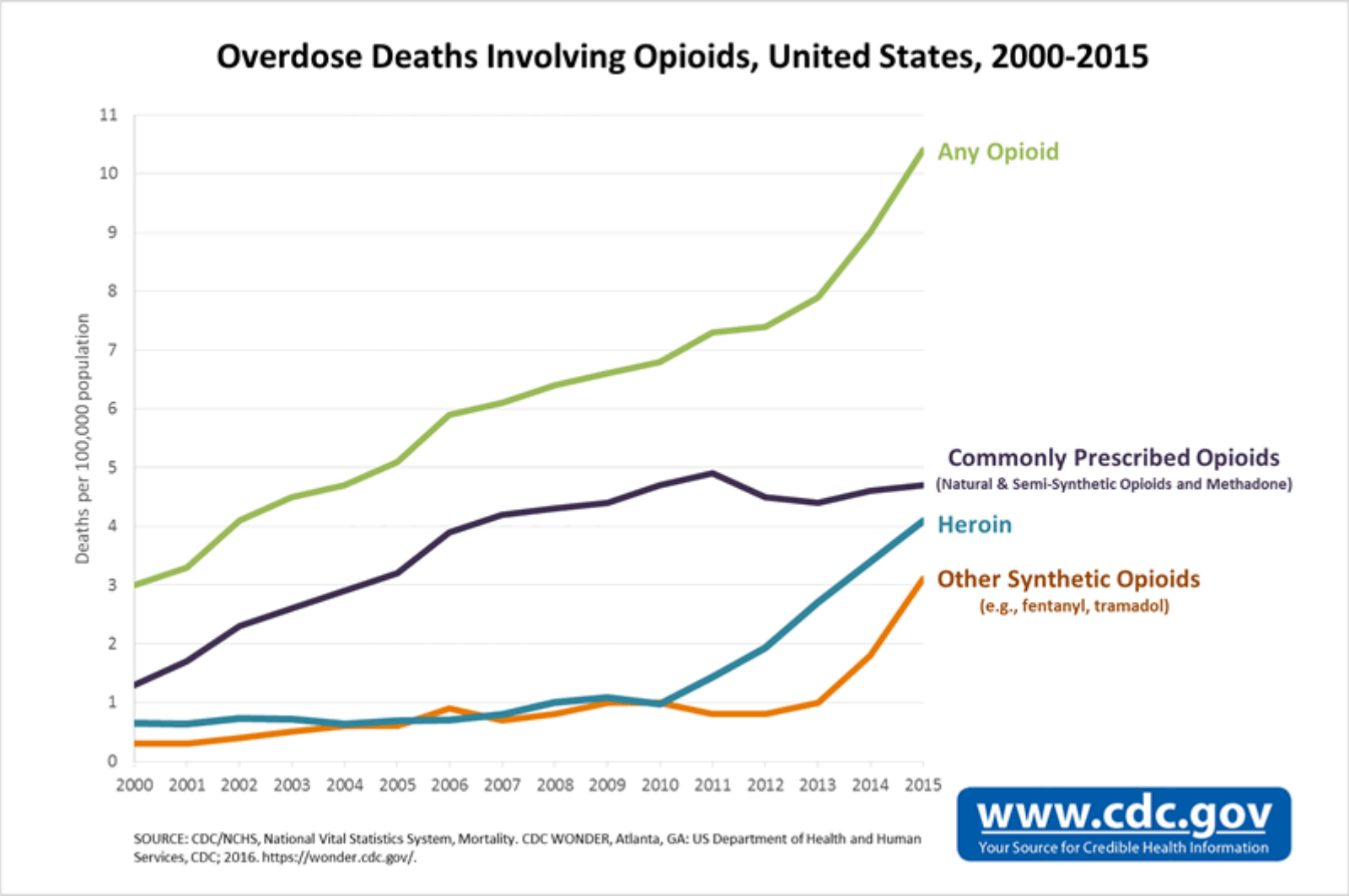
Abuse deterrent formulations

- ADFs are designed to deter specific routes of abuse (e.g. intranasal, injection).
- ADFs can use physical & chemical barriers, agonist/antagonist combinations, aversive agents, and prodrugs.
- The approved ADFs use physical & chemical barriers and agonist/antagonist combinations.
- FDA-Approved Abuse-Deterrent Labeling is based on pre-market assessments.

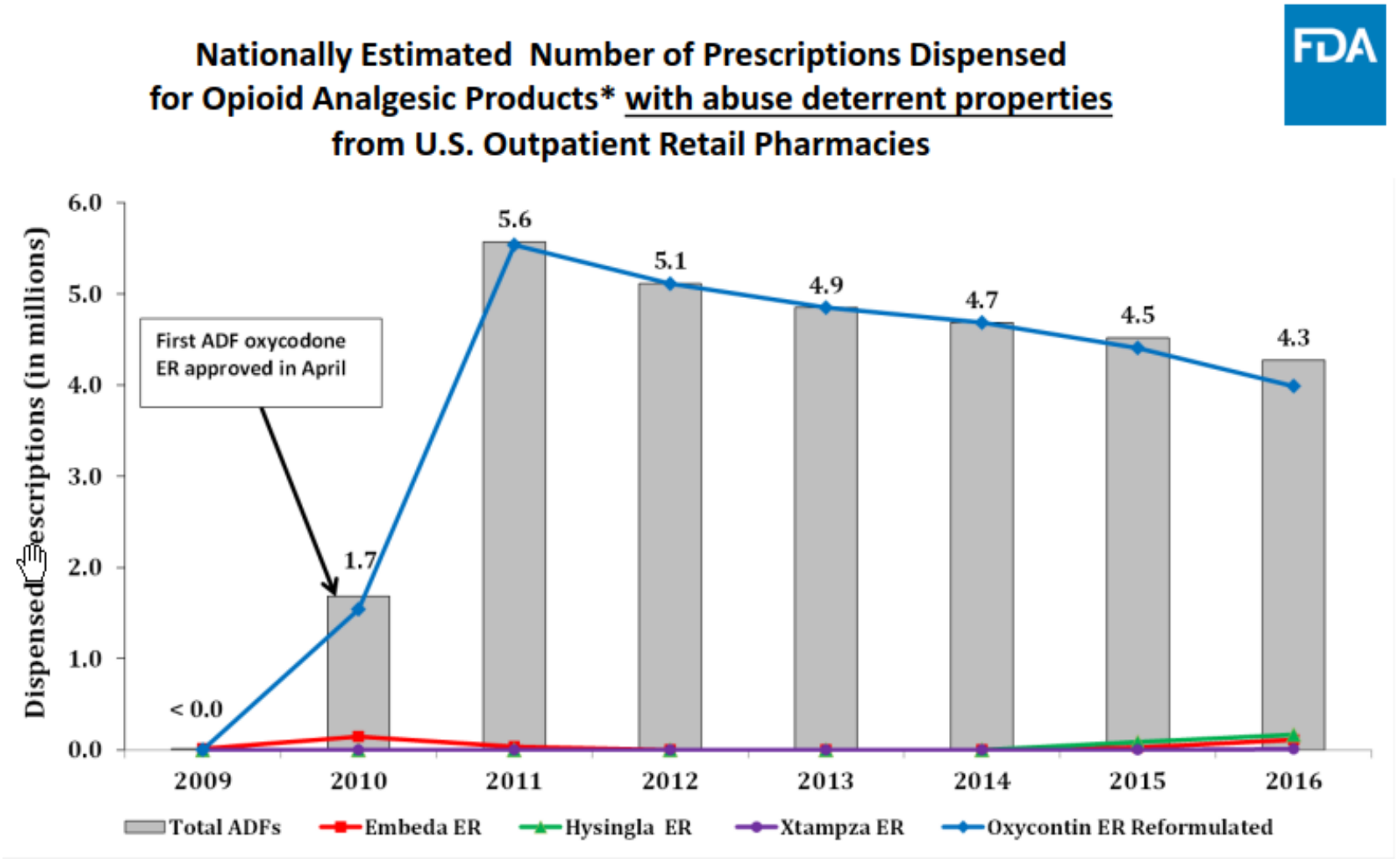
Opioid Products with FDA-Approved Abuse-Deterrent Labeling

ADF	Year of Approval	Commercially Available
OxyContin® TR (Oxycodone, Purdue)	2010	Yes
Embeda® (Morphine + naltrexone, Pfizer)	2014	Yes
Targiniq® (Oxycodone + naloxone ER, Purdue)	2014	No
Hysingla® ER (Hydrocodone, Purdue)	2015	Yes
Morphabond® (Morphine ER, Inspirion & Daiichi Sankyo)	2015	Yes
Xtampza® ER (Oxycodone, Collegium Pharmaceutical Inc.)	2016	Yes
Troxyca® ER (Oxycodone + naltrexone, Pfizer)	2016	No
Arymo® ER (Morphine, Egalet)	2017	Yes
Vantrela™ (Hydrocodone, Teva)	2017	No
RoxyBond® (Oxycodone, Inspirion & Daiichi Sankyo)	2017	No

The national context



Market Shares of different ADFs



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https://www.fda.gov/downloads/Drugs/NewsEvents/UCM565981.pdf#page=10

Testing your knowledge

- Select the ways abuse-deterrent opioids can be abused?
  - ❑ Swallowed
  - ❑ Crushed and swallowed
  - ❑ Crushed and snorted
  - ❑ Crushed and smoked
  - ❑ Dissolved and injected
  - ❑ Abuse-deterrent opioids CANNOT be manipulated and abused.

Testing your knowledge

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Testing your knowledge

- Which of the following is the most common form of abuse?
  - ❑Smoking
  - ❑Injecting
  - ❑Swallowing
  - ❑Snorting

Testing your knowledge

- Which of the following is the most common form of abuse?
  - ❑ Smoking
  - ❑ Injecting
  - ✓ **Swallowing**
  - ❑ Snorting

https://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM532123.pdf#page=12

Policies on opioid coverage and prescribing

- State Policies:
  - Five states require insurance carriers to cover ADFs with no additional barriers to access in comparison with non-ADF opioid equivalents.
  - Similar legislation was introduced in 20 states in 2016.

- The 2016 CDC Guideline for prescribing opioids for chronic pain in primary care settings prioritized nonpharmacologic and non-opioid therapy.

- Coverage policies:
  - OxyContin was most likely to be covered.
  - Xtampza (oxycodone) was least likely to be covered, fewer than one-quarter of plans reviewed.

Insights Gained from Discussions with Patients and Patient Groups

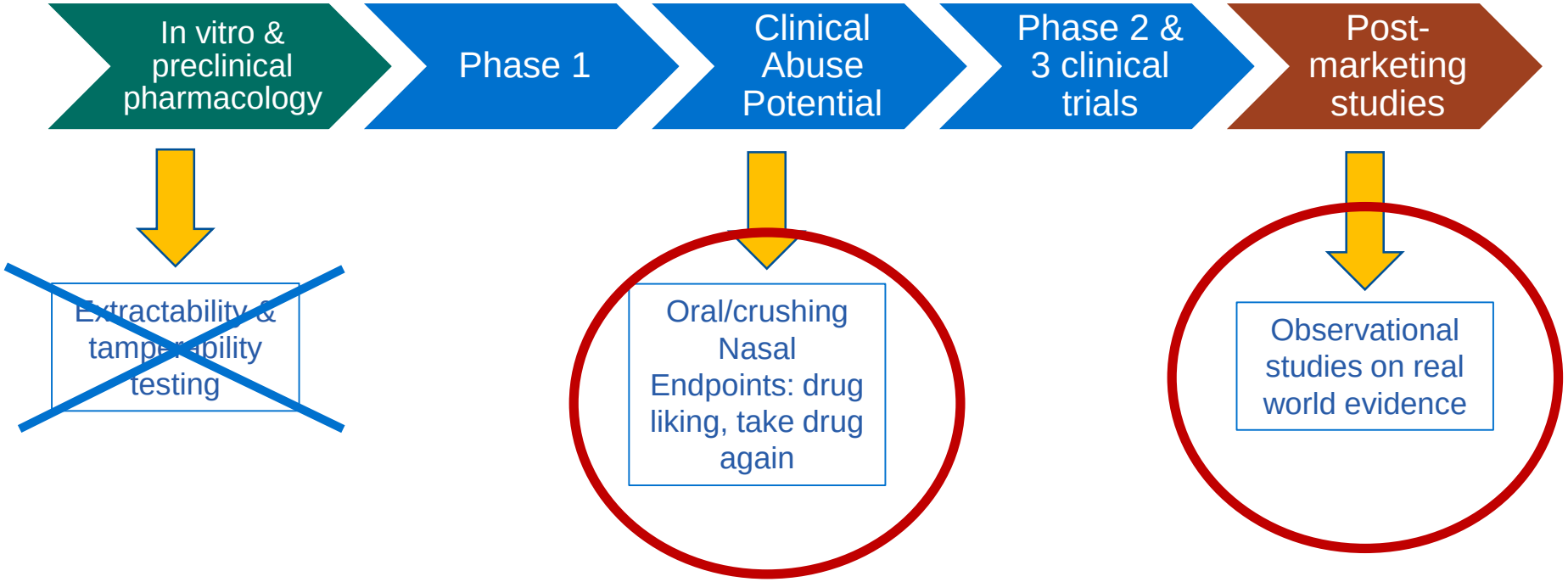
- Need for continued, affordable patient access to opioid therapy for daily function.

- Policy initiatives for reducing the overall use of opioids contributed to difficulties in obtaining prescriptions for long term opioid therapy.

- Difficulties accessing specialized multidisciplinary pain care.

How strong is the evidence that ADFs improve outcomes?

Assessment of abuse potential in clinical development



Casting the evidence net widely

- **Populations**: All persons using opioids for therapeutic and non-therapeutic purposes.
- **Interventions**: Abuse-deterrent opioid formulations with an FDA label.
- **Outcomes**: Patient/Population, Health System, Society.
- **Cut-off:** May 31, 2017.
- Included 15 pre-market RCTs, 26 post-market observational studies.

Premarket Studies of Abuse Potential: Study Design

- 15 randomized crossover trials evaluating **oral** or **intranasal** abuse potential of ER ADFs.
  - RoxyBond IR: no published studies; intranasal abuse potential data in FDA prescribing information was used.
- **Study participants**: Healthy, non-dependent recreational drug users (mean n=34).
- **Comparators**: Non-ADFs in the same class (e.g., oxycodone ADF vs. IR oxycodone).
- **Endpoints**: "Drug liking" and willingness to "take drug again" using VAS of 0-100.

Premarket Studies of Abuse Potential: Results

- Relative to non-ADF comparators, all ADFs produced statistically-significantly lower scores for drug liking.
  - Oral abuse potential: **7-25 point difference** between ADF and non-ADF comparators.
  - Intranasal abuse potential: **7-36 point difference** between ADF and non-ADF comparators.
    - RoxyBond IR: **12 point difference** between crushed RoxyBond IR and Oxycodone IR.
- Similar trends observed for “take drug again” endpoint.
- No established threshold for clinically-important difference.

Postmarket Studies (Real World Evidence): Study Design

- Postmarket data is an **FDA requirement for all ADFs:**
  - Data are currently available only for OxyContin.

- **26 post-market studies on OxyContin:**
  - **All were non-randomized studies** examining the aggregate periods before (1-2 years before) and after (1-4 years after) reformulation of OxyContin.
  - **Comparators**: Other prescription opioids (non-ADF), illicit drugs (e.g., heroin).
  - **Major outcomes**:
    - Abuse and misuse
    - Overdose and fatality
    - Diversion

Postmarket data sources

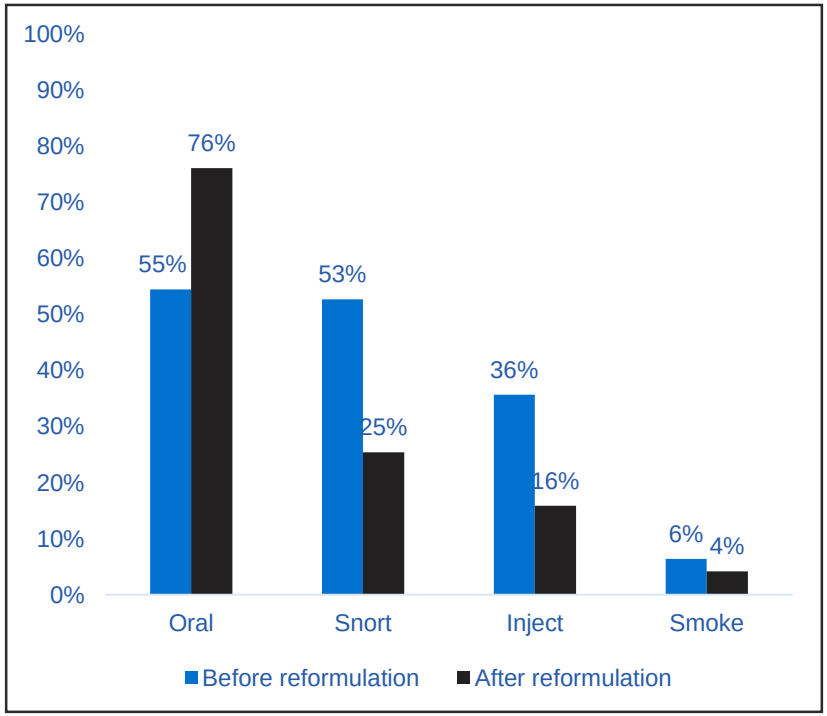
- Data for these studies were obtained from:
  - Patients entering substance abuse programs (***abuse***)
  - Calls/visits to poison control centers (***abuse***)
  - Population-based surveys (***abuse***)
  - Electronic health data/medical claims databases (***abuse***)
  - Reports on law enforcement activity (***diversion***)
  - Spontaneous adverse events (***overdose and fatality***)
- Outcome measure is specific to the data source:
  - Different populations examined
  - Definition of abuse differed across data sources
  - Varying time periods of analysis

Postmarket studies: Abuse and Misuse

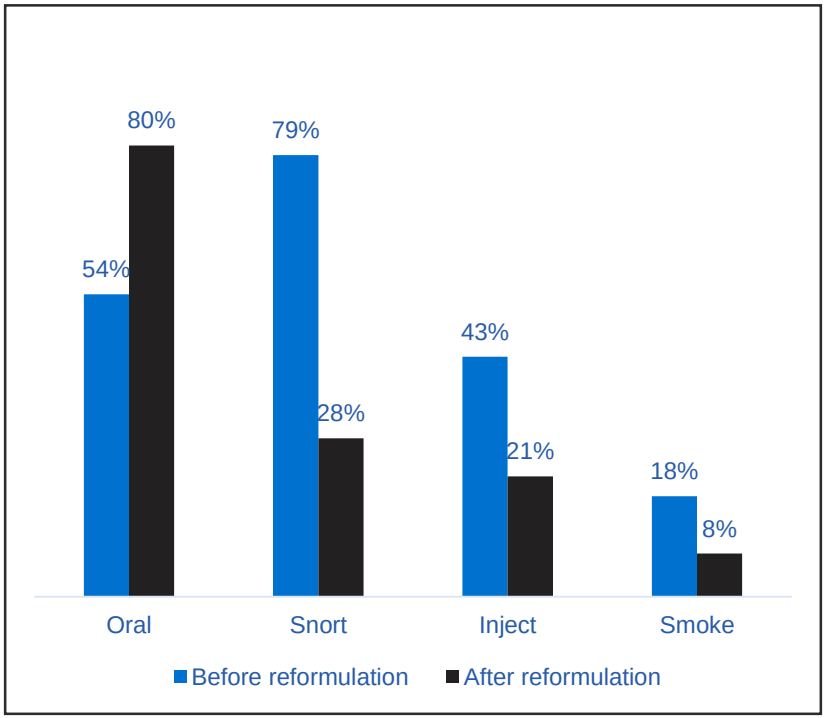
- 16 studies reported a **12% - 75%** decline in the rate of OxyContin abuse, in different study populations and at different time points.
  - 4 of the studies assessed changes in heroin abuse.
    - 3 studies reported a 42% to 100% increase.
    - 1 study observed an 11% decline.
  - 14 of the studies assessed changes in 1 or more other prescription opioids.
    - 8 studies reported a 5% to 246% increase.
    - 3 studies observed 3% to 33% decline in the opioid measured, while other studies observed no change.

Postmarket studies: Abuse and Misuse

Preferred route of abuse among patients entering substance abuse programs that abused OxyContin before and after reformulation



Data source: NAVIPPRO*

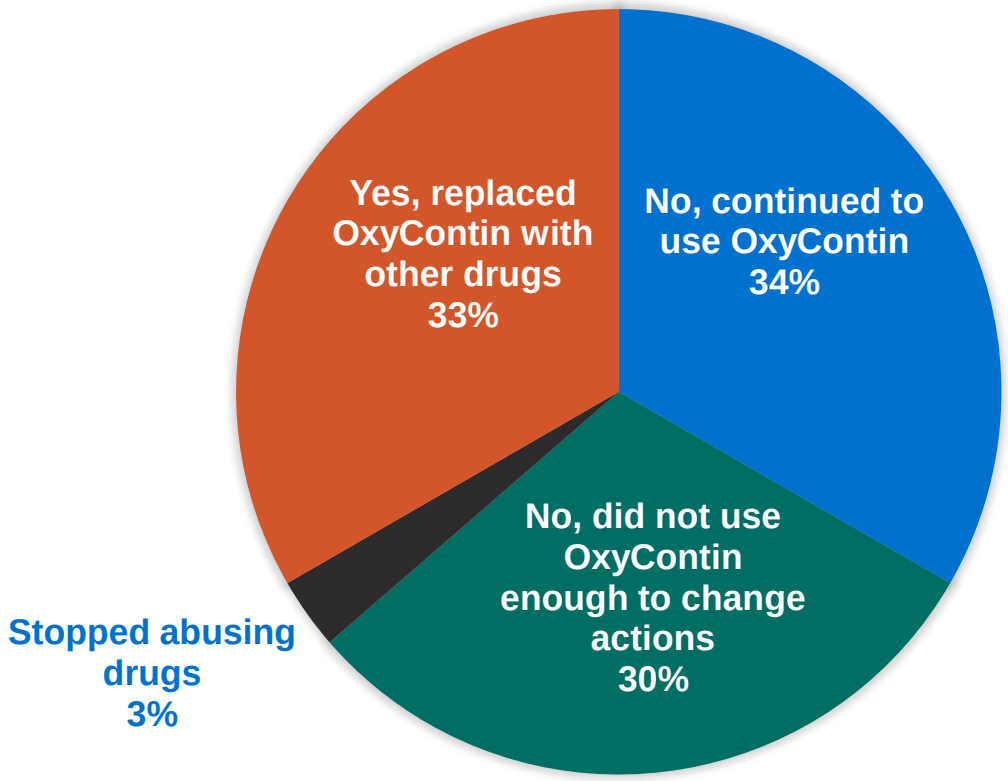


Data source: RADARS SKIP**

*Butler SF, Cassidy TA, Chilcoat H, et al. Abuse rates and routes of administration of reformulated extended-release oxycodone: Initial findings from a sentinel surveillance sample of individuals assessed for substance abuse treatment. *The Journal of Pain.* 2013;14(4):351-358.
**Cicero TJ, Ellis MS, Kasper ZA. A tale of 2 ADFs: Differences in the effectiveness of abuse-deterrent formulations of oxymorphone and oxycodone extended-release drugs. *Pain.* 2016;157(6):1232-1238.

Postmarket studies: Abuse and Misuse

Direct interview with 153 participants entering substance abuse program: *Did ADF OxyContin influence the drugs that participants used for abuse?*



Cicero TJ, Ellis MS. Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: Lessons learned from OxyContin. *JAMA Psychiatry.* 2015;72(5):424-429.

Postmarket studies: Overdoses & Fatalities

- Limited evidence: rates of overdose and overdose deaths attributed to OxyContin declined **20% - 65%.**

- Rates of OD deaths attributed to other Rx or illicit opioids **increased or remained stable.**
  - Each percentage point reduction of OxyContin misuse after reformulation associated with an increase of 3.1 heroin deaths per 100,000.*
  - Claims data showed 23% increase in heroin overdose rate (from 1.15 to 1.41 per 100,000 members).**

*Alpert A, Powell D, Pacula RL. *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids.* The National Bureau of Economic Research;2017.
**Larochelle MR, Zhang F, Ross-Degnan D, Wharam JF. Rates of opioid dispensing and overdose after introduction of abuse-deterrent extended-release oxycodone and withdrawal of propoxyphene. *JAMA Internal Medicine.* 2015;175(6):978-987.

Postmarket studies: Diversion

- 3 studies using data from RADARS Drug Diversion Program.
  - Quarterly reports from law enforcement officers on number of arrests, street buys/sales.

- In study with longest follow-up, OxyContin diversion decreased from **1.95 per million** in year prior to reformulation to **0.21 per million** at year 5 following reformulation.*
  - Diversion of other opioids: **-27% (from 13.4/million to 9.8/million).**

- Measure of law enforcement activity limited by available resources within reporting jurisdictions, local law enforcement priorities, the drugs targeted by investigators, and variations in reporting over time.

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*Severtson SG, Ellis MS, Kurtz SP, et al. Sustained reduction of diversion and abuse after introduction of an abuse deterrent formulation of extended release oxycodone. *Drug and Alcohol Dependence.* 2016;168:219-229.

Harms

- Harms were not assessed in drug likability studies.
- Harms from the ADF are the same as the non ADF active substance when taken as prescribed.
- An ADF with an agonist/antagonist combination can precipitate severe withdrawal symptoms when it is chewed or crushed.
- The introduction of some opioids with abuse deterrent properties has led to a shift from intranasal to intravenous abuse, leading to an outbreak of HIV, HCV and other severe health effects through IV abuse.

ICER Evidence Rating

- *For individual patients being considered for an opioid for therapeutic purposes*:
  - We judge the comparative clinical effectiveness of OxyContin to be **comparable or better ("C+").**
  - For all ADFs, excluding OxyContin, we judge the evidence to be **promising but inconclusive ("P/I")**.

- *For the overall population, including potential non-therapeutic users*:
  - **Insufficient evidence ("I")** to judge the net health benefit of the introduction or substitution of ADFs for non-ADF opioids.

Controversies and Uncertainties

- No conclusive evidence that premarket human abuse potential studies predict the impact of ADFs on real-world abuse.
- No prospective studies of patients who are newly-prescribed opioids that measured real-world incidence of abuse among ADF and non-ADF users.
- Lack of good evidence of the natural history of opioid abuse.
- Lack of population level evidence of a positive net impact of ADFs (shifts in abuse).

Can we predict patients at risk?

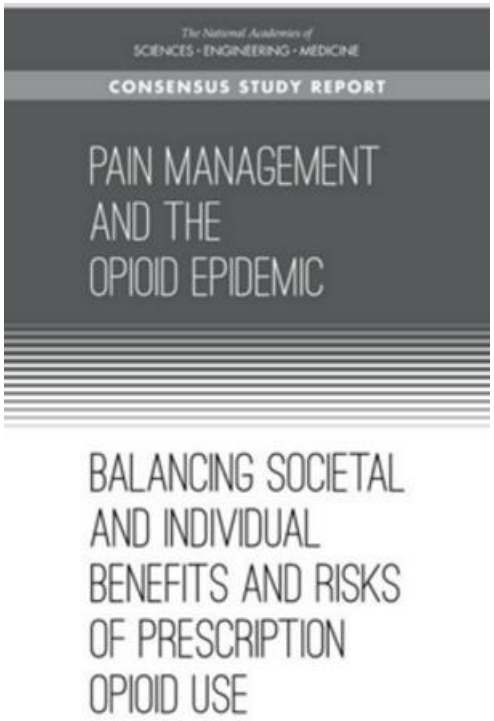
- Different risk stratification tools based on past substance abuse, mental health, physical abuse and other.
- Tools not sufficiently validated.
- Systematic contextual review for 2016 CDC guideline: "clinical evidence review found that currently available risk-stratification tools show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse."

Summary of Public Comments

- ADFs are not an isolated tool in combating opioid addiction and should be evaluated in the context of a holistic program of interventions.
- Conflicting comments about the importance of clinical tools to identify pain patients at higher risk of abuse.
- Disagreement with C+ evidence rating of ADFs in opioid naïve patients based on “likability” studies.
- Safety issue from using Opana.

Consistency with recent reports

Last week



July 10-11, 2017

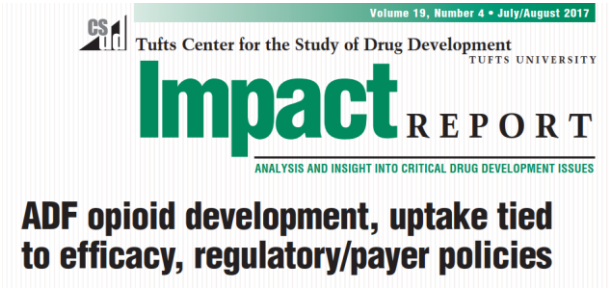
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2903]

Data and Methods for Evaluating the Impact of Opioid Formulations With Properties Designed To Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities; Public Workshop; Issues Paper; Request for Comments

Last week



Economic Evaluation

Rick Chapman, PhD

Director of Health Economics, ICER

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Key Review Team Members

Varun Kumar, MPH, MSc

Dan Ollendorf, PhD

We have no conflicts of interest to disclose.

Objective

To inform policy makers about the net costs and real-world impact of ADF opioids in preventing abuse, our objective was to attempt to answer two key research questions:

1) What are the potential outcomes and net costs of using ADF compared to non-ADF opioids?

2) What levels of effectiveness in abuse reduction and in price difference would be needed for ADF opioids to achieve cost neutrality or net savings relative to non-ADF opioids?

Methods Overview (1/2)

- **Model Type:** Cost-benefit model
- **Population:** Hypothetical cohorts of 100,000 adults with chronic non-cancer pain new to ER opioids
- **Perspective:** Health care system (direct medical care and drug costs)
- **Intervention:** ADF ER opioids*
- **Comparators**: Non-ADF ER opioids*
- **Time Horizon:** Five years
- **Setting:** United States
- **Discount Rate:** Not applied

*Market basket of opioids, weighted by market share in Massachusetts (2016)

Methods Overview (2/2)

- **Outcomes at five years for 100,000 ER opioid prescription users:**

  Base Case Analysis

  - Number of new cases of abuse
  - Net health system costs

  Scenario Analysis

  - Cost-neutrality threshold analysis
  - Scenario analysis including diversion*
  - Net costs from a modified societal perspective (including lost productivity, costs of criminal justice, and incarceration)

Massachusetts Policy Model

Outcomes and net health system costs of converting all ER opioid prescriptions to ADF opioid prescriptions over one year, using data from MA Health Policy Commission.

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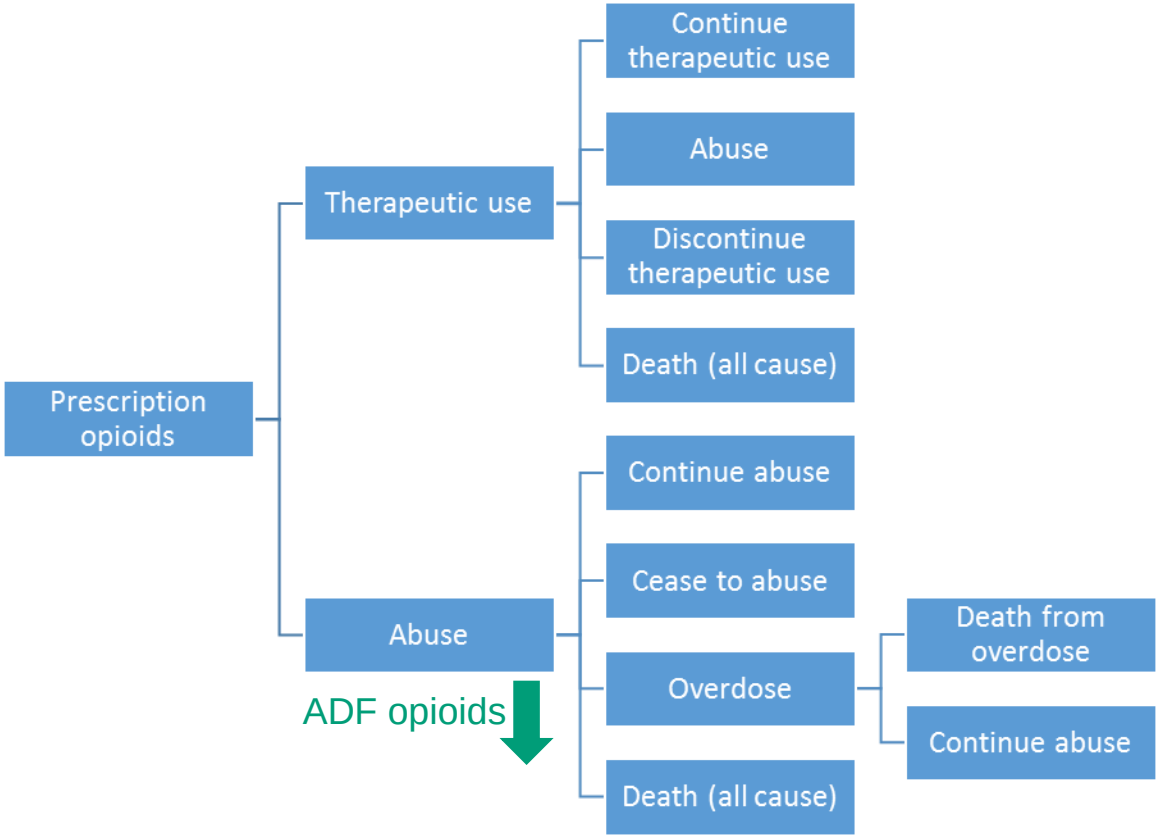
*Includes patients outside the initial cohort of 100,000

Model Schematic



Patients in the ADF and non-ADF opioid cohorts follow the same pathway.

Key Assumptions

- Difference in rates of abuse with ADF relative to non-ADF opioids kept constant throughout time horizon.
- Health care costs of abuse and therapeutic use were assumed the same across cohorts, although risk of abuse differed between the two cohorts.
- Same rate of discontinuation of therapeutic opioid use in both cohorts.
- Assumed annual rate of cessation of opioid abuse of 10%.

Model Inputs: Clinical

Input	Value	Source
Rate of non-ADF ER opioid abuse	3.7%	Rossiter et al., 2014
Rate of ADF ER opioid abuse (OxyContin)	2.8%	Rossiter et al., 2014
Annual discontinuation of prescription opioid use	Year 1 – 17.8% Year 2 – 28.4% Year 3 -- 34.6% Year 4 – 38.2% Year 5 – 40.4%	Martin et al., 2011
Death from opioid overdose	5.9/100,000	Compton et al., 2016

Model Inputs: Costs

Input	Value	Source
ADF Opioids – 90mg MED		
Cost per daily dose*	$11.60	FSS, 2017
Annual cost	$4,234	Calculation
Non-ADF Opioids – 90mg MED		
Cost per daily dose*	$5.82	FSS, 2017
Annual cost	$2,124	Calculation
Mean Annual Health Care Costs		
Therapeutic use	$27,689	Commonwealth of Massachusetts Health Policy Commission
Abuse	$38,145	

*Weighted average cost of drugs within each category, based on market share in Massachusetts (2016).

Base Case Results (1/2)

Clinical outcomes of non-ADF and ADF opioids for 100,000 patients at 5 years

Outcomes	Non-ADF cohort	ADF cohort	Difference (ADF cohort – Non-ADF cohort)
New cases of abuse	10,532	8,229	-2,303
Overdose deaths	1.77	1.38	<1

Base Case Results (2/2)

Health system cost of ADF and non-ADF opioids for 100,000 patients at 5 years

	ADF opioids	Non-ADF opioids	Difference (ADF – non-ADF)
Health care costs*	$8.8 billion	$8.9 billion	-$113.5 million
Prescription opioid costs (entire cohort)	$1.3 billion	$657 million	$646 million
Total costs	$10.1 billion	$9.5 billion	$533 million

Cost per incremental outcome using ADF versus non-ADF opioids

Incremental outcome	Cost
To prevent one new abuse case	$231,000
To prevent one new abuse year	$80,500
To prevent one overdose death	~$1.4 billion

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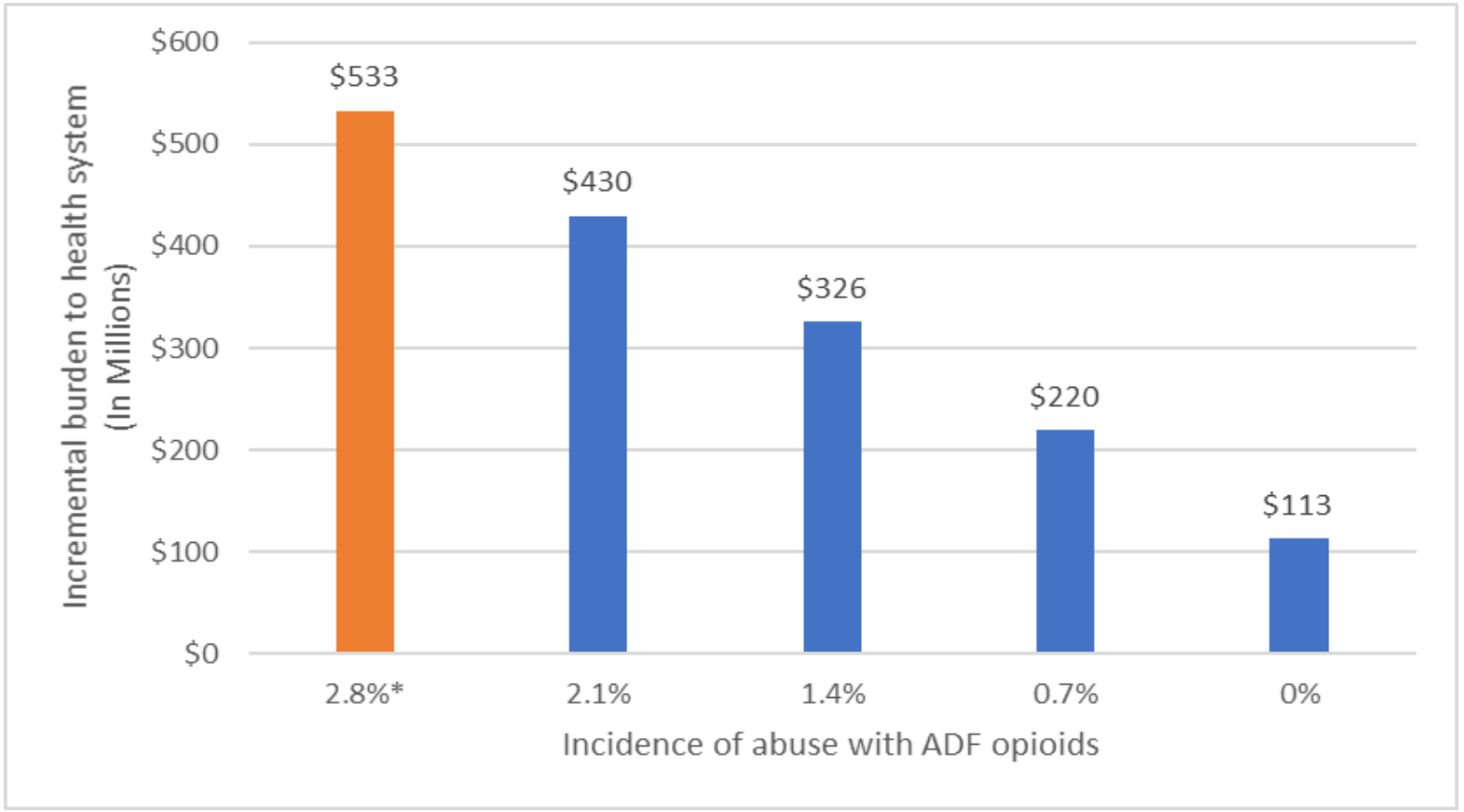
*Excluding prescription opioid costs

Threshold Analysis – Cost neutrality (1/2)

Increasing levels of ADF opioid effectiveness (decreasing rate of abuse)



*Represents base case

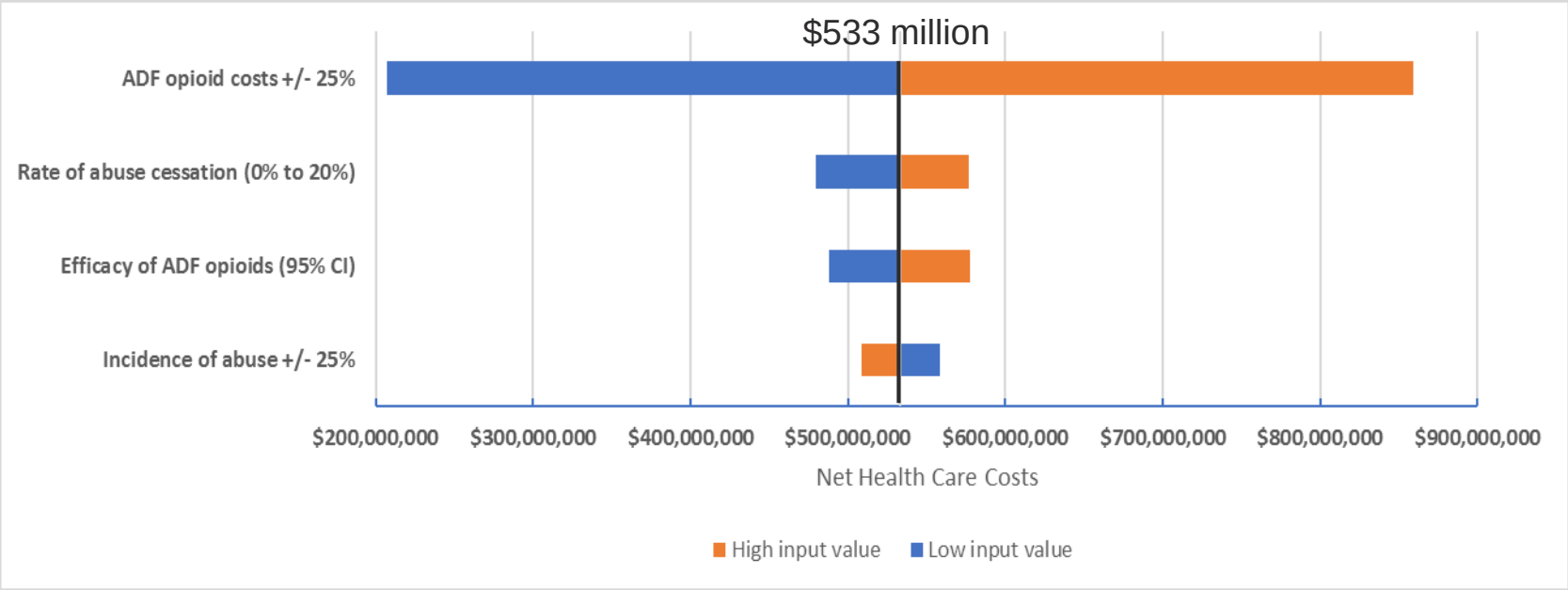
Threshold Analysis – Cost neutrality (2/2)

Varying cost of ADF opioid per day (90mg MED)

	Base case cost	Cost required to attain cost neutrality	% change
ADF opioid drug cost	$11.60	$6.86	-41%*

*The discount required to achieve cost-neutrality represents the discount from a market-share weighted average cost of ADFs, and does not represent the discount required by any individual ADF in the market.

One-Way Sensitivity Analysis



Base case net cost difference is $533 million for 100,000 ER opioid users over five years

Scenario Analysis – Modified Societal Perspective

	ADF opioids	Non-ADF opioids	Difference (ADF – non-ADF)
Societal costs (lost productivity, criminal justice and incarceration)	$492 million	$632 million	-$140 million
Total costs (health system + societal)	$10.6 billion	$10.2 billion	$393 million

Net health system cost difference is $533 million for 100,000 ER opioid users over five years

Massachusetts Policy Model (1/2)

Health and cost outcomes if all ER opioid users in Massachusetts were transitioned to using only ADF opioids over a one-year period.

Model changes:

- Hypothetical cohort in cost-benefit model replaced with prevalent users of ER opioids in Massachusetts – 173,000 in 2015.

  Non-ADF: 113,000 **ADF: 60,000**

Model assumptions:

- The proportion of prevalent ER opioid use was assumed to be the same as the proportion of ER opioid prescriptions filled
- Prevalent opioid use market share was assumed to be the same as that seen in the incident population
- Opioid daily costs derived from MA Health Policy Commission claims data analysis (2014)

Massachusetts Policy Model (2/2)

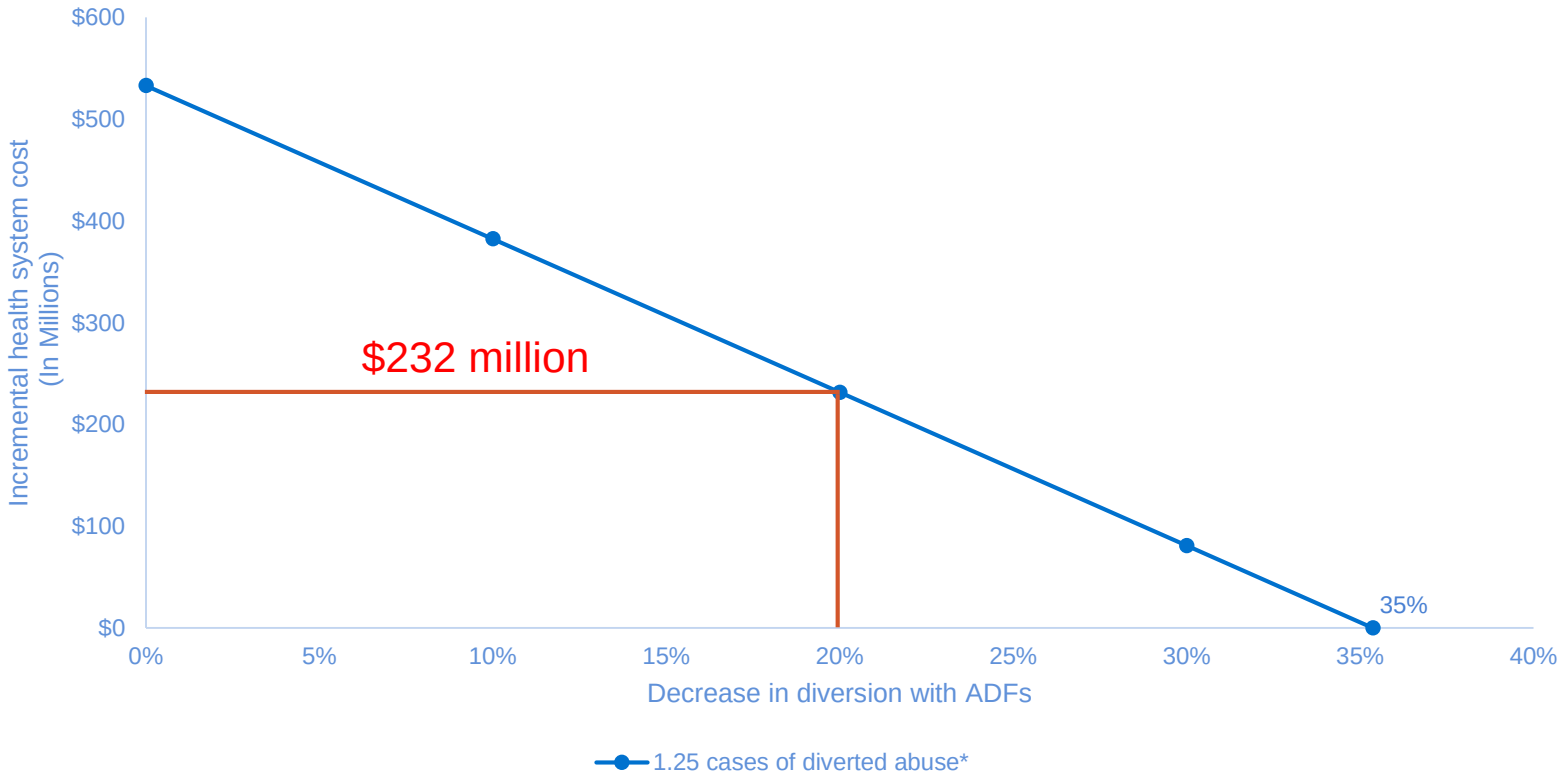
Outcomes when converting all non-ADF opioid prescriptions to ADF opioid prescriptions over one year

	Mixed ADF/non-ADF opioid use	All ADF opioid use	Difference
Abuse cases	5,229	4,387	-842
Abuse-related total health care costs	$225 million	$204 million	-$21 million
Prescription opioid costs	$490 million	$1 billion	$513 million
Total health care costs	$5.3 billion	$5.8 billion	$475 million
Cost to prevent one new case of abuse using ADF opioids			$599,000

Summary and Conclusions

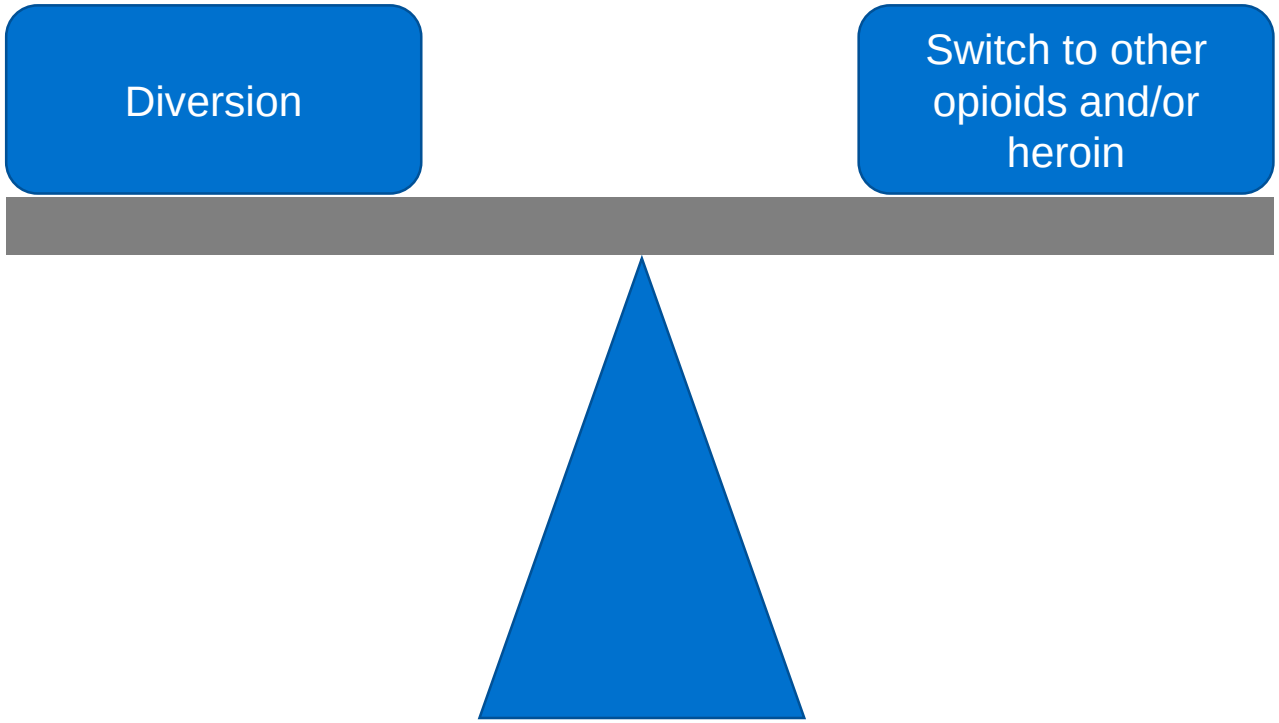
- In a hypothetical cohort model of **100,000 ER opioid users over five years,** use of ADF compared to non-ADF opioids was estimated to:
  - Prevent ~2,300 new cases of abuse.
  - Cost the health care system an additional $533 million.
  - Cost an additional $231,500 to prevent one new case of abuse.
- Cost neutrality could not be achieved even when the effectiveness of ADF opioids in preventing abuse was 100% (holding market-basket prices constant).
- Cost neutrality could be achieved if ADF opioids were discounted by 41% from the current market-basket price.
- In Massachusetts, converting all non-ADF to ADF opioids **over one year** was estimated to prevent ~850 new cases of opioid abuse, at a cost of $599,000 for each case prevented.

Diversion Scenario



*1.25 cases of diverted abuse for every one case of prescription abuse with non-ADF opioids

Diversion Scenario



Public Comments

Changes made in response to public comments:

Model estimates

- Rate of abuse changed to reflect true estimate as seen in the Rossiter et al. claims analysis.
- Health care costs from a claims analysis undertaken by the Commonwealth of Massachusetts Health Policy Commission.

Scenario analyses

- Modified societal perspective (costs for lost productivity, criminal justice and incarceration).
- Impact on health outcomes and costs when introducing the effect of diversion.

Supporting Slides

Model Cohort Characteristics

	Opioid abuse	Regular use	Primary source
Mean age (SD)	36.5 (14.6) years	37 (16.3) years	Rice et al. 2014
Male	56.4%	54.7%	
Mean Charlson comorbidity index (SD)	0.23 (0.7)	0.25 (0.7)	

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Public Comment: Manufacturer Representatives

Public Comment: Manufacturer Representatives

Name	Title	Company
Gwendolyn Niebler	Senior Vice President, Clinical Research and Medical Affairs	Egalet US Inc.
Sunny Cho	Director, Medical Affairs	Daiichi Sankyo, Inc.
Tracy Mayne	Head of Medical Affairs Strategic Research	Purdue Pharma, L.P.

Public Comment

Shaina Smith, Director of State Advocacy, U.S. Pain Foundation

Conflicts of interest:

- Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000
- Status or position as an officer, board member, trustee, owner or employee of a health care company, or an organization which receives more than 25% of its funding from health care companies

If yes, please describe the relationship(s) below.

The U.S. Pain Foundation receives grants from health care companies to fund educational programming

Sponsors listed from website include:
Amgen, Abbott, AbbVie, Genentech, Pfizer, AstraZeneca, Teva, Purdue, Collegium, Depomed, Endo, McNeil, UCB, Shinogi, Daiichi Sankyo, GlaxoSmithKline, Johnson and Johnson, Mallinckrodt, Pernix Therapeutics, Kaleo, PhRMA

Edmund Pezalla, CEO; Enlightenment Bioconsult, LLC

Conflicts of interest:

Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000

Manufacturer support of research in the clinical area of this meeting in which you are participating

If yes, please describe the relationship(s) below.

I am a consultant to Purdue on a regular basis advising on payer strategy and payment/access. Purdue has supported the article that I have authored along with Dr. Tracy Mayne on ADF opioids and modeling of impact.

Dan Cohen, Chair, Abuse Deterrent Coalition

Conflicts of interest:

Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $5,000

Equity interests such as individual stocks, stock options or other ownership interests in excess of $10,000. Ownership of stock in a mutual fund over which an individual has no trading control does not count toward this item.

Status or position as an officer, board member, trustee, owner or employee of a health care company, or an organization which receives more than 25% of its funding from health care companies

If yes, please describe the relationship(s) below.

EVP, Government and Public Relations, KemPharm Inc.

Dr. Richard Dart, Director, Rocky Mountain Poison and Drug Center; Denver Health and Hospital Authority

Conflicts of interest:

Manufacturer support of research in the clinical area of this meeting in which you are participating

If yes, please describe the relationship(s) below.

I am director of the RADARS System, which is operated by the Denver Health and Hospital Authority (governmental). The program is supported by subscription fees from multiple parties including many pharmaceutical companies and US government. All funds go the institution. No personal financial relationships are allowed.

Break for Lunch

Meeting will resume at 1:00PM

Voting Questions

Test question: Who is the only American President to be born in New Hampshire?

A. Calvin Coolidge

B. Josiah Bartlett

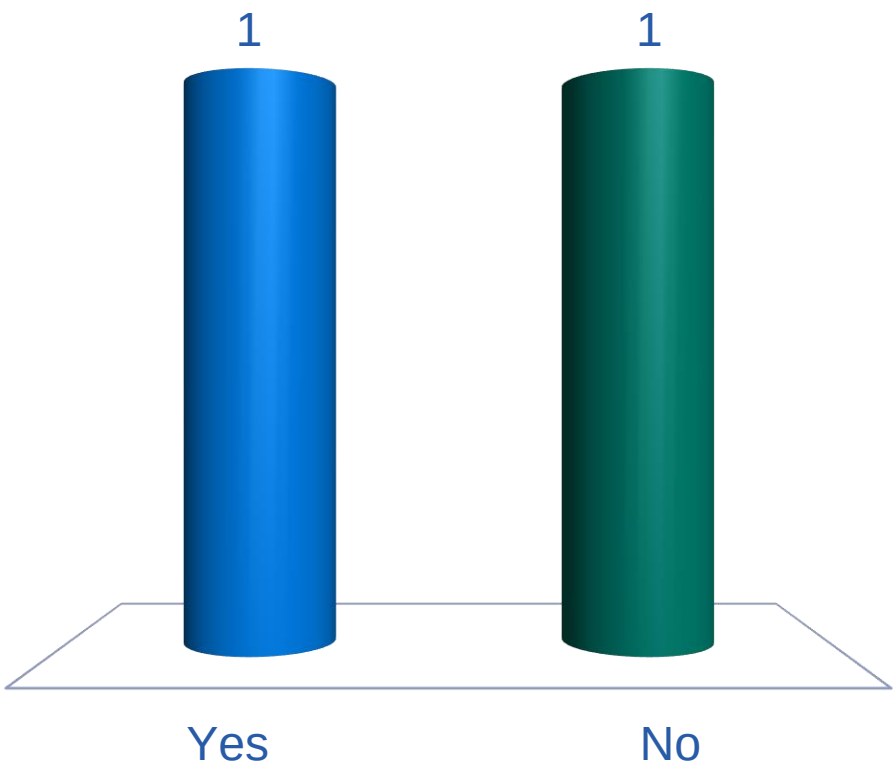
C. Franklin Pierce

D. Herbert Hoover

1. For a patient being considered for a prescription of an immediate release opioid, is the evidence adequate to demonstrate a reduced risk of abuse for patients using RoxyBond versus non-ADF immediate release opioids?

A. Yes

B. No



2. For a patient being considered for a prescription of an extended release opioid, is the evidence adequate to demonstrate a reduced risk of abuse for patients using OxyContin versus non-ADF extended release opioids?

A. Yes

B. No

3. For a patient being considered for a prescription of an extended release opioid, is the evidence adequate to demonstrate a reduced risk of abuse for patients using any of the available ADF extended release opioids (excluding OxyContin) versus non-ADF extended release opioids?

A. Yes

B. No

Policy Roundtable

Policy Roundtable

Marty Boldin, LICSW, MLADC, LCS Governor's Policy Advisor for Prevention, Treatment, & Recovery Office of the Governor Christopher T. Sununu	**Nathaniel Katz, MD, MS** Chief Executive Officer Analgesic Solutions
Dan Cohen Chair Abuse Deterrent Coalition	**Jeanmarie Perrone, MD** Director of the Division of Medical Toxicology Professor of Emergency Medicine University of Pennsylvania
Patrick Gleason, PharmD Senior Director, Health Outcomes Prime Therapeutics	**Shaina Smith** Director of State Advocacy & Alliance Development U.S. Pain Foundation Inc.
C. Bernie Good MD, MPH Chair, Medical Advisory Panel for Pharmacy Benefits Management Veterans Administration	

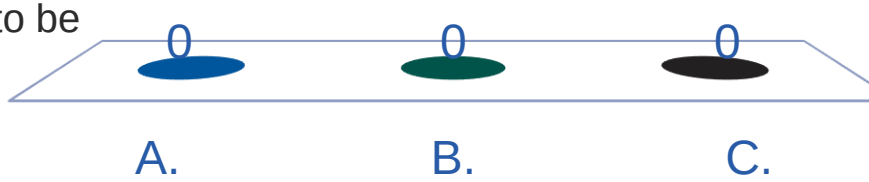
4. Clinicians and policymakers are making efforts to reduce the numbers of patients started on opioids, limit the time course and refills for opioid prescriptions, and enhance monitoring for potential diversion and misuse of opioids. In addition, ADF-substitution policies are being considered to shift opioid prescriptions toward abuse-deterrent formulations.

Considering the broad potential impact of substitution policies on patients, diversion, and illicit opioid use, which of the following policies do you believe would produce the most overall health benefit?

A. Allow physicians to determine whether to shift current patients to ADF opioids and whether to start new patients on ADF or non-ADF opioids.

B. Allow physicians to determine whether to shift current patients to ADF opioids; require all new opioid prescriptions to be written for an ADF opioid.

C. Require all current non-ADF prescriptions to be substituted with ADF and all new prescriptions to be written for an ADF opioid.



New England CEPAC Reflections

Adjourn