



### Mirror Mirror on the Wall: Who's the FDA's Fairest ADF of All?

Mark Garofoli, PharmD, MBA, BCGP, CPE

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#### Faculty



- Family of 8 Pharmacists  
- Wife, In-Laws, & Cousins
- Family Vineyard in the Marche Region of Italy



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#### Disclosures

- Nothing to disclose

This presentation was not a part of the presenter's official duties at the WVU and does not represent the opinion of WVU



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### Opinions...

**I have personal and professional opinions on pain management. However, some things are better left NSAID.**



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### Learning Objectives

- Identify the seven current types of abuse-deterrent formulations
- Recall all available abuse-deterrent formulation opioid medications, with particular attention to the select few that are both FDA approved specifically as ADF opioid medications and available on the US market
- Discuss common methods of manipulation of abuse-deterrent formulation opioid medications



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### 2016 CDC Chronic Pain Opioid Guidelines

The collage includes three main components:
 

- Left:** A poster titled "GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN" with the sub-header "IMPROVING PRACTICE THROUGH RECOMMENDATIONS". It lists key recommendations such as "Prescribe the lowest effective dose of an immediate-release opioid analgesic" and "Avoid long-acting or extended-release opioids as first-line therapy for chronic pain."
- Middle:** The cover of the **MMWR** (Morbidity and Mortality Weekly Report) issue dated August 18, 2016, featuring the title "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016".
- Right:** A detailed page from the guideline, titled "KEY POINTS FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN", which provides a structured overview of the recommendations and their implications for clinical practice.



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### CDC Chronic Pain Opioid Guidelines

**Opioid Use Decision**

1. Non-Pharm, Non-Opioid, then Opioid
2. Treatment Goals
3. Risk Assessments & Side Effects




CDC  
CENTERS FOR DISEASE  
CONTROL AND PREVENTION

**Dose/Amount/Time of Opioid**

4. IR not ER
5. MME  $\geq$  50/day: Use caution  
No increasing MME  $\geq$  90 unless justified
6. Acute pain: Short duration
7. Re-evaluate 1 month, then every 3 months.

**Risk/Harms of Opioid Use**

8. Higher risk  $\rightarrow$  naloxone
9. PDMP initially + every 1-3 months
10. UDT initially + annually
11. Avoid combining opioids & benzos
12. Opioid Use Disorder: Offer MAT



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### CDC MME Thresholds & Driving Speed Limits

**Caution**  
**50 MEDD**

**Avoid**  
**Increasing**  
**Speed Limits**  
 **$\geq$  90 MEDD**



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### CDC MME Thresholds & Driving Speed Limits

**Caution**  
**50 MEDD**



**Avoid**  
**Increasing**  
**90 MEDD**



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### Driving & Opioid Risk Reduction

**SEAT BELTS SAVE LIVES**

**BUCKLE UP EVERY TIME**

<b>PDMP Review</b>
Physical exam
Urine drug screening
Use caution with methadone
Short duration of initial opioid
Avoid sedative co-prescribing
Patient & provider agreement/contract
MEDD cautionary threshold
Gradual tapering plan
<b>ABUSE-DETERRENT FORMULATIONS</b>

PainWeek Adapted from <http://www.pain.gov/resources/pain5500041.pdf>

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### Opioid Abuse Transition

Hydrocodone  
Combo  
Tablets

\$5-10/Tab

Oxycodone  
Combo IR  
Products

\$10-15/Tab

Oxycodone  
Sole ER/IR  
Products

\$1.50/mg

Heroin  
(\$10/Bag)

PainWeek Shah N, et al. Characteristics of Initial Prescription Opioid Use and Likelihood of Long-Term Opioid Use - United States, 2000-2015. *MMWR* / March 21, 2017 / 66(10): 245-249. [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

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### Opioid Abuse Transition

Research

Original Investigation

The Changing Face of Heroin Use in the United States  
A Retrospective Analysis of the Past 50 Years

Theodore J. Cicero, PhD; Matthew S. Ellis, MPE; Hilary L. Surratt, PhD; Steven P. Kurtz, PhD

75% of Heroin Users  
Started with  
Prescription Opioids

PainWeek Cicero T, et al. The Changing Face of Heroin Use in the United States. *JAMA* December 16, 2014

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### Opioid Abuse Transition

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Research

Original Investigation  
**The Changing Face of Heroin Use in the United States**  
 A Retrospective Analysis of the Past 50 Years

Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, Steven P. Kurtz, PhD

75% of Heroin Users  
 Started with  
 Prescribed Opioids

Family, Friends, Theft ???

Healthcare Professional(s)

**PainWeek**

© Cicero et al. (2014). The Changing Face of Heroin Use in the United States. *PLoS Medicine*. 11(12)

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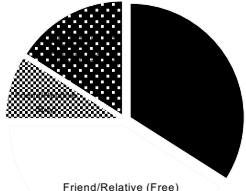
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### Where are these opioids coming from...



**HEALTHCARE  
 PROFESSIONAL**  
**~1/3<sup>rd</sup>**

**PainWeek**

2017 DEA National Drug Threat Assessment: [https://www.dea.gov/docs/DR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/docs/DR-040-17_2017-NDTA.pdf)

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### Opioid Abuse Transition

ADF Opioid Formulations

Physical Barrier

Aversion

Chemical Barrier

Delivery System

Hydrocodone  
Combo  
Tablets  
\$5-10/Tab

Oxycodone  
Combo IR  
Products  
\$10-15/Tab

Oxycodone  
Sole ER/IR  
Products  
\$1.50/mg

Heroin  
(\$10/Bag)

Agonist/  
antagonist  
opioid  
combinations

Combination  
of Any

Prodrug

ADFs

**PainWeek**

Opioid Epidemic and Burden of Long-Term Opioid Use - United States, 2000-2015. *MMWR*. March 17, 2017 / 166(10): 241-248

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### Types of Abuse-Deterrent Formulations (ADFs)

ADF Type	Description
1. Physical barrier	Prevent chewing, crushing, cutting, grating, or grinding
2. Chemical barrier	Resists extraction of the opioid through use of common solvents including water, alcohol or other organic solvents
3. Agonist/antagonist opioid combinations	Antagonist is added to the formulation to interfere with release if taken in any other way than it was intended
4. Aversion	Substances are added to the dosage form to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or if a higher dosage than directed is used
5. Delivery system	Alternative delivery systems that are more difficult to manipulate (such as a depot injectable, an implant, or transdermal application)
6. Prodrug	Medication contains a prodrug that lacks opioid activity until it has been transformed in the gastrointestinal tract
7. Combination of the above	

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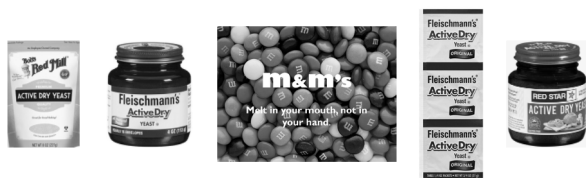
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### Sophisticated Science?



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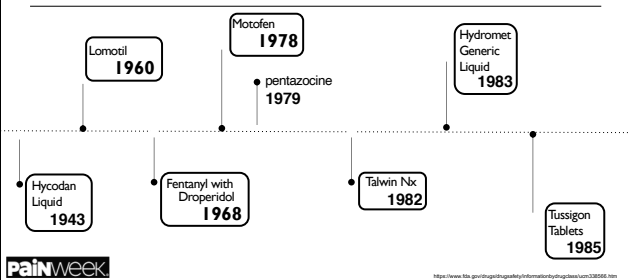
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### FDA Opioid Timeline



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### The Early “ADFs”

#### Hydrocodone & homatropine

- Tussigon tablets 5 mg/1.5 mg (FDA 1985)
- Hydromet liquid 5 mg/1.5 mg per 5 ml (FDA 1943, generic 1983)
- Homatropine
  - Anticholinergic similar to atropine (aversion)



<https://www.fda.gov/oc/opa/foia/foia-requests/foia-requests-030506.htm>

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### The Early “ADFs”

#### Phenylpiperidine opioids (diarrhea treatment)

- Lomotil® (diphenoxylate & atropine, 1960)
- Motofen® (difenoixin & atropine, 1978): metabolite of diphenoxylate
- Atropine
  - Produces *dysphoria* in large doses (aversion)
  - Anticholinergic: blurred vision, constipation, visual disturbances



<https://www.fda.gov/oc/opa/foia/foia-requests/foia-requests-030506.htm>

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### The Early “ADF’s”

#### Fentanyl with droperidol

- Dr. Robert Dripps (U of Penn) strong opponent due to abuse concerns
- Dr. Janssen (Janssen Pharmaceuticals) & Dr. Dripps developed the combination product of droperidol to fentanyl in a 50:1 ratio (FDA approved 1968)
- Dr. de Castro (Europe) recommended ratio based on his patient treatments including the droperidol to produce dysphoria if abused
- FDA later approved fentanyl as solo products



Stanley, T. The Fentanyl Story. The Journal of Pain, Vol 15, No 12 (December), 2014, pp 1215-1226.

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## The Early “ADFs”

Pentazocine and naloxone (FDA approved in 1982)

- Pentazocine single product
  - Kappa agonist, mu antagonist
  - Single product pentazocine FDA approved 1967
  - Observed to be crushed, mixed w/ antihistamine pyribenzamine, & injected
    - “Pinks & blues”
  - 1<sup>st</sup> DEA reclassification: pentazocine (single product) to CIV in 1979



<https://www.fda.gov/oc/opa/whistleblowers/whistleblowers-032008.htm>

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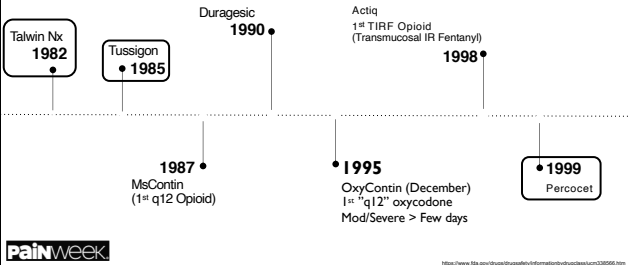
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## FDA Opioid Timeline



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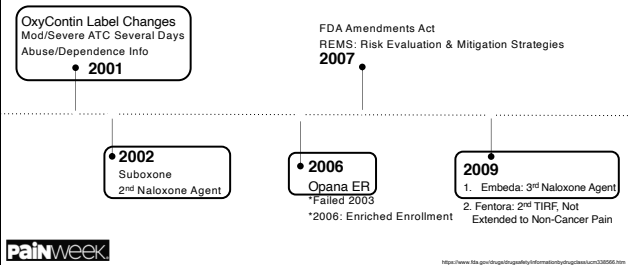
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## FDA Opioid Timeline



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### FDA Opioid Timeline

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Reformulation of Opana ER (2006)  
**2011**

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**2010**  
 1. Reformulation of OxyContin (OP)  
 2. Propoxyphene Voluntary Withdrawal Recommended

**PainWeek**

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### The Opana Story

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**2011**  
 –FDA approved Opana ER reformulation from Endo Pharmaceuticals, but without ADF Labeling

**2012**  
 –Endo submitted a citizen's petition to the FDA to remove original formulation generic oxymorphone products from the market. The petition was denied, and the FDA noted that the rate of IV abuse of the newly designed opioid had been increasing in the months after its introduction to the market

**PainWeek**

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### The Opana Story

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**2017 (March)**  
 –Endo presented post-marketing data to the FDA that contained evidence of serious health concerns with IV abuse of the reformulated product, such as thrombotic thrombocytopenic purpura and an outbreak of HIV infections in Indiana  
 • High molecular weight of the polyethylene oxide (PEO) coating that became lodged in the arterioles of the kidneys of IV abusers

**2017 (July)**  
 –FDA recommended Endo remove Opana ER from market, and Endo did so

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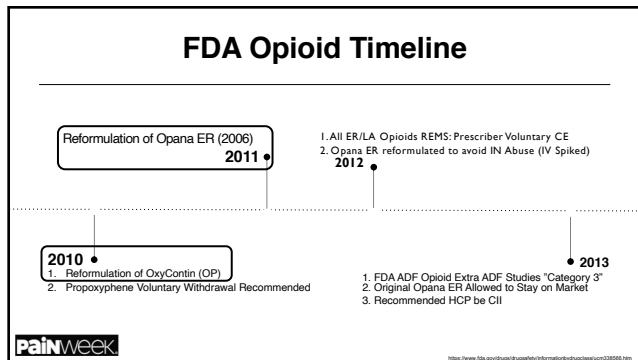
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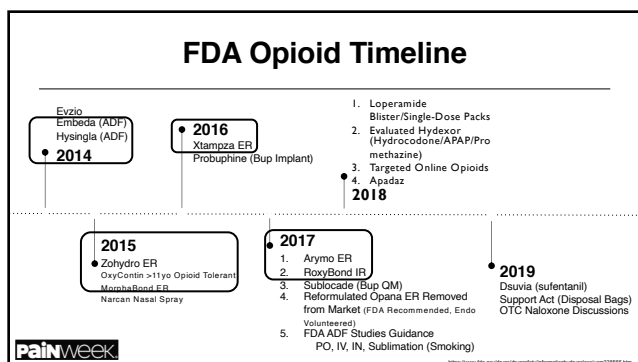
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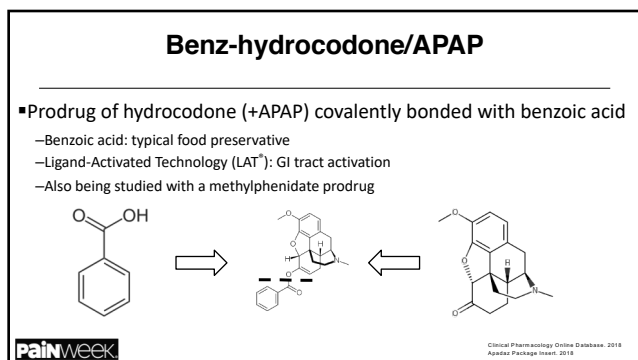
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### Benz-hydrocodone/APAP

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- Controlled Substance Class 2 (just as hydrocodone/apap)
- Indicated for the short-term (*no more than 14 days*) management of *acute* pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
- NOT FDA approved as an abuse-deterrent formulation (ADF) opioid
- Benzhydrocodone/APAP 6.12/325 mg = hydrocodone/APAP 7.5/325 mg

**Painweek** Clinical Pharmacology Online Database 2018  
Abuse Package Insert 2018

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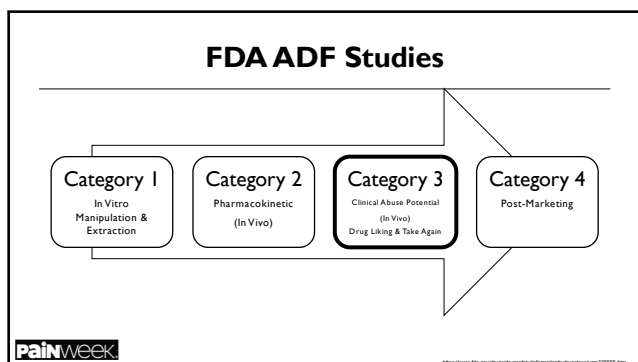
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### Category 3: Abuse Potential Studies

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Physically manipulated products compared to regular product <ul style="list-style-type: none"> <li>• Cutting</li> <li>• Grafting</li> <li>• Milling</li> <li>• Chewing</li> <li>• ± Heat</li> </ul>	<u>Routes of Administration</u> <ul style="list-style-type: none"> <li>– <b>Ingestion (oral route)</b> <ul style="list-style-type: none"> <li>• Oral bioavailability</li> </ul> </li> <li>– <b>Injection (parenteral route)</b> <ul style="list-style-type: none"> <li>• Extractability and syringeability</li> </ul> </li> <li>– <b>Insufflation (nasal route)</b> <ul style="list-style-type: none"> <li>• Nasal bioavailability &amp; PD effects</li> </ul> </li> <li>– <b>Smoking (inhalation route)</b> <ul style="list-style-type: none"> <li>• Ability to sublimate</li> </ul> </li> </ul>
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**Painweek** https://www.fda.gov/oc/officeofdrugevaluation/officeofdrugevaluation/20180501.html

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### Category 3: Abuse Potential Studies

In Vitro Studies	In Vivo Studies
Extractability Studies	Nasal & Oral PK
Performed at both room temp & elevated temp	Multiple strengths tested
Solvents • Level 1: deionized water • Level 2: vinegar, 0.2% baking soda solution, 40% ethanol, & carbonated drink • Level 3: 100% ethanol, 100% isopropyl alcohol, acetone, 0.1 N HCl, & 0.1 N NaOH	Agonist/antagonist levels

**Painweek**

[https://www.fda.gov/oc/ohrt/dupra\\_060409040907.pdf](https://www.fda.gov/oc/ohrt/dupra_060409040907.pdf)

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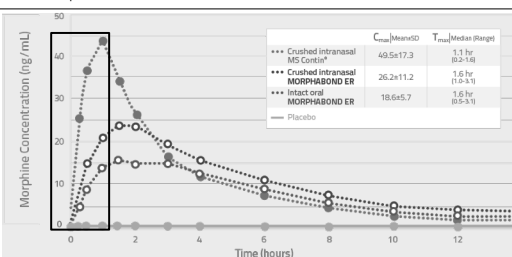
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### ADF Pharmacokinetics

Derived from MorphaBond Data



**Painweek**

<https://morphabond.com/>

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So who made the cut...pun intended



**Painweek**

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FDA Approved ADF Opioids available on US Market (January 2021)

Abuse Deterrent Formulation (ADF) Opioids			
Active Ingredient	Product	FDA ADF Approval	Formulation
oxycodone	Xtampza ER®	IN, IV, & PO Chew	ER Capsule
	Xartemis ER® (+APAP)	-	IR/ER Tablet
	OxyContin®	IN & IV	ER Tablet
	Troxyca®	IN, IV, PO Crush	ER Capsule
	Oxaydo®	-	IR Tablet
	RoxyBond®	IN & IV	IR Tablet
tapentadol	Nucenta ER®	-	ER Tablet
hydromorphone	Exalgo®	-	ER Tablet
morphine	Embeda®	IN & PO Crush	ER Tablet
	Arymo®	IV	ER Tablet
	MorphaBond®	IN & IV	ER Tablet
hydrocodone	Hysingla®	IN, IV, & PO Chew	ER Tablet
	Zohydro ER®	-	ER Capsule
	Vantrela ER®	IV	ER Tablet
	Hydromet®	-	Liquid
benzhydrocodone	tusigon®	-	Tablet
peniazocine	Apizaco®	-	Tablet
	Yalwin NX®	-	Tablet

\*Targiniq (oxycodone) & Opana (oxymorphone) are Off Market\*

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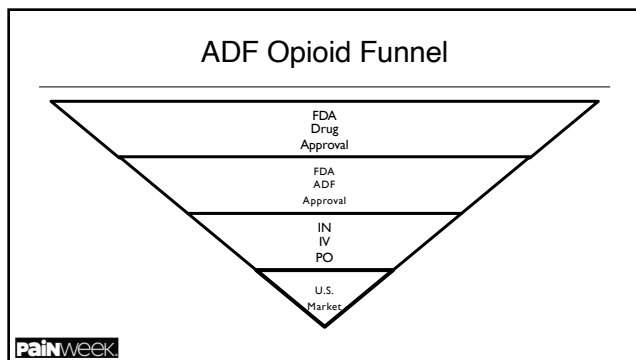
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### FDA Approved ADF Opioids on US Market (January 2021)

Medicine	Product	FDA ADF Approval			Formulation
Oxycodone	Xtampza ER®	IN	IV	PO Chew	ER Capsule
	OxyContin®	IN	IV		ER Tablet
Hydrocodone	Hysingla®	IN	IV	PO Chew	ER Tablet
Morphine	Arymo®		IV		ER Tablet

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## Xtampza ER®

- DETERx technology
  - Waxy microspheres solidify in a needle
- FDA ADF approved
  - IN, IV, & PO
- Take with food
  - GI activated, not pH
- Can be opened and sprinkled into a G-tube or on food

Microspheres made of PLGA and wax impart extended-release properties

Inactive components are made of hydrophilic waxy resins

Drug is homogeneously dispersed within each microsphere

Drug binds chemically with inactive components

**PainWeek**

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Xtampza ER <small>(oxycodone) Dosage</small>	Equivalent to	Extended-release Oxycodone HCl <small>Dosage</small>
9 mg		10 mg
13.5 mg		15 mg
18 mg		20 mg
27 mg		30 mg
36 mg		40 mg
27 mg + 27 mg		60 mg
36 mg + 36 mg		80 mg

**PainWeek**

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## OxyContin®

- Original formulation (1996-2009): “OC” imprint
- Newer formulation (2010-present): “OP” imprint

Strength	10 mg	15 mg	20 mg	30 mg	40 mg	80 mg
Comparison of original (first) versus reformulated OxyContin® tablets (second).						

**PainWeek**

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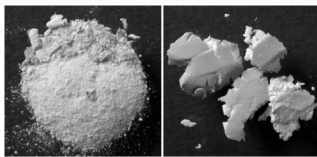
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## OxyContin®

- RESISTEC technology
  - Forms a viscous gel with water
- ADF Category 3 study (IN/IV)
  - 57% reduction in drug liking
  - 43% no reduction in drug liking
- Phase 4
  - ~50% decrease in doctor shopping, overdoses, & poison center calls (heroin replaced?)
- Q12h dosing ???



Original OxyContin®

New abuse-deterrent OxyContin®



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**Homophone**

the same      sound

right ✓	see 👁️	hair 👱
write ✍️	sea 🌊	hare 🐰



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## Oxy-Crisping

### Tools of the Trade

- Grater (PediEgg)
- Ceramic/glass plate
- Paper towel
- Microwave
- Fridge/freezer



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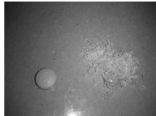
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### Oxy-Crisping

**Tools of the Trade**

- Grater  (lemon zester)
- Ceramic/glass plate
- Paper towel
- Microwave
- Fridge/freezer

**PainWeek** www.hsni.org

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### FDA Approved ADF Opioids on US Market

(January 2021)

Medicine	Product	FDA ADF Approval			Formulation
Oxycodone	Xtampza ER <sup>®</sup>	IN	IV	PO Chew	ER Capsule
	OxyContin <sup>®</sup>	IN	IV		ER Tablet
Hydrocodone	Hysingla <sup>®</sup>	IN	IV	PO Chew	ER Tablet
Morphine	Arymo <sup>®</sup>		IV		ER Tablet

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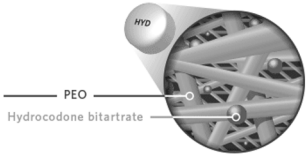
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### Hysingla<sup>®</sup>

- RESISTEC technology (\*same as OxyContin)
  - Forms a viscous gel around water
- ADF Category 3 studies (IN, IV, & PO): ~80% reduction in drug liking

HYdrocodone  
SINGle dose  
Long Acting



**PainWeek**

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### Hysingla®

Hydrocodone/paral 10 mg/325 mg  
1 T q 4 to 6 h  
???

**Painweek**

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### FDA Approved ADF Opioids on US Market (January 2021)

Medicine	Product	FDA ADF Approval			Formulation
Oxycodone	Xtampza ER®	IN	IV	PO Chew	ER Capsule
	OxyContin®	IN	IV		ER Tablet
Hydrocodone	Hysingla®	IN	IV	PO Chew	ER Tablet
Morphine	Arymo®		IV		ER Tablet

**Painweek**

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### Arymo®

- Guardian technology (polymer matrix)
  - Physical & chemical barrier
- FDA ADF approved for IV
- Oxycodone product in pipeline

**Painweek**

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### FDA Approved ADF Opioids on US Market (January 2021)

Medicine	Product	FDA ADF Approval			Formulation
Oxycodone	Xtampza ER <sup>®</sup>	IN	IV	PO Chew	ER Capsule
	OxyContin <sup>®</sup>	IN	IV		ER Tablet
Hydrocodone	Hysingla <sup>®</sup>	IN	IV	PO Chew	ER Tablet
Morphine	Arymo <sup>®</sup>		IV		ER Tablet

**PainWeek**

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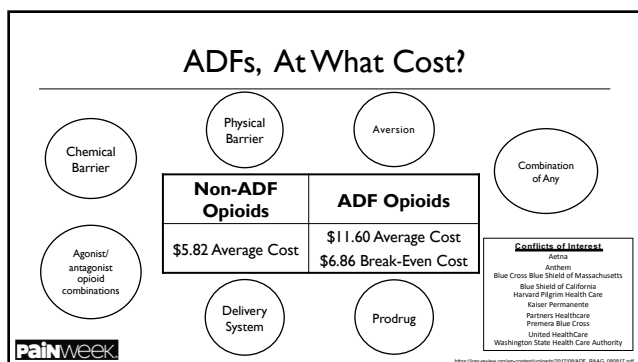
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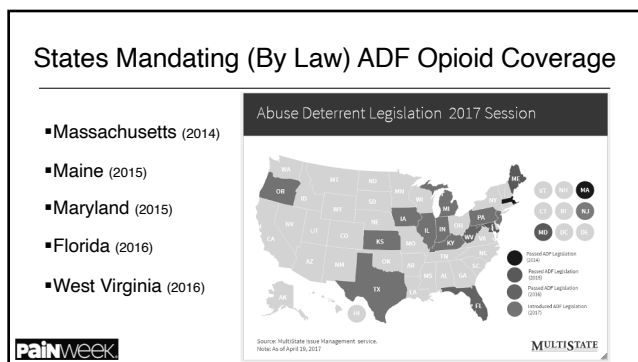
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PainWeek

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### ADF Opioid Pipeline TAAP

- TAAP (Trypsin Activated Abuse Protection)
  - Trypsin is found only in the small intestine
- MPAR (Multi-Pill Abuse Resistance)
  - A small amount of trypsin inhibitor (soybeans & egg whites) added to each pill not affecting opioid release
  - If multiple pills are ingested (on purpose or accidentally) the trypsin inhibitor blocks the activation of the opioid prodrug

PainWeek

<http://www.antiopice.com/bio-md-lect>

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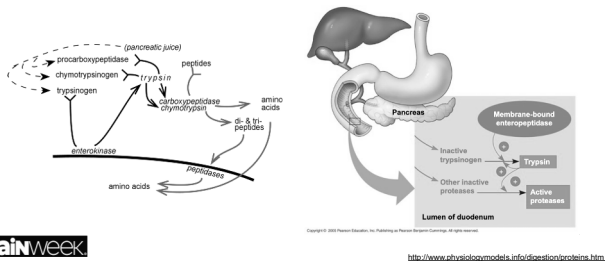
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### Trypsin → Protein Breakdown



PainWeek

<http://www.physiologymodels.info/education/lectures.html>

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### ADF Opioid Pipeline TAAP & MPAR

- Oxycodone (PF614)
  - 12-hour t<sub>1/2</sub> (true BID dosing)
- Hydromorphone ER (PF329)
- Amphetamine (PF8001/8026)
  - ADHD
- R-Methadone (PF26810)
  - Medication assisted treatment

**PF614 PROVEN TO BE TAMPER-PROOF**

TAAP™: PHASE I CLINICAL DATA

**Painweek**  
tamper-resistant technology

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### ADF Opioids

Hydrocodone  
Combo  
Tablets  
\$5-10/Tab

Oxycodone  
Combo IR  
Products  
\$10-15/Tab

Oxycodone  
Sole ER/IR  
Products  
\$1.50/mg

Heroin  
(\$10/Bag)

Medicine	Product
Oxycodone	Xtampza ER <sup>®</sup> OxyContin <sup>®</sup>
Hydrocodone	Hysingla <sup>®</sup>
Morphine	Arymo <sup>®</sup>

**Painweek**  
Shah, A. et al. Characteristics of Retail Prescription Opioids and Effect of Long-Term Opioid Use - United States, 2006-2011. Morbidity & Mortality Weekly Report, March 11, 2017 (MMWR) 365-200. www.cdc.gov

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### Audience Question #1

While performing an opioid risk assessment for a 45yo patient with chronic lower back pain (utilizing morphine ER 30 mg BID), you find out that the patient lives in a house with a spouse who has a substance use disorder. Which of the following FDA approved ADF ER opioids is readily available on the US market and most appropriate for this patient?

- a) Arymo ER 15 mg BID
- b) Arymo ER 30 mg BID
- c) Xtampza ER 13.5 mg BID
- d) Xtampza ER 27 mg BID




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### Audience Question #1 (ANSWER)

While performing an opioid risk assessment for a 45yo patient with chronic lower back pain (utilizing morphine ER 30 mg BID), you find out that the patient lives in a house with a spouse who has a substance use disorder. Which of the following FDA approved ADF ER opioids is readily available on the US market and most appropriate for this patient?

- a) Arymo ER 15 mg BID
- b) ARYMO ER 30 MG BID [CORRECT]
- c) Xtampza ER 13.5 mg BID
- d) Xtampza ER 27 mg BID

Medicine	Product
Oxycodone	Xtampza ER <sup>®</sup>
Hydrocodone	OxyContin <sup>®</sup>
Morphine	Arymo <sup>®</sup>




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### Audience Question #2

While performing an opioid risk assessment for a 55yo patient with chronic lower back pain (utilizing oxycodone ER 20 mg BID), you find out that the patient has a history of marijuana addiction, and that the patient would prefer to sprinkle his medication on his food instead of swallowing the pill whole. Which of the following FDA approved ADF ER opioids is readily available on the US market and most appropriate for this patient?

- a) Arymo ER 15 mg BID
- b) Arymo ER 30 mg BID
- c) Xtampza ER 20 mg BID
- d) Xtampza ER 18 mg BID




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### Audience Question #2 (ANSWER)

While performing an opioid risk assessment for a 55yo patient with chronic lower back pain (utilizing oxycodone ER 20 mg BID), you find out that the patient has a history of marijuana addiction, and that the patient would prefer to sprinkle his medication on his food instead of swallowing the pill whole. Which of the following FDA approved ADF ER opioids is readily available on the US market and most appropriate for this patient?

- a) Arymo ER 15 mg BID
- b) Arymo ER 30 mg BID
- c) Xtampza ER 20 mg BID
- d) XTAMPZA ER 18 MG BID [CORRECT]

Medicine	Product
Oxycodone	Xtampza ER®
	OxyContin®
Hydrocodone	Hyzinta®
Morphine	Arymo®




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### Audience Question #3

Which of the following states have legislation mandating the prescription insurance benefit coverage of abuse-deterrent formulation (ADF) opioid medications in at least some manner?

- a) Massachusetts
- b) Maryland
- c) Florida
- d) All of the above




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### Audience Question #3

Which of the following states have legislation mandating the prescription insurance benefit coverage of abuse-deterrent formulation (ADF) opioid medications in at least some manner?

- a) Massachusetts
- b) Maryland
- c) Florida
- d) ALL OF THE ABOVE [CORRECT ANSWER]

- Massachusetts (2014)
- Maine (2015)
- Maryland (2015)
- Florida (2016)
- West Virginia (2016)




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