Abuse Deterrent Opioid Formulations and Their Relation to Heroin

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Judging by the size and frequency of the droppings, I’d say we’ve found the campaign trail.
What is an Abuse Deterrent Formulation?

• Abuse-deterrent properties
  – meaningfully deter abuse, even if they do not fully prevent abuse.

• Abuse
  – intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desirable psychological or physiological effect.

• FDA definition of Misuse
  – intentional therapeutic use of a drug in an inappropriate way.

FDA ADF Guidance
Current ADFs in the United States

• **OxyContin**, ER oxycodone tablet reformulated in 2010 to crushing or making a solution

• **Embeda**, ER morphine pellets in a sequestered core of the opioid antagonist naltrexone. If crushed, chewed, or dissolved, naltrexone is released.

• **Hysingla ER**, ER hydrocodone tablet with same formulation as OxyContin.

• **Targiniq ER**, ER oxycodone and naloxone, similar to Embeda

• **Morphabond**, ER morphine with physicochemical barriers
Oxycodone Extended Release

Original Formulation (OC)  Abuse Deterrent Formulation (OP)
Oxycodone ADF – Reduced Use
Number of People Filling Prescriptions

![Graph showing change from baseline average (%) over time since reformulation. The graph compares different categories: ADF, Other, and OP. The X-axis represents time since reformulation, and the Y-axis represents change from baseline average (%). The graph illustrates the decrease in prescription filling over time for each category.]
The Law Of Unintended Consequences
Past-Month Use of Oxycodone (OP) or Heroin Before and After Reformulation

Cicero & Ellis. doi:10.1001/jamapsychiatry.2014.3043
How Could Heroin Increase Develop?

- Person in Chronic Pain
- Pain Relief from Opioid

Rx Opioid Abuse in the US
- Chew
- Crush
- Swallow
- Snort

Susceptible Pain Patient

- Treatment
- Other Opioids incl Heroin
- Death

Dart RC. Can J Diag 2015
Fact Check

- Oxycodone ADF comprises less than 5% of the US opioid market
- Despite its reputation, most abuse of oxycodone ADF is oral
- Are there enough abusers leaving oxycodone to account for the increase in heroin?
Increase in Heroin Started Before First ADF

Figure 2. Rate of Reported Heroin Use in the National Survey on Drug Use and Health (SAMHSA)
Other Factors

• Cost
  – Every $100 decrease in price of pure gram of heroin resulted in a 2.9% increase in number heroin overdose hospitalizations
  – Price point phenomenon

• Availability (*Dreamland*)

• Most abusers use multiple opioids

• Other opioids
  – Hydrocodone-acetaminophen >90 million prescriptions per year
  – Oxycodone-acetaminophen
  – Morphine
  – Hydromorphone
  – Oxymorphone

• Other Drugs

Groups at Risk for Heroin Abuse or Dependence

Abuse or dependence on other substances significant predictors of heroin abuse or dependence

- Alcohol; aOR=1.8**
- Marijuana; aOR=2.6**
- Cocaine; aOR=14.7***
- Rx opioids; aOR=40.0***

Jones CM, MMWR, 2015.
Relationship between Nonmedical Prescription-Opioid Use and Heroin Use

Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H.
Conclusions

• Good news – Prescription Drug Abuse is decreasing in the US

• ADFs appear effective in reducing abuse of specific drugs.

• Bad news – Heroin abuse is increasing in the US
  – Prescription opioids contribute, and ADFs are one type of ADF
  – Cost and availability are likely larger factors
Thank you!

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