The Importance of Measuring Real World Abuse Deterrence of Generic Opioids: *In Vitro and HAL Data are not Enough*

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Generics Dominate the Opioid Market

• By pill count about 96%-97% of the opioids prescribed are generics

• The ADF market is dominated by OxyContin
Abuse is Determined By Multiple Complex Factors
What determines choice of drug and type of abuse?

- Availability
- Quality of High--Liking (speed + intensity)
- Effort (Prep time + waste)
- Local Cost
- Abuse Ecology (What are the alternatives available?)
- Social Network and Personal Environment
- Severity of Addiction = **ABUSE**

- **RED** = Formulation related qualities
Drug Discussion Forum Initial Reaction to ADF

79 Days: ~80,000 views
Abuse of New Opioids are Dynamic and Changing: Internet Data

As soon as a drug is put on the market the “hacking” begins:

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The best thing I can offer is to make sure you get the generic. The name brand has been reformulated and are these plasticky convex pill that you cannot crush. People were passing them whole; body wasn’t even breaking it down. If you have had them before, the generics work like the old stop signs.
Recipe Trends

• 2-year period following OxyContin reformulation
  • 688 recipe-related posts
  • 319 posts with “successful” results—(Note that successful recipes may not always be useful because they are too time-consuming, complex or undesirable in various ways).
Reformulated products: Recipes

[Graph showing the proportion of recipe posts from Q3* to Q3* over the years 2010 to 2012, with a notable increase in Q3*.]
A Few “Modest Proposals”

• Basic, minimal (plain vanilla) ADF technology should be required for every generic opioid

• A branded product that demonstrates two years of real world abuse deterrence (Category 4) should get an additional year of exclusivity

• Dynamic labeling—reevaluated every 3-5 years

• Ongoing epidemiological, real-time assessment of every opioid product

• Generics must be physically easily distinguishable from the branded product
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