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

Simon Budman, Ph.D.
Chief Strategy Officer & Founder
Inflexxion, Inc.

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 **x**

Quality of High--Liking (speed + intensity) **x**

Effort (Prep time + waste) **x**

Local Cost **x**

Abuse Ecology (What are the alternatives available?) **x**

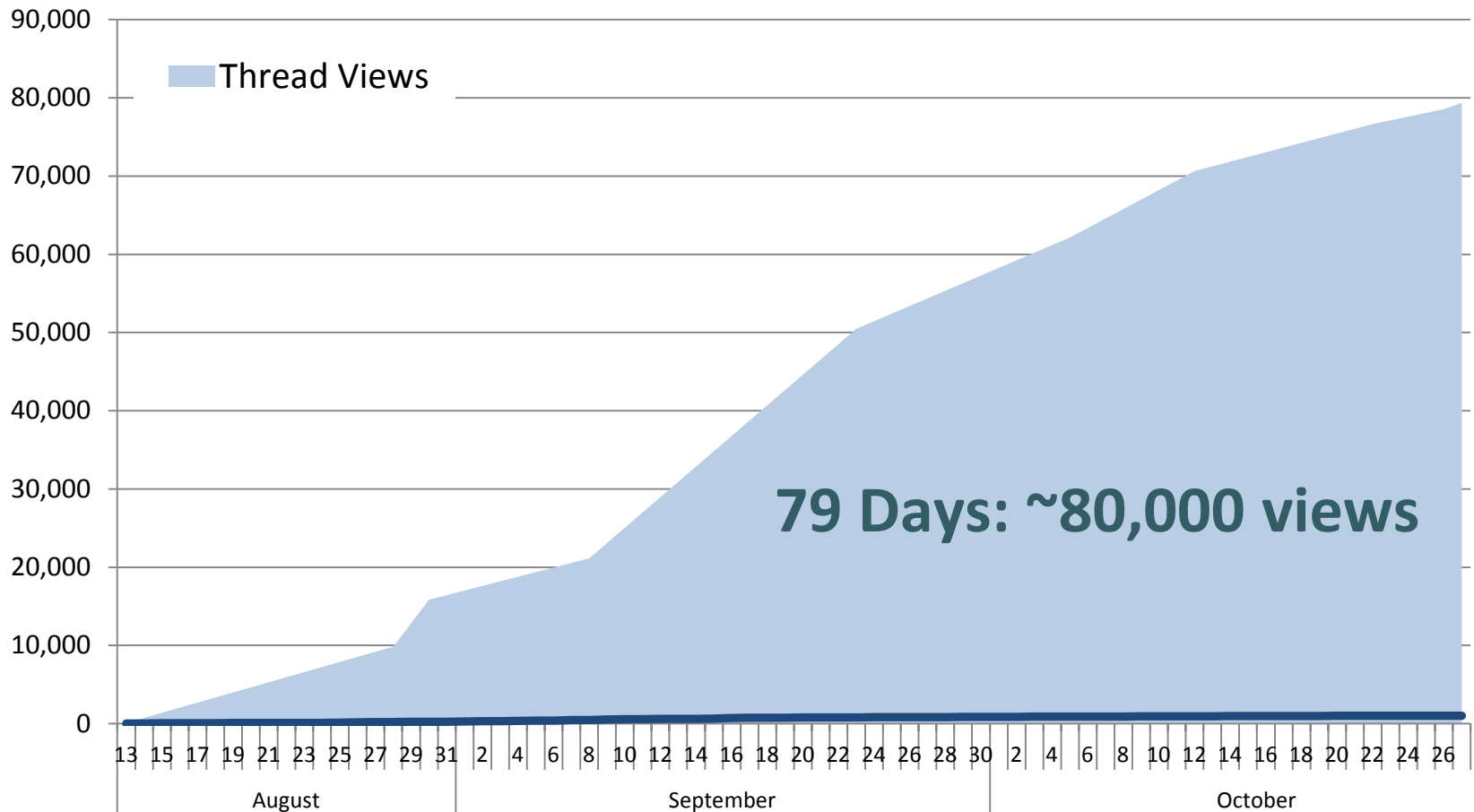
Social Network and Personal Environment **x**

Severity of Addiction =

ABUSE

- **RED** = Formulation related qualities

Drug Discussion Forum Initial Reaction to ADF



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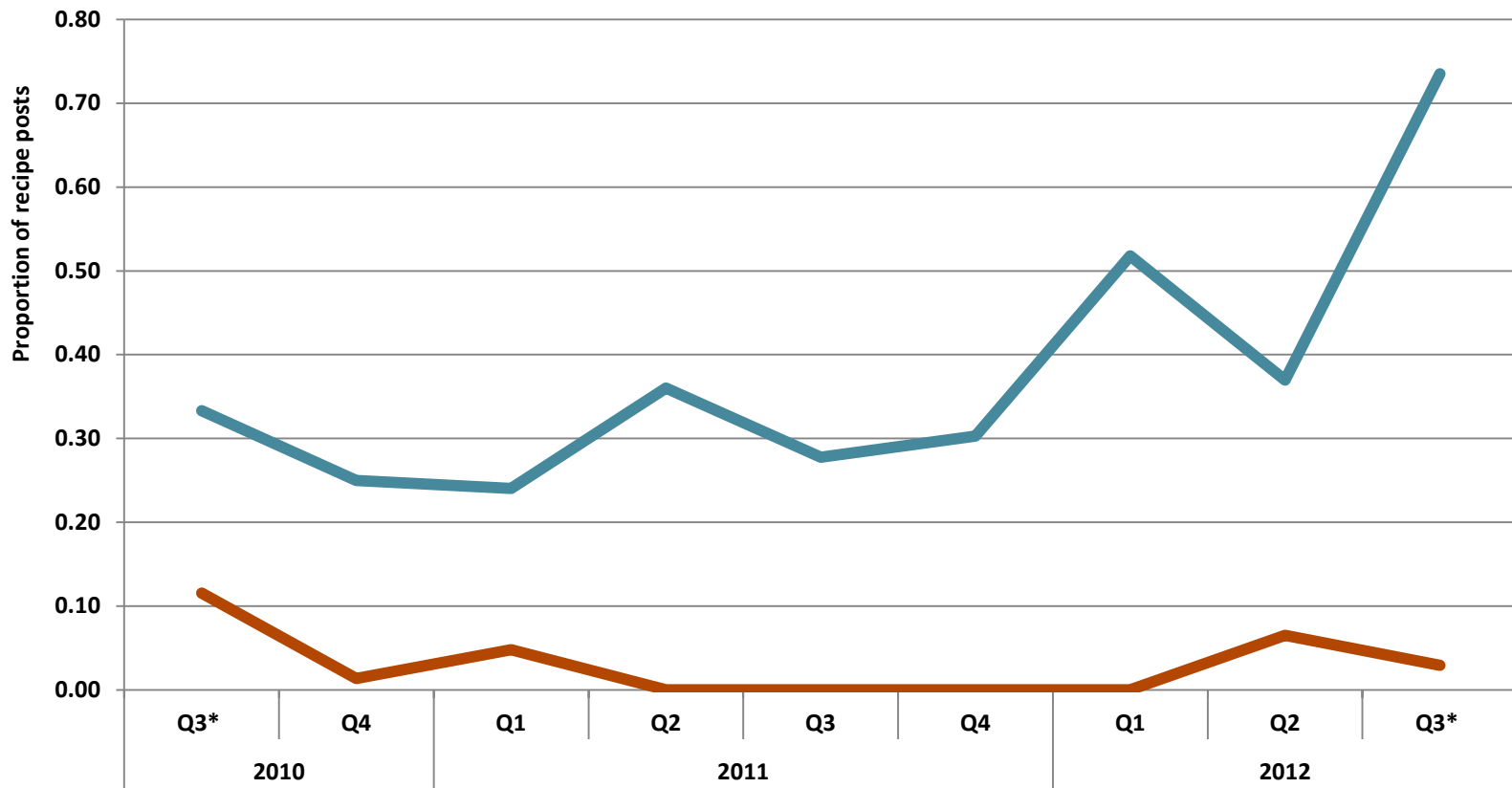
The best thing I can offer is to make sure you get the generic. The name brand has been reformulated and are these plasticky convex pill that you cannot crush. People were passing them whole; body wasn't even breaking it down. If you have had them before, the generics work like the old stop signs.



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



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



For more information contact:

Sue Grosso, Inflexxion
sgrosso@inflexxion.com