

What have we learned?

- Patients need opiates but
 - How much and for how long?
 - Control Rx
 - Therefore, attempt to limit “residence time in the home”
 - Actual removal is the goal
 - Efficacy of timely reminders delivered when Rx complete (Penn)
 - Multiple successful state initiatives which should not be ignored
 - Take Back, Mail Back, Collections—all effective and do not carry any toxicity risk
 - Kathleen Egan showed importance of actual messaging content
 - Loss of disposal boxes—funding?

In Home Drug Disposal

What does the FDA need to know—Efficacy

- Need demonstration of superiority to matched campaign of return/removal
 - Study design needs to be agreed in advance with FDA
 - Appropriate controls—matched return/removal
 - Predefined end-points, sample size and effect size—nothing unusual there
- Nobody underestimates the importance of the opiate crisis but that means adopting solutions that have been demonstrated to be safe and effective
 - Based on a clear understanding of the safety and efficacy of the systems
 - From appropriately designed and powered studies
 - Based on an understanding of the risks of the known chemicals being brought into the home
 - Based on understanding of efficacy in presence of non opiate drugs

In Home Drug Disposal

What does the FDA need to know—Safety

- By definition, chemical exposure not seen with “return/removal” options—so efficacy standard must be higher
- Safety minimum level of knowledge
 - Public List of ingredients (all ingredients)
 - Are ingredients safe for a home?
 - Unknown if ingredients are secret—remember Poison Centers comments
 - Demonstration of safety and efficacy in the presence of other drugs
 - Certainty is that opiates will not be the only drugs used in disposal system
 - Is efficacy maintained with other drugs present?
 - Does presence of other drugs affect adsorption /chemical reaction?
 - Does chemical reaction with other drugs produce potentially toxic products?
 - Based on ingredients which drugs should be studied? FDA decides in advance
 - Safety of product after addition of drug(s)—safety of the “slurry”
 - Ingestion
 - Exposure
 - Disposal in waste stream

Unsupervised High School Chemistry Class

Actual Use Studies

- Patient comprehension studies
 - Demonstrate patient understanding
 - Correct use by patients
 - Patient understanding of safe use and storage
 - Patient understanding of safe disposal of slurry
- Low health literacy
- Diverse populations
- In some groups the responsibility to use this will fall to the children

Final Panel—Synthesis

- Mark Bicket
- Jeff Horwitz
- Laura Bix
- Patrick Raulerson