

## Exploring Options for Safe and Effective In-Home Opioid Disposal

Virtual Private Workshop

June 28 & 29, 2021

### Agenda

#### Day 1 | Monday, June 28, 2021

**2:00 p. m.      Welcome and Introductions**  
Gillian Schmidler, Duke-Margolis Center for Health Policy

**2:10 p. m.      FDA Opening Remarks**  
Patrizia Cavazzoni, U.S. Food and Drug Administration

**2:25 p. m.      Session 1: The Current Landscape for In-Home Opioid Disposal**

There are several in-home opioid disposal products available that offer patients an alternative to disposal mechanisms such as drug take back programs and flushing. In this session, participants will explore the current recommendations and best practices used for safe opioid disposal, including state and voluntary efforts and how in-home opioid disposal products could complement these efforts. Participants will also discuss practical considerations for the distribution of in-home disposal products by health professionals.

#### Presentation

- **Patrick Raulerson**, U.S. Food and Drug Administration

#### Reactant Remarks

- **Carly Bartz-Overman**, Washington State Department of Health
- **Kevin Nicholson**, NACDS
- **J. Douglas Thornton**, University of Houston College of Pharmacy

#### Open Discussion

*Moderator:* Gillian Schmidler/Mark McClellan, Duke-Margolis Center for Health Policy

#### Questions to address:

1. What in-home opioid disposal products are commercially available? What are the advantages and disadvantages of these different products?
2. How well can in-home opioid disposal products reliably and quickly render drugs unusable? What is their expected public health value?
3. How are in-home opioid disposal products being prescribed and distributed? What are important considerations for product use and distribution?
4. How much training is required for providers who offer in-home opioid disposal products to patients?
5. What state and voluntary efforts exist surrounding safe opioid disposal?

**3:30 p. m.**      **Break (15 min)**

**3:45 p. m.**      **Session 2: Exploring the Use of In-Home Opioid Disposal Products**

In this session, participants will discuss the use of in-home opioid disposal products from the perspectives of patients, families, clinicians, pharmacies, and payors. Participants will consider patient preferences and how they receive information about safe opioid disposal. The session will also explore research and evidence needs for determining how patients interact with in-home opioid disposal products and their impact on long-term public health outcomes.

**Presentation**

- **Chad Brummett**, University of Michigan

**Reactant Remarks**

- **Margaret Shield**, Community Environmental Health Strategies, LLC
- **Nicole Harrington**, CVS Health
- **Eileen McDonald**, Johns Hopkins University
- **Cindy Steinberg**, U.S. Pain Foundation

**Open Discussion**

*Moderator:* Mark McClellan, Duke-Margolis Center for Health Policy

**Questions to address:**

1. How well do in-home opioid disposal products encourage patients to remove drugs out of their homes? How can this be assessed?
2. What factors affect patient reluctance to dispose of opioids?
3. Which safe opioid disposal options do consumers prefer?
4. How do human factors affect the efficacy of in-home opioid disposal products? What can we learn from human factors analysis and implementation science to assess effectiveness of these products?
5. What are the environmental concerns associated with in-home opioid disposal products compared to current disposal recommendations (i.e. FDA's flush list)?

**5:00 p. m.**      **Day 1 Adjournment**

Mark McClellan, Duke-Margolis Center for Health Policy

**Day 2 | Tuesday, June 29, 2021**

**2:00 p. m. Welcome and Summary of Day 1**

Mark McClellan, Duke-Margolis Center for Health Policy

**2:10 p. m. Session 3: Next Steps in Ensuring Safe Opioid Disposal at Home**

In this session, participants will evaluate current safe opioid disposal efforts, including distribution of in-home products, state policies, and voluntary programs. Participants will also consider the use of FDA's REMS authority for opioid disposal and how to assess the potential public health impact of a potential REMS. Participants will discuss how to support safer and more effective in-home opioid disposal, identify areas where further research is needed, and consider the potential, unintended consequences of a REMS.

**Panelist Remarks**

- **Douglas Throckmorton**, U.S. Food and Drug Administration
- **Stephanie Crawford**, University of Illinois Chicago College of Pharmacy
- **Elizabeth Skoy**, American Pharmacists Association
- **Liz Whalley Buono**, WestRock-MPS Healthcare

**Session 3, Part 1 Discussion: Exploring Policy Options**

*Moderator:* Elaine Morrato, Loyola University Chicago

**Questions to address:**

1. Which state and voluntary opioid disposal efforts have been most effective for patients?
2. What gaps exist in current state and voluntary disposal efforts? How can existing efforts better target patients that have a need for safe opioid disposal options?
3. What logistical barriers exist surrounding widespread implementation of in-home opioid disposal products for patient use?
4. How could a potential FDA mandate interact with and complement current voluntary and state efforts rather than detract from them?

**3:30 p. m. Break (15 minutes)**

**3:45 p. m. Session 3, Part 2 Discussion: Potential Implications of a REMS**

*Moderator:* Elaine Morrato, Loyola University Chicago

**Questions to address:**

1. What benefit could a REMS that requires in-home disposal products to be distributed have in encouraging safe disposal of opioids?
2. What burdens on stakeholders and the health care system could a REMS potentially create?
3. How could the public health impact of this regulatory action be assessed?

**5:00 p. m. Closing Remarks**