

**Exploring Packaging, Storage, and Disposal Solutions to Enhance Opioid Safety**

Duke-Margolis Center for Health Policy Conference Center  
1201 Pennsylvania Ave NW, Suite 500, Washington, DC 20004  
June 1, 2017

**Meeting objectives:** The objective of this expert workshop is to examine data needs and guiding design principles for developing packaging, storage, and disposal solutions for opioid products that have the potential to enhance opioid safety and deter misuse and abuse. Specifically, participants will examine:

- 1) The potential role of packaging, storage, and disposal solutions in addressing factors that enable opioid abuse and misuse and inappropriate access.
- 2) The current landscape of existing packaging, storage, and disposal solutions that may prevent or deter abuse and misuse or inappropriate access of prescription opioids.
- 3) Approaches to evaluating the impact of packaging, storage, and disposal solutions to deter misuse, abuse and inappropriate access.
- 4) Considerations for integrating the use of opioid safety-enhancing packaging, storage, or disposal solutions into healthcare and pharmacy systems.

**8:30 a.m. Registration**

**9:00 a.m. Welcome, Overview, and Meeting Objectives**  
Greg Daniel, Duke-Margolis Center for Health Policy

**9:10 a.m. Welcoming Remarks**  
Robert Califf, Duke University School of Medicine

**9:20 a.m. FDA Opening Remarks**  
Greg Daniel – *Moderator*

*Objective:* This introductory session will focus on the public health rationale for developing packaging, storage, and disposal solutions as a tool in mitigating the misuse, abuse and inappropriate access of prescription opioids, as well as inappropriate access.

**Presenter**  
Doug Throckmorton, US Food and Drug Administration

**Q & A**

**9:40 a.m. Session I: The role of packaging, storage, and disposal solutions in addressing factors for opioid abuse, misuse and inappropriate access**  
Greg Daniel – *Moderator*

*Objective:* This session will explore how safety-enhancing packaging, storage, and disposal solutions can target the factors that enable misuse, abuse of, and inappropriate access to opioids.

**Presenter**

- **Chris Jones**, U.S. Department of Health and Human Services

#### Panelists

- **Shruti Kulkarni**, Center for Lawful Access and Abuse Deterrence
- **Melinda Campopiano**, Substance Abuse and Mental Health Services Administration
- **Nathan Langley**, Gatekeeper Innovation
- **Bill Davies**, Defense Health Agency

#### Moderated Discussion

**10:50 a.m. Break**

**11:05 a.m. Session II: The current landscape of existing packaging, storage, and disposal solutions that may prevent or deter misuse, abuse, and appropriate access to prescription opioids**

Greg Daniel – *Moderator*

*Objective:* This session will examine currently available packaging, storage, and disposal solutions that may have the potential to reduce the likelihood of misuse or abuse of opioids. Such solutions may include unit-of-use blister packaging to facilitate medication adherence, solutions that limit unauthorized third-party access through locks or lockout features, solutions that render unused substances inert, solutions that employ track and trace technology, or solutions that combine multiple features to target more than one factor. The discussion will include the available data that support these currently available solutions.

#### Presenters

- **Onur Babat**, Lehigh University P.C. Rossin College of Engineering and Applied Sciences
- **Stella Kim**, U.S. Food and Drug Administration

#### Panelists

- **Matt Ervin**, MedicaSafe
- **Walter Berghahn**, Healthcare Compliance Packaging Council
- **Hayden Bosworth**, Duke University Medical Center
- **Dan Budnitz**, The Centers for Disease Control and Prevention

#### Moderated Discussion

**12:15 p.m. Lunch**

**1:15 p.m. Session III: Approaches to evaluating the impact of packaging, storage, and disposal solutions to deter misuse, abuse and inappropriate access**

Greg Daniel – *Moderator*

*Objective:* This session will examine the types of scientific data and testing that may be appropriate to support evaluation by FDA and more widespread adoption of packaging, storage and disposal solutions having features to deter misuse, abuse, and inappropriate access.

**Panelists**

- **Michael Fraser**, American Association of Poison Control Centers
- **Liz Whalley Buono**, WestRock /MeadWestVaco Healthcare
- **Laura Bix**, Michigan State University School of Packaging
- **Jon Easter**, University of North Carolina Eshelman School of Pharmacy

**Moderated Discussion**

**2:30 p.m. Break**

**2:45 p.m. Session IV: Integration of safety-enhancing opioid packaging, storage, or disposal solutions into existing healthcare and pharmacy systems**  
Greg Daniel – *Moderator*

*Objective:* This session will discuss considerations for integration of safety-enhancing packaging, storage, or disposal solutions into the existing healthcare and medication use systems, while taking into consideration lawful, therapeutic use.

**Panelists**

- **Kevin Webb**, Mallinckrodt Pharmaceuticals
- **Paul Gileno**, U.S. Pain Foundation
- **Bernadette Loftus**, Kaiser Permanente - Mid-Atlantic Permanente Medical Group
- **Kevin Nicholson**, National Association of Chain Drug Stores
- **Thomas Emmendorfer**, U.S. Department of Veterans Affairs

**Moderated Discussion**

**4:00 p.m. Closing Remarks**  
**Greg Daniel**, Duke-Margolis Center for Health Policy

**4:15 p.m. Adjournment**

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