

Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics- A Workshop

June 26, 2023, 9:00 am – 5:30 pm (ET)

June 27, 2023, 8:30 am – 1:00 pm (ET)

**National Academies Keck Center, Room 100
500 5th Street NW, Washington, DC 20001**

Join online [HERE](#).

PURPOSE

This public workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation will provide a venue for stakeholders to discuss the development and use of in-home drug disposal systems with a focus on removing unused opioid analgesics from the home.

The public workshop will feature invited presentations and discussions to:

- Explore the types of in-home drug disposal systems, other than mail back envelopes, that could be used to remove unused opioid analgesics from the home.
- Examine the current landscape of laws and regulations that apply to in-home drug disposal systems.
- Discuss scientific, behavioral, health equity, and policy considerations for assessing the safety, use, and effectiveness of in-home drug disposal systems, including the following questions:
 - What is known/unknown about the methods (e.g., sequestration, adsorption, absorption) used in in-home disposal systems for rendering opioids unavailable for nonmedical use assuming the product is used as intended?
 - What approaches/methodologies are needed to evaluate the safe and correct use of in-home drug disposal systems in real-world settings?
 - How could person-centered design inform the development and use of in-home drug disposal systems?
- Consider potential strategies for encouraging and assessing the development and use of in-home drug disposal systems that support the public health goal of mitigating the risk of nonmedical use or overdose associated with opioids.

DAY 1: MONDAY, JUNE 26, 2023

9:00 am WELCOME

ALASTAIR WOOD, *Workshop Co-chair*
Professor of Medicine Emeritus
Vanderbilt University

9:05 am FDA AUTHORITY FOR IN-HOME OPIOID DISPOSAL

MARTA SOKOLOWSKA
Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

9:15 am FIRESIDE CHAT: LIFECYCLE OF PRESCRIBED OPIOIDS

ROBERT HOFFMAN, *Speaker*
Professor, Department of Emergency Medicine
New York University Grossman School of Medicine

BETH MCGINTY, *Workshop Co-chair, Moderator*
Chief, Division of Health Policy and Economics
Professor, Department of Population Health Sciences
Weill Cornell Medicine

9:55 am SESSION I: ENVISIONING DISPOSAL SYSTEMS TO REMOVE OPIOIDS FROM THE HOME

Session Objectives:

- Describe the properties or characteristics that an ideal in-home disposal system might possess such that it minimizes barriers to patient use.
- Consider under what circumstances people will use an in-home disposal system, with a focus on conditions that impede use and how those can be overcome.
- Discuss how human-centered design can inform the goals, development, and use of in-home disposal systems.
- Discuss health equity considerations developing and implementing in-home disposal systems.

9:55–10:15 Presentation

LAURA BIX
Assistant Dean for Teaching, Learning and Academic Analytics
Michigan State University College of Agriculture & Natural Resources

10:15–11:15 Panel Discussion

RUCHI FITZGERALD, *Moderator*
Assistant Professor, Rush University
Service Chief of Inpatient Addiction Medicine, PCC Community Center

Panelists

Health Care Innovation Perspective

ANISH AGARWAL
Assistant Professor of Emergency Medicine
University of Pennsylvania Perelman School of Medicine

Behavioral Science Perspective

KATHLEEN EGAN

Assistant Professor, Health Education and Promotion
East Carolina University College of Health and Human Performance

Consumer/Patient Perspective

LINDSAY BARAN

Senior Research Director
Health Care Evaluation Department
NORC at University of Chicago

Opioid Stewardship Perspective

LYEN HUANG

Assistant Professor of Surgery
University of Utah Spencer Fox Eccles School of Medicine

11:15–11:45 *Coffee Break (30 minutes)*

11:45 am SESSION II: REGULATORY LANDSCAPE FOR HOUSEHOLD OPIOID DISPOSAL

Session Objectives:

- Examine the current landscape of laws and regulations that apply to in-home drug disposal systems.
- Explore the role of state and local policies on drug disposal and how FDA regulations may interact with those policies, including any unintended consequences.
- Consider the intersection of federal, state, and local waste disposal policies regarding the use of in-home disposal systems for opioid analgesics.

11:45–12:05 **Presentation**

HANZ ATIA

Associate, Policy and Programs
Product Stewardship Institute

12:05–1:05 **Panel Discussion**

LEWIS GROSSMAN, *Moderator*

Professor
American University College of Law

Panelists

EPA Regulatory Perspective

KRISTIN FITZGERALD

Environmental Protection Specialist
Office of Resource Conservation and Recovery
U.S. Environmental Protection Agency

State Drug Disposal Policy Perspective

MARY KELLINGTON

Safe Medication Return Program Manager
Washington State Department of Health

FDA Regulatory Perspective

PATRICK RAULERSON
Senior Regulatory Counsel
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Federal Opioid Policy Perspective

UTTAM DHILLON
Partner
Michael Best & Friedrich LLP

1:05–2:00 *Lunch Break (55 minutes)*

2:00 pm **SESSION III: SCIENTIFIC CONSIDERATIONS FOR IN-HOME OPIOID DISPOSAL**

Session Objectives:

- Identify ideal characteristics of an in-home disposal system from a mechanistic, safety, and environmental perspective.
- Explore the scientific considerations for in-home drug disposal systems that could be used to remove unused opioid analgesics from the home.
- Discuss what is known/unknown about available and developing methods (e.g., sequestration, adsorption, absorption) by which in-home disposal systems work, assuming the product is used as intended.
- Discuss scientific approaches for assessing and gathering data on the environmental impact for in-home drug disposal systems.

2:00–2:20 **Presentation**
MARGARET SHIELD
Owner and Principal
Community Environmental Health Strategies LLC

2:20–3:20 **Panel Discussion**
JESSICA YOUNG, *Moderator*
Chief, Recycling and Generator Branch
U.S. Environmental Protection Agency

Panelists

Opioid Chemistry Perspective

ANDREW COOP
Professor, Pharmaceutical Sciences
Associate Dean for Academic Affairs
University of Maryland School of Pharmacy

Toxicology Perspective

KAITLYN BROWN
Clinical Managing Director
America's Poison Centers

FDA Perspective

MARTA SOKOLOWSKA
Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Environmental Chemistry Perspective

PAUL BRADLEY

Project Lead

Drinking-Water and Wastewater Infrastructure Integrated Science Team

Ecosystems Mission, Environmental Health Program

U.S. Geological Survey

3:20-3:50

Coffee Break (30 minutes)

3:50 pm

SESSION IV: REAL-WORLD USE AND IMPLEMENTATION OF IN-HOME OPIOID DISPOSAL SYSTEMS

Session Objectives:

- Consider what approaches/methodologies are needed to evaluate the safe and correct use of in-home drug disposal systems in real-world settings.
- Explore approaches for engaging consumers on how to use in-home disposal systems safely and as intended.
- Consider best practices to promote safe and effective use of in-home disposal systems, including the roles of clinicians, prescribers, and pharmacists.
- Discuss use studies to lay out tangible examples of unintended consequences.

3:50-4:10

Presentation

CHAD BRUMMETT

Bert N LaDu Professor of Anesthesiology

Co-Director, Opioid Research Institute

Co-Director, Opioid Prescribing Engagement Network

University of Michigan

4:10-5:20

Panel Discussion

MARK BICKET, *Moderator*

Assistant Professor, Department of Anesthesiology

Director, Pain & Opioid Research, Institute for Healthcare Policy and Innovation

University of Michigan Medical School

Panelists

Implementation Perspective

ANDREA TSATOKE

Injury Prevention Specialist

Indian Health Service, Headquarters

Program Evaluation Perspective

ELEANOR LEWIS

Deputy Director, Program Evaluation & Resource Center

U.S. Department of Veterans Affairs

REMS Design & Implementation Perspective

JAMES SHAMP

Vice President for Data Intelligence & Program Analytics

United BioSource LLC

Retail Pharmacy Perspective

KEVIN NICHOLSON

Vice President, Public Policy, Regulatory, and Legal Affairs
National Association of Chain Drug Stores

Behavioral Science and Communication Perspective

TAMAR KRISHNAMURTI

Assistant Professor, Medicine and Clinical and Translational Science
Department of Medicine Center for Research on Health Care
University of Pittsburgh

5:20 pm DAY 1 SUMMARY REMARKS

ALASTAIR WOOD, *Workshop Co-chair*

END OF DAY 1

DAY 2: TUESDAY, JUNE 27, 2023

8:30 am DAY 2 OPENING REMARKS

BETH MCGINTY, *Workshop Co-chair*

8:50 am RISK EVALUATION AND MITIGATION STRATEGIES: AN OVERVIEW

LYNN MEHLER

Practice Area Lead, Pharmaceuticals & Biotechnology
Hogan Lovells LLP

9:15 am SESSION V: THE ROLE OF IN-HOME OPIOID DISPOSAL

Session Objectives:

- Consider the role of an ideal in-home disposal system in addressing the public health goal of mitigating the risk of nonmedical use or overdose associated with opioids.
- Discuss how previous workshop discussions may inform the design, implementation, and evaluation of in-home disposal systems.
- Consider data needs and practical approaches for assessing the use and effectiveness of disposal systems in real-world settings.

9:15-9:35

Presentation

KATHLEEN EGAN

Assistant Professor, Health Education and Promotion
East Carolina University College of Health and Human Performance

9:35-10:45

Panel Discussion

ROBERT MORONES, *Moderator*

Injury Prevention Coordinator
Indian Health Service (Phoenix Area)
U.S. Department of Health & Human Services

Panelists

Pediatric Injury Prevention Perspective

CHRISTOPHER GAW

Pediatric Emergency Medicine Fellow

Associate Fellow, Center for Injury Research and Prevention

Children's Hospital of Philadelphia

Overdose Prevention Perspective

JEFF HORWITZ

Chief Executive Officer

SAFE Project

Harm Reduction Perspective

SUSAN SHERMAN

Bloomberg Professor of American Health

Department of Health, Behavior and Society

Johns Hopkins Bloomberg School of Public Health

National Institute on Drug Abuse Perspective

WILSON COMPTON

Deputy Director, National Institute on Drug Abuse

National Institutes of Health

10:45-11:15 *Coffee Break (30 minutes)*

11:15 am **SYNTHESIS DISCUSSION**

Purpose:

- Integrate information gathered throughout the workshop in a discussion on the properties and characteristics of an ideal in-home disposal system, factors impacting implementation, and regulatory considerations for household opioid disposal.

11:15-12:15 **Moderated Panel Discussion**

ALASTAIR WOOD, *Workshop Co-chair, Moderator*

Panelists

Pharmaceutical Sciences Perspective

ANDREW COOP

Professor, Pharmaceutical Sciences

Associate Dean for Academic Affairs

University of Maryland School of Pharmacy

Implementation Perspective

MARK BICKET

Assistant Professor, Department of Anesthesiology

Director, Pain & Opioid Research, Institute for Healthcare Policy and Innovation

University of Michigan Medical School

Overdose Prevention Perspective

JEFF HORWITZ
Chief Executive Officer
SAFE Project

Human-Centered Design Perspective

LAURA BIX
Assistant Dean for Teaching, Learning and Academic Analytics
Michigan State University College of Agriculture & Natural Resources

Food and Drug Administration Perspective

PATRICK RAULERSON
Senior Regulatory Counsel
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

12:15-12:45 **Panel Discussion with Audience Engagement**

12:45 pm **CLOSING REMARKS**

BETH MCGINTY, *Workshop Co-chair*

MEETING ADJOURNS