

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)***
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 17-18, 2018

AGENDA

The committees will provide input and advice on strategies to increase the availability of naloxone products intended for use in the community. The committees will be asked to consider various options for increasing access to naloxone, weighing logistical, economic, and harm reduction aspects and whether naloxone should be co-prescribed with all or some opioid prescriptions to reduce the risk of overdose death. Because of the potential, significant costs and burdens that may be associated with naloxone co-prescribing (e.g., economic costs to consumers and health systems, adjusting to manufacturing volume growth, drug shortages), the committees will also be asked to consider the potential burdens that may be associated with naloxone co-prescribing for all or some prescription opioid patients.

Day 1: Monday December 17, 2018

8:00 a.m.	Call to Order and Introduction of Committee	Raeford E. Brown, Jr., MD, FAAP Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Acting Designated Federal Officer, AADPAC
8:10 a.m.	FDA Opening Remarks: Overview of the Issues in Question	Sharon Hertz, MD Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	INDUSTRY PRESENTATIONS	
	Naloxone Co-prescribing	Robert G. Kramer President & Chief Operating Officer Adapt Pharma/Emergent Biosolutions
	Co-prescribing of Naloxone	Dean Mariano, DO Senior Director, Clinical Development/Medical Affairs Insys Therapeutics, Inc.
	Role of Naloxone in the Opioid Overdose Public Health Crisis	Charles E. Argoff, MD Professor of Neurology Albany Medical College
	Role of Naloxone in the Opioid Overdose Public Health Crisis	Omar Khalil General Manager, Neurology & Addiction kaléo, Inc.

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AGENDA (cont.)

9:20 a.m. Clarifying Questions

9:35 a.m. **FDA PRESENTATIONS**

Clinical and Regulatory Overview of
Naloxone Products Intended for Use
in the Community

Timothy Jiang, MD, PhD
Medical Officer
DAAAP, ODE-II, OND, CDER, FDA

Drug Utilization of Naloxone

Shekhar Mehta, PharmD, MS
Drug Utilization Analyst, Division of Epidemiology II
Office of Pharmacovigilance and Epidemiology
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

Estimates of the Annual Health System
Costs of Naloxone Co-Prescribing

Matthew Rosenberg, MSPPM
Operations Research Analyst, Economics Staff
Office of Program and Strategic Analysis
Office of Strategic Programs, CDER, FDA

10:35 a.m. Clarifying Questions

10:50 a.m. **BREAK**

11:05 a.m. **SPEAKER PRESENTATION**

Candidates for Naloxone:
What the Data Tell Us

Christopher M. Jones, PharmD, MPH
CAPT, US Public Health Service
Senior Advisor and Director of Strategy and Innovation
National Center for Injury Prevention and Control
U.S. Centers for Disease Control and Prevention (CDC)

11:25 a.m. **GUEST SPEAKER PRESENTATIONS**

Naloxone Dispensing via Retail
Pharmacies

Alexander Y. Walley, MD, MSc
Associate Professor of Medicine
Boston University School of Medicine
Director, Addiction Medicine Fellowship
Boston Medical Center
Medical Director
Opioid Overdose Prevention Pilot Program
Massachusetts Department of Public Health

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AGENDA (cont.)

11:45 a.m. **GUEST SPEAKER PRESENTATIONS
(CONT.)**

Naloxone Co-prescribing

Phillip O. Coffin, MD, MIA, FACP, FIDSA
Director of Substance Use Research
San Francisco Department of Public Health
Assistant Professor
University of California San Francisco

12:05 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. **SPEAKER PRESENTATION**

Opioid Overdose Education and
Naloxone Distribution (OEND)
Within the Veterans Health
Administration

Elizabeth M. Oliva, PhD
VA National OEND Coordinator
VA Program Evaluation and Resource Center
VA Office of Mental Health and Suicide Prevention
U.S. Department of Veterans Affairs (VA)

1:50 p.m. **GUEST SPEAKER PRESENTATIONS**

Take-Home Naloxone Use in
New Mexico

Joanna Girard Katzman, MD, MSPH
Senior Associate Director, ECHO (Extension for
Community Healthcare Outcomes) Institute,
Project ECHO
Professor, Neurology University of New Mexico
School of Medicine, UNM Health Sciences Center

Development, Manufacturing, and
Commercialization Costs for
Naloxone and Other Nasal Sprays

Daniel Wermeling, PharmD, FCCP, FASHP
Emeritus Professor
University of Kentucky College of Pharmacy

2:30 p.m. Clarifying Questions

3:00 p.m. **BREAK**

3:15 p.m. **SPEAKER PRESENTATION**

Legal Regimes: Naloxone Access

Joy E. Gamber, PharmD, BCPP
Clinical Pharmacy Specialist, Mental Health
Veterans Affairs North Texas Health Care System

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AGENDA (cont.)

3:35 p.m. **GUEST SPEAKER PRESENTATIONS**

Narcan Distribution Collaborative:
Expanding Access in Hamilton
County, Ohio and the Impacts

Tim Ingram, MS
Health Commissioner
Hamilton County Public Health

Community Naloxone Programs

Peter Davidson, PhD
Associate Professor
Department of Medicine
University of California at San Diego

4:15 p.m. Clarifying Questions

4:30 p.m. **FDA PRESENTATION**

Nonprescription Model Drug Facts
Label Project

Barbara R. Cohen, MPA
Social Science Analyst
Division of Nonprescription Drug Products
Office of Drug Evaluation IV, OND, CDER/FDA

4:50 p.m. Clarifying Questions

5:00 p.m. **ADJOURNMENT**

Day 2: Tuesday, December 18, 2018

8:00 a.m. Call to Order and Introduction of
Committee

Raeford E. Brown, Jr., MD, FAAP
Chairperson, AADPAC

8:05 a.m. Conflict of Interest Statement

Jennifer Shepherd, RPh
Acting Designated Federal Officer, AADPAC

8:10 a.m. FDA Opening Remarks:
Overview of the Issues in Question

Sharon Hertz, MD
Director, DAAAP
ODE-II, OND, CDER, FDA

8:30 a.m. **OPEN PUBLIC HEARING**

11:00 a.m. **BREAK**

11:15 a.m. Charge to the Committee

Sharon Hertz, MD

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AGENDA (cont.)

11:20 a.m. Questions to the Committee/
Committee Discussion

12:00 p.m. **LUNCH**

1:00 p.m. Questions to the Committee/
Committee Discussion

2:30 p.m. **BREAK**

2:45 p.m. Questions to the Committee/
Committee Discussion

4:00 p.m. **ADJOURNMENT**