

Training for Opioid Analgesic Prescribers –Exploring the Path Forward –An FDA Workshop

Meeting Purpose:

The Food and Drug Administration (FDA) is announcing a public workshop to obtain input on issues and challenges associated with Federal efforts to train prescribers on pain management and the safe use of opioids. The public workshop seeks to obtain additional insight from a variety of stakeholders on how best to ensure that prescribers and other health care providers directly involved in the management or support of patients with pain receive training in pain management and the safe use of opioids. Current training efforts by states, hospitals and health care systems, Federal agencies, professional associations and others will be considered in order to strategize how best to accomplish training for all prescribers and other health care providers.

Agenda

May 9, 2017

- 8:30 am Opening Remarks - Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)
- 8:45 am Ongoing Efforts to Address the Opioid Epidemic – Douglas C. Throckmorton, MD, Deputy Director for Regulatory Programs, CDER, FDA
- 9:00 am FDA ER/LA Opioid Analgesic REMS– Claudia Manzo, PharmD, Director, Office of Medication Error Prevention and Risk Management (OMEPRM), CDER, FDA
- 9:15 am Opioid Prescribing Education and Prescription Drug Monitoring: A State by State Overview - Lisa A Robin, Chief Advocacy Officer, Federation of State Medical Boards (FSMB)
- 9:30 am Overview of State Efforts to Promote Prevention and Education: National Governors Association (NGA) Experience – Melinda Becker, Senior Policy Analyst, Health Division, National Governors Association Center for Best Practices
- 9:45 am New Mexico - A State Experience: Implementation, Maintenance, and Evaluation - Joanna G. Katzman, MD, MSPH, Associate Professor, University of New Mexico, Director, UNM Pain and Project Extension for Community Healthcare Outcomes (ECHO) Pain & Opioid Management
- 10:00 am Questions and Answers
- 10:10 am Break

- 10:20 am Provider Education and Outcomes - Fred Brason II, President and CEO, Project Lazarus
- 10:35 am Federal Healthcare System Experience: VA Implementation, Maintenance, and Evaluation – Chester “Bernie” Good, MD, Chair, Medical Advisory Panel for Pharmacy Benefits Management, Department of Veterans Affairs, Professor of Medicine and Pharmacy, University of Pittsburgh
- 10:50 am Private Healthcare System: Kaiser Permanente – Carol Havens, MD, Director of Physical Education and Development, Kaiser Permanente Northern California and Clinical Lead, TPMG Opioid Initiative
- 11:05 am Questions and Answers

Federal Mechanisms for Required Training

- 11:15 am Prescriber Education: FDA REMS Options and Considerations– Doris Auth, PharmD, Associate Director (Acting), OMEPRM, CDER, FDA
- 11:30 am DEA Perspective- James (Jim) Arnold, Chief, Liaison and Policy, Diversion Control Division, Drug Enforcement Agency (DEA)
- 11:45 am Questions and Answers
- 12:00pm Lunch
- 1:00pm Open Public Hearing
- Norman Kahn, MD
 - Thomas Sullivan
 - Cynthia Kear
 - Eunan Maguire
 - Katherine Cates-Wessel
 - Richard Lawhern
 - Laura Wooster
 - Clif Knight
 - Ilana Hardesty
 - Steven Passik
 - Ashley Walton
 - Linda Cheek
 - Kara Gainer
- 1:45 pm Professional Associations – Terry Toigo, MBA, RPh, Associate Director for Drug Safety Operations, CDER, FDA

- American Medical Association – Patrice A. Harris MD, MA, Chair, American Medical Association Board of Trustees,
- American Academy of Physician Assistants – Marie Michele Leger, MPH, PA-C, Director, Clinical Education
- American Association of Nurse Practitioners – Anne Norman, DNP, APRN, FNP-C, FAANP, Vice President of Education
- American Academy of Integrative Pain Management – Robert (Bob) Twillman, PhD, FAPM, Executive Director
- American Society of Addiction Medicine – R. Corey Waller, MD, MS, DFASAM
- American Pharmacists Association – Anne Burns, RPh, Vice President, Professional Affairs
- American Dental Association – Paul Moore, DMD, MPH, Ph.D., Professor, Dental Anesthesiology and Dental Public Health, University of Pittsburgh
- American Osteopathic Association – Katherine Galluzzi, DO, Professor and Chair, Department of Geriatrics, Philadelphia College of Osteopathic Medicine
- American Pain Society – Gregory Terman, MD, PhD, Professor, Department of Anesthesiology and Pain Medicine, University of Washington

3:00 pm Questions and Answers

3:15 pm Break

3:30 pm State Panel Discussion – Peter Lurie, MD MPH, Associate Commissioner for Public Health, Strategy and Analysis, Office of the Commissioner, FDA

- Virginia Department of Health Professions – David E. Brown, DC, Director
- Federation of State Medical Boards - Lisa A. Robin
- National Governors Association - Melinda Becker
- Project Lazarus - Fred Brason, II
- University of New Mexico - Joanna Katzman, MD

4:45 pm Questions and Answers

5:00pm Closing Remarks – Douglas C. Throckmorton, MD

May 10, 2017

8:20 am Opening Remarks – Douglas C. Throckmorton, MD

8:30 am Open Public Hearing

- Dean Beals
- Pat daCosta
- Lynda Martin
- Thomas Berger
- Larry Twersky
- Andrew Rosenberg
- James Anderson
- Joseph Brence
- Shruti Kulkarni
- Christopher Hulin

9:00 am Health System Panel – Wilson Compton, MD, MPE, Deputy Director, National Institute on Drug Abuse

- Permanente Medical Group, Northern California – Carol Havens, MD
- Moffitt H. Lee Moffitt Cancer Center and Research Institute -David Craig, PharmD
- Veterans Administration - C. Bernie Good, MD, MPH
- Department of Defense - Chester “Trip” Buckenmaier, III, MD, Colonel, US Army (Retired), Program Director and Principal Investigator for Uniformed Services University, Defense and Veterans Center for Integrative Pain Management
- Duke University - Lawrence Greenblatt, MD, Professor of Medicine and Professor of Community and Family Medicine
- Indian Health Service - Beverly Cotton, DNP, CPNP-PC, Director, Division of Behavioral Health, Indian Health Service Headquarters

10:15 am Questions and Answers

10:30 am Break

10:45 am Patient and Consumer Advocates– Sara Eggers, PhD, Office of Program and Strategic Analysis, Office of Strategic Programs, CDER, FDA

- Myra Christopher, LHN (hon), Kathleen M. Foley Chair for Pain and Palliative Care, Director of the Pain Action Alliance to Implement a National Strategy (PAINS)
- Maria Lowe, PharmD, BPCS, Health Data and Drug Information Clinical Specialist, PatientsLikeMe
- Penney Cowan, Founder, CEO, American Chronic Pain Association
- Jan Favero Chambers, President, National Fibromyalgia & Chronic Pain Foundation
- Teresa Carr, Senior Editor, Best Buy Drugs, Consumer Reports
- Greg Williams, MA, Executive Vice President, Facing Addiction

12:00 pm Questions and Answers

12:15pm Lunch

Federal Panel –Christopher Jones, PharmD, MPH, Acting Associate Deputy Assistant Secretary, Science and Data Policy, Office of the Assistant Secretary for Planning, HHS

1:15 pm Spotlight on SAMHSA Resources – Mitra Ahadpour, MD, DABAM, Director, Division of Pharmacology Therapies, Substance Abuse and Mental Health Administration

1:20 pm Continuing Education Resources from the CDC – Deborah Dowell, MD, MPH, CDR, US Public Health Service, Senior Medical Advisor, Division of Unintentional Injury Prevention, CDC

1:25 pm Key NIH/NIDA Activity - Wilson M. Compton, MD, MPE, Deputy Director, NIDA

1:30 pm Opioid Monitoring System Impact - Jeffrey Kelman, MMSc, Chief Medical Officer, Center for Medicare, CMS

1:35 pm Panel Discussion

- Mitra Ahadpour, MD – SAMHSA
- James Arnold – DEA
- Doris Auth, PharmD - FDA
- Wilson Compton, MD – NIDA
- Deborah Dowell, MD – CDC
- Jeffrey Kelman, MD - CMS

2:35 pm Questions and Answers

2:45 pm Break

3:00 pm Large Panel Discussion–Meeting Summary and Actionable Next Steps – Douglas C. Throckmorton, MD and Trip Buckenmaier III, MD

4:30 pm Closing Remarks – Douglas C. Throckmorton, MD