

**FDA's Standards for Future Opioid Analgesic Approvals
and Incentives for New Therapeutics To Treat Pain and Addiction;
Public Hearing**

September 17, 2019

FDA White Oak Campus

10903 New Hampshire Ave, Building 31, Room 1503, Sections B and C
Silver Spring, Maryland 20993

AGENDA

Each presentation is allotted ten minutes. Three minutes [noted in brackets] are allotted following each presentation to offer an opportunity for the panel to ask clarifying questions.

9:00 – 9:15 am Opening Remarks

Dr. Douglas C. Throckmorton Food and Drug Administration
Presiding Officer
Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research

9:15 – 9:25 am [9:25 – 9:28 am]

Prof. Richard J. Bonnie
Prof. Margaret Riley University of Virginia
“Comments on Behalf of Authors of NASEM Consensus Report on Pain Management and the Opioid Epidemic (2017)”

9:28 – 9:38 am [9:38 – 9:41 am]

Dr. Michael Carome Public Citizen
“FDA’s Response to the National Academies 2017 Recommendations for a New Opioid Regulatory Framework: Woefully Inadequate in Substance, Devoid of Necessary Urgency”

9:41 – 9:51 am [9:51 – 9:54 am]

Ms. Kristin McGarity, DMA National Council on Independent Living
“FDA Opioid Drug Labels: A Disability Rights Perspective”

9:54 – 10:04 am [10:04 – 10:07 am]

Mr. Anthony LaGreca Fed-Up
“Fed-Up’s Opinion on Opioid Analgesic Drugs”

10:07 – 10:17 am [10:17 – 10:20 am]

Dr. Janetta L. Iwanicki Denver Health and Hospital Authority
“Benefit-Risk Assessment of Opioids: Oxycodone as a Case Study”

10:20 – 10:40 am BREAK

10:40 – 10:50 am [10:50 – 10:53 am]

Dr. Richard C. Dart Denver Health and Hospital Authority
“Role of Postmarketing Surveillance in Opioid Approvals”

10:53 – 11:03 am [11:03 – 11:06 am]

Ms. Tasha Olson Member of the Pain Community
“Opioid and Alternative Pain Management Effectiveness and Obstacles”

11:06 – 11:16 am [11:16 – 11:19 am]

Dr. Andrew Kolodny Brandeis University
“Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction”

11:19 – 11:29 am [11:29 – 11:32 am]

Dr. Diana Zuckerman
National Center for Health Research
“What Research Tells Us that Can Improve FDA Approval Standards and REMS for Opioids”

11:32 – 11:42 am [11:42 – 11:45 am]

Dr. Danielle Friend
Biotechnology Innovation Organization
“Incentives for New Therapeutics to Treat Pain and Addiction: An Industry Perspective”

11:45 am – 1:00 pm LUNCH

1:00 – 1:10 pm [1:10 – 1:13 pm]

Mr. Matthew Iorio, RAC, MS RAHP
Eighty Eight Pharma, Inc.
“Barriers to Innovation”

1:13 – 1:23 pm [1:23 – 1:26 pm]

Dr. James N. Campbell
Centrexion Therapeutics
“FDA Supporting Innovation in Pain Therapeutics: An Industry Perspective”

1:26 – 1:36 pm [1:36 – 1:39 pm]

Mr. Edwin Thompson
PMRS, Inc.
Untitled

1:39 – 1:49 pm [1:49 – 1:52 pm]

Dr. Judy Ashworth
Pinney Associates, Inc.
“Assessing the Value of Novel Opioid Analgesics”

1:52 – 2:02 pm [2:02 – 2:05 pm]

Dr. Chris Storgard
Heron Therapeutics
“Opioid-Sparing Indication, a Pre-Approval Incentive for New Therapeutics to Treat Acute Pain”

2:05 – 2:15 pm [2:15 – 2:18 pm]

Dr. David J. Hewitt
Karuna Therapeutics
“Considerations for Accelerating the Development of Non-Opioid Analgesics”

2:18 – 2:28 pm [2:28 – 2:31 pm]

Dr. Beatrice Setnik
Altasciences
“Abuse Deterrence and Other Novel Approaches to Address the Prescription Opioid Epidemic”

2:31 – 2:45 pm BREAK

2:45 – 3:45 pm OPEN PUBLIC HEARING

3:45 – 4:00 pm Concluding Remarks

Dr. Douglas C. Throckmorton
Food and Drug Administration
Presiding Officer
Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research