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

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)”

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: Oxymorphone 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”

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

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