

1 FOOD AND DRUG ADMINISTRATION
2 CENTER FOR DRUG EVALUATION AND RESEARCH
3 OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
4 NATIONAL INSTITUTES OF DRUG ABUSE
5 CENTERS FOR DISEASE CONTROL AND PREVENTION

6
7 Role of Naloxone in Opioid Overdose
8 Fatality Prevention
9

10
11 Thursday, April 12, 2012

12 8:30 a.m. to 5:30 p.m.
13

14
15
16 FDA White Oak Campus
17 White Oak Conference Center
18 Building 31, The Great Room
19 Silver Spring, Maryland
20
21
22

A Matter of Record
(301) 890-4188

1	C O N T E N T S	
2	AGENDA ITEM	PAGE
3	Welcome and Opening Remarks	
4	Peter Lurie, M.D., M.P.H.	5
5	Panel 1 - Naloxone Safety and Effectiveness in	
6	Treating Opioid Overdose	
7	Moderator	
8	Bob Rappaport, M.D.	15
9	Populations at Risk	
10	Len Paulozzi, M.D., M.P.H.	17
11	Public Health Interventions	
12	Nicholas Reuter	33
13	Naloxone: Effects and Side Effects	
14	Gregory Terman, M.D., Ph.D.	54
15	Questions and Answers	68
16	Panel 2 - Opioid Overdose Interaction with	
17	Naloxone in Extra-Medical Settings: Review and	
18	Examples of Current Practices	
19	Moderator	
20	Wilson Compton, M.D., M.P.E.	77
21		
22		

A Matter of Record
(301) 890-4188

1	C O N T E N T S (continued)	
2	AGENDA ITEM	PAGE
3	Overview, Criminal Justice and	
4	Other Special Settings	
5	Ingrid Binswanger, M.D., M.P.H.	82
6	Bystander Overdose Education and	
7	Naloxone Distribution in Massachusetts	
8	Alex Walley, M.D.	101
9	Project Renaissance: Overdose Prevention among	
10	IDUs in Kazakhstan	
11	Nabila El-Bassel, M.D.	120
12	Questions and Answers	137
13	Panel 3 - Product Development Issues	
14	Related to Naloxone	
15	Moderator	
16	Douglas Throckmorton, M.D.	158
17	Naloxone for Outpatient Use: Data Required to	
18	Support an NDA	
19	Sharon Hertz, M.D.	164
20	Expanded Access: OTC Status	
21	Andrea Leonard-Segal, M.D.	174
22		

A Matter of Record
(301) 890-4188

1	C O N T E N T S (continued)	
2	AGENDA ITEM	PAGE
3	Development and Marketing of	
4	Needleless Naloxone	
5	Dan Wermeling, Pharm.D.	191
6	Ethical and Regulatory Considerations for	
7	IN Naloxone	
8	Robert Nelson, M.D.	214
9	Questions and Answers	231
10	Open Public Hearing	252
11	Panel 4 - Social and Legal Aspects of	
12	Wider Naloxone Availability	
13	Moderator	
14	Peter Lurie, M.D., M.P.H.	307
15	Lessons Learned from Implementation of	
16	HPV Vaccine	
17	Gregory Zimet, Ph.D.	309
18	Panel Discussion	322
19	Questions and Answers	355
20	Closing Remarks	395
21		
22		

A Matter of Record
(301) 890-4188

P R O C E E D I N G S

(8:37 a.m.)

Welcome and Opening Remarks

DR. LURIE: Good morning, everybody. My name is Peter Lurie. I'm a senior advisor here in the Office of Policy and Planning here at FDA, the Office of the Commissioner. And I'm pleased to welcome you this morning to our meeting on the Role of Naloxone in Opioid Overdose Fatality Prevention.

We put on a lot of meetings here at FDA. I think this one is cut from a different cloth. And I think for all of us, it is a very exciting opportunity for us to engage in conversation with you about this interesting and important topic.

This meeting is put on collectively by the FDA, by the National Institute of Drug Abuse, by the Centers for Disease Control and Prevention, and by the Office of the Assistant Secretary for Health in the Department of Health and Human Services.

The problem before us, as everybody in this audience knows, is an enormous one. We have enormous increase in the use of opioid analgesics,

A Matter of Record
(301) 890-4188

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.