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2 FOOD AND DRUG ADMINISTRATION
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7 EXPLORING NALOXONE UPTAKE AND USE
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9 Public Meeting
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11
12 Wednesday, July 1st, 2015
13 8:03 a.m. to 4:59 p.m.
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18
19 White Oak Campus
20 10903 New Hampshire Avenue
21 Silver Spring, Maryland
22

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P R O C E E D I N G S
 (8:03 a.m.)

DR. LURIE: All right. Could everybody take a seat, please? Good morning, everybody. I'm Peter Lurie. I'm an associate commissioner for public health strategy and analysis. And part of my job is to keep everybody on time during a very tightly-structured meeting. I can assure you, we'll be done by 3:00 tomorrow because my wife and children will be outside Building One, picking me up to go camping. So, we're going to keep to a tight schedule here. So, good morning, and welcome to FDA. As I look out over here, I see a large number of familiar faces, including many who attended our first meeting on sure th on these very premises -- I think in this room -- in April 2012. As Dinah Washington might have said, "What a difference three years makes."

Just a couple of weeks ago, CDC published in its MMWR -- and some of the authors are here today -- a report on the growth of naloxone distribution programs between 2010 and 2014. And the growth really is remarkable -- a 243 percent increase in the number of

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local sites providing naloxone, a 183 percent increase in the number of laypersons providing naloxone kits, and most importantly, a 160 percent increase in the number of overdose reversals reported. Those reversals now total over 26,000, going back to the beginning of these programs. And 8,000 of those are reported to have taken place in 2013 alone. These accomplishments are the results of the hard work and dedication of people in this very room, people who pioneered these programs, who were willing to advocate for them, to actually carry them out when they were more controversial than they are today, and when their future was less clear.

You can see some of the differences between the 2012 meeting and today. And the differences, I think, are instructive. Like last time, this meeting is sponsored by a number of HHS agencies -- FDA, National Institute on Drug Abuse, CDC, Substance Abuse and Mental Health Services Administration, and -- new to the table this time -- the Health Resources and Services Administration, HRSA. And we also have a representative from CMS in the room, who've been

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involved in planning our meeting. All of those agencies were involved, also, in drafting the HHS secretary's opioid initiative, which has only three elements. And one of those is naloxone, a sign of how accepted this intervention has become. And of course, in a moment, ONDCP Director Botticelli will be making some introductory remarks, a further sign of the commitment of the administration on this issue. And I'd also like to welcome Dr. Stephen Ostroff, who's sitting next to Dr. Botticelli, who's acting commissioner and has been a big supporter of this meeting.

When we last met over here at -- FDA was describing the regulatory path to approval for new products. And indeed, in April 2014, the auto-injector EVZIO was approved and now can be used by family members or caregivers to treat a person known or suspected to be suffering from an overdose. But at this meeting, you'll hear about intranasal products currently under development, a further sign of progress. We will revisit some of the same topics that we looked at last time. But today's agenda is much

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1 more comprehensive. We have panels on naloxone use in
 2 clinical and nonclinical settings, questions of access,
 3 state law, over-the-counter status, training, and
 4 evaluation. We'll have discussions on ways to include
 5 police and fire departments, to expand naloxone
 6 availability on ambulances, and to address issues of
 7 cost, logistics, and supply. And finally, we have a
 8 broader audience even than last time -- and, I think,
 9 by the time everybody makes it through FDA's vaunted
 10 security system, a larger audience.
 11 [laughter]
 12 That audience is reflected in the makeup of
 13 the speakers in our open public hearing and sessions,
 14 which many of you have signed up, and in the audience
 15 more generally -- members of community-based
 16 organizations that first pioneered the administration
 17 of naloxone, medical professionals, policymakers,
 18 public health officials, first responders, product
 19 developers, researchers, and of course, patients and
 20 their families. All of us are united in a common goal
 21 -- to reduce the massive toll opioid overdoses are
 22 exacting on our country. In sum, the meeting builds on

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1 There will be kiosks set up outside the
 2 meeting room where refreshments will be sold during the
 3 breaks and at lunch. And while you're at it, after our
 4 first break, you should preorder your lunch to be more
 5 efficient when it comes to lunchtime. And lunch will
 6 include offerings such as salads, sandwiches, and other
 7 refreshments. Remember that only those who have FDA
 8 badges will be able to venture past our vaunted
 9 security folks, so stay within the general confines of
 10 this meeting area. You should know that the meeting is
 11 currently being webcast live and will be archived and
 12 available to view after the meeting. And a transcript
 13 of the meeting will be made available within 45 days of
 14 this meeting. The slides will be -- that are being
 15 presented today will be made available unless the
 16 speakers prefer not. But you should be able to get
 17 those on the web after the meeting. And we'll post a
 18 meeting summary as well. Should you have any comments
 19 on this meeting, you can submit written or electronic
 20 comments at www.regulations.gov.
 21 Please turn off your cellphones because that
 22 can interfere with our transcriber, who's recording the

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1 the good work already done by those in this room to
 2 examine what I think we might call second-generation
 3 questions -- growth and sustainability of the programs.
 4 Their usefulness is no longer in question. But how we
 5 grow and sustain them is the subject of this meeting.
 6 What a difference three years makes.
 7 Let me just finish with a couple of, more than
 8 a couple of logistic issues, just to make sure
 9 everybody's on the same page. As I hinted already,
 10 there is going to be a Q&A session after each and every
 11 panel, in which people can go to the mics and ask any
 12 questions they might have of the speakers. We also
 13 have two one-hour open public sessions, one today and
 14 one tomorrow, at which one can make any comment of
 15 their choosing. And people have signed up for those,
 16 and they're quite packed, so we look forward to those.
 17 If you come to the microphone at any of those
 18 circumstances, please identify yourself and the
 19 organization you're representing and any conflict of
 20 interest you might have. For the press, our press
 21 officer today is Eric Pahon. I can introduce you to
 22 him if you need to.

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1 meeting. You can find the bathrooms to the left. You
 2 can find the bathrooms to the right. And then, I just
 3 wanted to thank Mary Gross, who's sitting over here to
 4 my right, and Georgiann Ienzi as well, who helped me
 5 pull this meeting together. We had a series, a large
 6 series of meetings with people from across the
 7 department who were involved in pulling this together.
 8 But I think, really, the heart and soul of all of it
 9 was Mary. So, thank you very much for everything you
 10 did.
 11 [applause]
 12 And finally, thanks to all of you for coming,
 13 especially on the cusp of a holiday weekend. And we
 14 look forward to a very informative two days. And with
 15 that, I'd like to introduce Director Botticelli. Thank
 16 you for coming.
 17 MR. BOTTICELLI: Good morning, everybody.
 18 Good morning, everybody. I know this crowd is a lot --
 19 makes a lot more noise than they just did. First of
 20 all, I really want to thank my colleagues at the FDA --
 21 Dr. Ostroff, Peter Lurie, Chris Jones -- who've been
 22 incredible partners, not just on the work with

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1 naloxone, but in all of our work as it relates to the
 2 prescription drug and opioid epidemic that we have in
 3 the United States. They've been huge colleagues, as
 4 well as other federal colleagues that we have here
 5 today. And I know I'm going to miss folks -- Grant
 6 Baldwin, Wilson Compton from NIDA.

7 You know, I'd like to give a particular shout-
 8 out to my colleagues from Massachusetts, Dr. Alex
 9 Walley and Sarah Ruiz. And, you know, I often get
 10 credit for what happened in Massachusetts, but all I
 11 did was listen to what they suggested that we needed to
 12 do. And we were able to do it. You know, I can't help
 13 but think back of being in this room a number of years
 14 ago -- three years ago. And I was actually in the
 15 holding pattern for deputy director. And I had to sit
 16 in the back, and I couldn't open my mouth at that point
 17 -- which, for people who know me, know it's a really
 18 challenging feat --

19 [laughter]

20 -- particularly as it relates to issues around
 21 overdose prevention. So, I really want to thank you
 22 all for being here today and particularly thank our

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1 federal colleagues. As director of the Office of
 2 National Drug Control Policy, our office establishes
 3 policies, priorities, and objectives for the nation's
 4 drug control programs, and ensures that adequate
 5 resources are provided to implement them. We also
 6 develop, evaluate, coordinate, and oversee the
 7 international and domestic drug policy efforts of the
 8 executive branch agencies and ensure that such efforts
 9 sustain and complement state and local drug
 10 initiatives. I really appreciate being here today to
 11 address the public health consequences of non-medical
 12 use of opioid drugs, and the critically important role
 13 that naloxone plays in preventing overdose deaths. I
 14 am particularly appreciative of the individuals who
 15 have been working on this issue for many, many years.
 16 We at ONDCP are pleased to have worked with all of you
 17 over the years, with law enforcement communities who
 18 have responded in an extraordinary manner to the
 19 overdose crisis. Their work builds upon the tireless
 20 work of community organizations who have been at the
 21 forefront of this issue for many, many years.

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1 I think you all know the data, but according
 2 to the CDC, every day in America 100 people -- 120
 3 people, on average, die every day from a drug overdose.
 4 That's nearly 44,000 overdose deaths a year. And
 5 opioid pain relievers are involved in more than 16,000
 6 of them, and heroin in over 8,000. Overall, drug use -
 7 - overdose deaths now outnumber deaths from motor
 8 vehicle crashes in the United States. While we are
 9 heartened to see some of the numbers around overdosing
 10 on prescription drugs decrease in 2013, that number has
 11 been offset by the number of people dying of heroin
 12 overdoses. Heroin is striking a younger, more rural
 13 and suburban population, overwhelming already-strained
 14 criminal justice and treatment systems, and often in
 15 parts of the country with little or no health
 16 infrastructure. Besides putting people at risk for
 17 overdose, injection drug use is also contributing to
 18 the spread of HIV and hepatitis C. I think all of us
 19 have been particularly concerned with the HIV outbreak
 20 in Scott County, Indiana, something that can be
 21 prevented through the availability of syringe services

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1 programs and better access to both substance use
 2 disorder treatment and infectious disease services.

3 Many of us in this room today were also at the
 4 National Prescription Drug Meeting in Atlanta, Georgia,
 5 in April. The annual meeting, organized by Congressman
 6 Hal Rogers, brings together academics, law enforcement
 7 professionals, parents, and others interested in the
 8 opioid abuse epidemic to arrive at solutions to this
 9 national problem. At the conference, we stressed that
 10 we don't have time to wait. The time for urgent action
 11 is now. And I say this not because I'm concerned about
 12 leaving a mark as the director of ONDCP. I say that
 13 because of the people who die every day from drug
 14 overdoses -- people who did not have to die, people
 15 whose lives we can save, and who can enter treatment
 16 and who can recover and who can go on to live full,
 17 healthy, and happy lives.

18 After this meeting, I will participate in a
 19 phone call with over 200 parents who have lost their
 20 children to the disease of addiction. These are really
 21 tough meetings. But it's important to meet with
 22 parents and people in recovery because it keeps me

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1 connected to the work that we do. If you ever wonder
 2 whether the work you do is important, I can tell you
 3 about the lunch I had with a father who lost his son to
 4 an overdose. This man clearly loved his son and had
 5 done everything he could do to help. He was wracked
 6 with guilt over what he could have done or should have
 7 known, not because he didn't have resources, he did;
 8 not because he was not educated, he was. This
 9 concerned parent did not know about medication-assisted
 10 treatment because the program didn't offer it, though
 11 his son had been in treatment for opioid use disorders.
 12 And he was sad to tell me that he also did not know
 13 about naloxone, a drug that could have saved his son's
 14 life. And that is why we are here today. We are here
 15 today because we still have more to do, and that urgent
 16 action is needed.

17 We have come a long way since the days when
 18 people in positions of authority would publicly state
 19 that naloxone would enable more use, and that we should
 20 not expand naloxone because it would send the wrong
 21 message. But we also know that there are too many
 22 barriers to naloxone, and there are opportunities that

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1 exist. We know that price is a barrier. We know that
 2 prescribing practices continue to fuel this epidemic.
 3 We know that availability is a barrier, and knowledge
 4 is a barrier. What is not a barrier is the will of the
 5 public, and the people in this room to make a
 6 difference. And with this, we can and we will save
 7 lives. Naloxone is one piece of the puzzle. The other
 8 pieces remain prevention, treatment, recovery support
 9 services. But based on the most recent national survey
 10 on drug use and health, far too few people who need
 11 substance use disorder treatment actually receive it.

12 To address this challenge in the final years
 13 of the Obama administration, we are promoting two
 14 complementary approaches. The first is overdose
 15 education and increasing access to naloxone for at-risk
 16 patients and all first responders. The second is
 17 better access to evidence-based treatment for
 18 prescription drug and heroin use disorders,
 19 particularly medication-assisted treatment. Prior to
 20 2012, just six states had laws that expanded access to
 21 naloxone or limited criminal liability. As of April,
 22 33 states had passed laws allowing naloxone

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1 distribution to third parties or first responders via
 2 direct prescription or standing order. Additionally,
 3 25 states and the District of Columbia passed laws
 4 offering protections from charge or prosecution for
 5 possession of a controlled substance and/or
 6 paraphernalia if the person was seeking assistance for
 7 someone experiencing an opiate overdose.

8 The federal government has focused a great
 9 deal of time and effort on expanding access to
 10 naloxone. The Substance Abuse and Mental Health
 11 Services Administration updated its Opioid Overdose
 12 Prevention Toolkit. And the Department of Justice
 13 created a naloxone toolkit for law enforcement. The
 14 Veterans Health Administration added naloxone to its
 15 formulary and created a policy for naloxone co-
 16 prescribing. President Obama announced an executive
 17 action directing the Department of Defense law
 18 enforcement officers to carry naloxone. Additionally,
 19 SAMHSA permits the use of block grant funds for
 20 naloxone purchase. And the president's FY 2016 budget
 21 request adds an additional \$12 million in grants to be
 22 issued to first responders in high-risk communities

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1 with this lifesaving medication. Our administration
 2 continues to support the co-prescribing of naloxone
 3 with opioid medication prescriptions, expansion and use
 4 of standing orders and collaborative practice
 5 agreements between health care practitioners and
 6 pharmacists that allow patients to purchase naloxone
 7 without a prescription, and efforts to make naloxone
 8 available over-the-counter.

9 But it's not enough to simply reverse an
 10 overdose. We must connect overdose victims and people
 11 struggling with opioid use disorders to treatment
 12 facilities and doctors that offer MAT. Today, thanks
 13 to the work of the FDA and NIDA, we have approved
 14 medications available for care for people with opioid
 15 abuse disorders -- methadone, injectable naltrexone,
 16 and medications containing buprenorphine. Medication-
 17 assisted treatment involves using one of these
 18 medicines, along with a full array of counseling,
 19 diversion prevention efforts, and recovery support
 20 services, so patients learn the skills they need to
 21 function in recovery. There is clear and convincing
 22 evidence that maintenance with MAT is more effective

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