FOOD AND DRUG ADMINISTRATION

EXPLORING NALOXONE UPTAKE AND USE

Public Meeting

Wednesday, July 1st, 2015

8:03 a.m. to 4:59 p.m.

White Oak Campus

10903 New Hampshire Avenue

Silver Spring, Maryland

C O N T E N T S

C O N T E N T S (continued)

C O N T E N T S (continued)

C O N T E N T S (continued)

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

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

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

more comprehensive. We have panels on naloxone use in clinical and nonclinical settings, questions of access, state law, over-the-counter status, training, and evaluation. We'll have discussions on ways to include police and fire departments, to expand naloxone availability on ambulances, and to address issues of cost, logistics, and supply. And finally, we have a broader audience even than last time -- and, I think, by the time everybody makes it through FDA's vaunted security system, a larger audience.

[laughter]

That audience is reflected in the makeup of the speakers in our open public hearing and sessions, which many of you have signed up, and in the audience more generally -- members of community-based organizations that first pioneered the administration of naloxone, medical professionals, policymakers, public health officials, first responders, product developers, researchers, and of course, patients and their families. All of us are united in a common goal -- to reduce the massive toll opioid overdoses are exacting on our country. In sum, the meeting builds on

the good work already done by those in this room to examine what I think we might call second-generation questions -- growth and sustainability of the programs. Their usefulness is no longer in question. But how we grow and sustain them is the subject of this meeting. What a difference three years makes.

Let me just finish with a couple of, more than a couple of logistic issues, just to make sure everybody's on the same page. As I hinted already, there is going to be a Q&A session after each and every panel, in which people can go to the mics and ask any questions they might have of the speakers. We also have two one-hour open public sessions, one today and one tomorrow, at which one can make any comment of their choosing. And people have signed up for those, and they're quite packed, so we look forward to those. If you come to the microphone at any of those circumstances, please identify yourself and the organization you're representing and any conflict of interest you might have. For the press, our press officer today is Eric Pahon. I can introduce you to him if you need to.

There will be kiosks set up outside the meeting room where refreshments will be sold during the breaks and at lunch. And while you're at it, after our first break, you should preorder your lunch to be more efficient when it comes to lunchtime. And lunch will include offerings such as salads, sandwiches, and other refreshments. Remember that only those who have FDA badges will be able to venture past our vaunted security folks, so stay within the general confines of this meeting area. You should know that the meeting is currently being webcast live and will be archived and available to view after the meeting. And a transcript of the meeting will be made available within 45 days of this meeting. The slides will be -- that are being presented today will be made available unless the speakers prefer not. But you should be able to get those on the web after the meeting. And we'll post a meeting summary as well. Should you have any comments on this meeting, you can submit written or electronic comments at www.regulations.gov.

Please turn off your cellphones because that can interfere with our transcriber, who's recording the

meeting. You can find the bathrooms to the left. You can find the bathrooms to the right. And then, I just wanted to thank Mary Gross, who's sitting over here to my right, and Georgiann Ienzi as well, who helped me pull this meeting together. We had a series, a large series of meetings with people from across the department who were involved in pulling this together. But I think, really, the heart and soul of all of it was Mary. So, thank you very much for everything you did.

[applause]

And finally, thanks to all of you for coming, especially on the cusp of a holiday weekend. And we look forward to a very informative two days. And with that, I'd like to introduce Director Botticelli. Thank you for coming.

MR. BOTTICELLI: Good morning, everybody. Good morning, everybody. I know this crowd is a lot -- makes a lot more noise than they just did. First of all, I really want to thank my colleagues at the FDA -- Dr. Ostroff, Peter Lurie, Chris Jones -- who've been incredible partners, not just on the work with

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

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

[laughter]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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