FDA: Exploring Naloxone Uptake and Use

Day 2

C O N T E N T S

AGENDA ITEM PAGE

Welcoming Remarks
Peter Lurie, MD, MPH  6

Panel 5: Impediments to Wider Ambulance Availability
Moderator Nisha Patel, MA, CHES  7
Naloxone Use by EMS Providers
Mark Faul, PhD, MA  10
Naloxone and Emergency Medical Services: One State's Perspective and a National Legal Review
Michael W. Dailey, MD, FACEP  21
Naloxone and Emergency Medical Services: Improved Patient Care through Teamwork
Drew Dawson  34

Panel 6: Expanding the Role of Police and Fire Departments
Moderator Mark Faul, PhD, MA  65
Saving Lives in New Ways: Law Enforcement’s Role in Preventing Overdose Deaths
Tara Kunkel, MSW  65

Panel 7: Bringing New Products to Market
Moderator Jennifer Fan, PharmD, JD  92
Intranasal Naloxone: Characteristics of a New Formulation
Seamus Mulligan  93
Indivior’s Intranasal Naloxone
Stephen Hebert  102
Regulatory Approaches for Rx to OTC Switch
Theresa M. Michele, MD  118
Access to Naloxone for Those Who Need It Most
Alice Bell, LCSW  133

Panel 8: Cost, Logistics, and Supply Issues
Moderator Mary Beth Bigley, PhD, MSN, ANP  144
Beacon Health Options White Paper: Confronting the Crisis of Opiate Addiction
B. Steven Bentsen, MD, DFAPA  145

Panel 9: Measuring Progress and Impact
Moderator Phil Skolnick, PhD, BSc (hon.)  241
Evaluating the Impact of Overdose prevention Education and Naloxone Rescue Kits in Massachusetts
Alexander Y. Wailey, MD, MSc  241
Evaluating Implementation of Life-Saving Opioid Overdose Education and Naloxone Distribution within the Veterans Health Administration
Melissa L. D. Christopher, PharmD  257
Measuring Progress and Impact: Where We Need to Go
CDR Christopher M. Jones  273

Contents (continued)

AGENDA ITEM PAGE

Ensuring Access to Naloxone for Community-Based Distribution Programs: An Overview of Cost, Supply, and Procurement Issues
Eliza Wheeler, MS, MHA  153
Community Pharmacy Perspective
Krystalyn K. Weaver, PharmD, RPh  165
Open Public Hearing  196

Panel 8: Cost, Logistics, and Supply Issues
Moderator Mary Beth Bigley, PhD, MSN, ANP  144
Beacon Health Options White Paper: Confronting the Crisis of Opiate Addiction
B. Steven Bentsen, MD, DFAPA  145

Panel 9: Measuring Progress and Impact
Moderator Phil Skolnick, PhD, BSc (hon.)  241
Evaluating the Impact of Overdose prevention Education and Naloxone Rescue Kits in Massachusetts
Alexander Y. Wailey, MD, MSc  241
Evaluating Implementation of Life-Saving Opioid Overdose Education and Naloxone Distribution within the Veterans Health Administration
Melissa L. D. Christopher, PharmD  257
Measuring Progress and Impact: Where We Need to Go
CDR Christopher M. Jones  273

Contents (continued)

AGENDA ITEM PAGE

Ensuring Access to Naloxone for Community-Based Distribution Programs: An Overview of Cost, Supply, and Procurement Issues
Eliza Wheeler, MS, MHA  153
Community Pharmacy Perspective
Krystalyn K. Weaver, PharmD, RPh  165
Open Public Hearing  196

Panel 9: Measuring Progress and Impact
Moderator Phil Skolnick, PhD, BSc (hon.)  241
Evaluating the Impact of Overdose prevention Education and Naloxone Rescue Kits in Massachusetts
Alexander Y. Wailey, MD, MSc  241
Evaluating Implementation of Life-Saving Opioid Overdose Education and Naloxone Distribution within the Veterans Health Administration
Melissa L. D. Christopher, PharmD  257
Measuring Progress and Impact: Where We Need to Go
CDR Christopher M. Jones  273
AGENDA ITEM PAGE

Closing Remarks  306

Kimberly Jeffries Leonard, PhD  306

PROCEEDINGS

(8:05 a.m.)

DR. LURIE: Mary, I got it. Okay, good morning, everybody. Here we are back for a second day. Some of the same people, of course, are back and I’m glad to see you and a few new people today. So I hope everybody gets as much enjoyment as I know I did out of yesterday’s, which I thought was just very productive and quite exciting. Today, we zoom in a little bit on more specific topics, in a way, fire, ambulance, first responder. In general, we focus in on cost and logistics and then we close off with the all-important question of evaluation. So that’s the plan for today.

A couple of small changes compared to yesterday, one is for those of you who will be speaking, and for that matter, those of you who will be observing the speakers, we’re going to make more active use of this today. This is not a reflection of the events of yesterday at all, it’s just that we don’t have a placard this time. So, for speakers, this orange light will come on two minutes before the noose descends to extract you from the meeting altogether, and then it will turn red when your time is fully up. So that’s one item. And the other is many of you will have seen a sign outside about lunch and the way to avoid what happened yesterday will be to preorder if at all possible before 9:00 just by going to the open hatch where they’re currently serving coffee and stuff and you can just put your order in. Then there’ll be a separate table this time. As you go back down this corridor to the left and all the lunches should be laid out and somebody will be there to help you get your drink and your lunch as well. So hopefully that will take care of that problem.

So with that, I’m going to hand it over to Nisha and the first panel. Enjoy the day.

MS. PATEL: Great, well thank you so much, Peter, and good morning everyone. I’m Nisha Patel. I’m with the Department of Health and Human Services, Health Resources and Services Administration where I work for the Federal Office of Rural Health Policy and I’m really pleased to be here to facilitate this very important meeting on addressing opioid addiction and the use of naloxone in both urban and rural communities. This light just made my job a lot easier because I was just trying to figure out how I was going to flag people with a two to three-minute warning, so that’s really great. As one of the priority areas for the department, this epidemic has really provided an opportunity for federal and state entities to be able to collaborate, strategize, and learn from one another, and then also identify areas that are very meaningful and impactful. And so our office, the Federal Office of Rural Health Policy, we’ve been really excited to start getting engaged on this issue while, you know, this has really become an increasing problem, an issue across the United States. As you all know, people in rural communities are very vulnerable and more likely to overdose on prescription pain killers and a lot of this is obviously due to some of the challenges rural communities face including access to care, transportation, geography, and a lack of providers.
And so in fiscal year 15, our office actually received a little over a hundred -- a million dollars to focus on opioid overdose in rural and we are in the process of making some awards to rural communities, which we’re really excited about. In particular, we’re really focused in on the purchase and placement of naloxone and I think this session is very timely with the EMS providers, also the training of healthcare providers, and then the referral component, which we’re really heavily focused in on, being able to refer patients to appropriate treatment centers and then really be able to start thinking about how to put the patient needs first and start really focusing in on care coordination. And so we’re really hoping to gain some valuable lessons from the grantees that we’re going to award, and we’re hoping that these lessons are going to help us build upon the rural evidence base that we’re starting to develop within our office.

And so with that, I’m very excited to hear from the speakers this morning just to learn from will have some better understanding of naloxone administration in an EMS setting. We’re going to talk a little bit about general practice and barriers to administration.

As we all know in the presentations, this is a well-informed audience, many naloxone distribution programs exist. Normally when you talk about this subject, you have to make a distinction between family programs and what EMS is doing. EMS is a unique part of the naloxone picture. EMS is actually part of the health system. We forget that sometimes. The overall protocols and functions and what EMS does is generally governed by a document called “The Scope of Practice Model.” It was written by NHTSA in 2007 but states and local authorities can always override that policy statement, and they do in many cases.

According to one study, just to show the magnitude of naloxone use at the EMS level, naloxone was the most commonly administered drug to adolescents in a prehospital setting. That study has some data on it, 1991. Our data, we didn’t look them and also really hear about some of the barriers on naloxone use to the EMS providers, ways to increase the use in ambulances, and the importance of a care coordination approach where the patient needs are put first. And so I will turn it over to our first speaker, Mark Faul, who will come up and introduce himself.

Presentation - Mark Faul

DR. FAUL: Hello. My name is Mark Faul. I work for the Centers for Disease Control in the Injury Center, the Division of Unintentional Injury Prevention. It’s a mouthful. This is a small --

we’re here to present some data on a small study we did. It’s a small sliver of what CDC does with opioid overdose work. Okay. I have nothing to disclose. I’m a federal employee. I really don’t own much.

[laughter]

I do need to say the findings and the conclusion in this article reflect the author’s views and not the official position of the CDC. The overall goal of this session is the participants will have some better understanding of naloxone administration in an EMS setting. We’re going to talk a little bit about general practice and barriers to administration.

As we all know in the presentations, this is a well-informed audience, many naloxone distribution programs exist. Normally when you talk about this subject, you have to make a distinction between family programs and what EMS is doing. EMS is a unique part of the naloxone picture. EMS is actually part of the health system. We forget that sometimes. The overall protocols and functions and what EMS does is generally governed by a document called “The Scope of Practice Model.” It was written by NHTSA in 2007 but states and local authorities can always override that policy statement, and they do in many cases.

According to one study, just to show the magnitude of naloxone use at the EMS level, naloxone was the most commonly administered drug to adolescents in a prehospital setting. That study has some data on it, 1991. Our data, we didn’t look at compared to all drugs but that’s -- this is a really popular topic in the EMS community. It led us to the research question, “What are the barriers to naloxone use among EMS providers?” And we actually did a study and we have it published in the American Journal of Public Health. I’ll go ahead and take the time to acknowledge some of the authors, one of which is here today which is Michael Dailey, David Sugerman, and Scott Sasser, Ben Levy, and Len Paulozzi who I’m sure you’ve seen his name everywhere. I also want to thank Chris Jones from the FDA who helped us frame and get our brain around this study a little bit better. We’re going to talk about the data results of this study.

What we used is a national EMS system. The 2012 data contains approximately 20 million records.

It is important to note that it contains all EMS events which includes a lot of non-injury, heart attack, stroke, you name it. It includes inter-facility transfers and it includes non-911 events.

At the time in 2012, the dataset is growing but there were 42 states participating and 12 states...
For our study, we defined drug overdose as either ingestion or a poisoning for either the dispatch complaint or the EMTs that filled out the system to populate NEMSIS. They either identified it as an ingestion reporting or the complaint came in as that. We used logistic regression procedure and the dependent variable wasn’t lives saved or anything like that. It was whether or not naloxone was issued when we roughly defined these drug cases. We looked at a small, relatively small portion of NEMSIS. We looked at EMS certification level, some basic demographics, urbanicity, and primary symptoms. The red is not showing up on the graphic for some reason but -- there we go. Breathing -- what we did is there were 262,000 records identified using this description of drug cases and what we found was what we would expect to find, is that naloxone was used primarily when the symptoms called for it. Breathing problems are 20 times more likely to use naloxone when there were no breathing -- when there was no symptoms at all. Changes in responsiveness, malaise, is only approximately two times, and change in responsiveness is the odds of naloxone use is 13 times higher. Malaise is only two times higher roughly, and then weakness. We didn’t have EMS using naloxone under the wrong symptoms. I think this is an important finding. It’s what you would expect to find. For some of the demographic variables, we found that males were less likely to receive naloxone at about the odds of them receiving that is about 10 percent less. We had a robust -- a fairly robust discussion yesterday about gender and this helps inform that a little bit in that males are receiving naloxone in the EMS environment at a lower rate. Some people, when we looked at this data and we talked it over, some of the people had experience with some males getting violent out of the use of -- after being administered naloxone because they just came off their great high and they don’t like that. What we particularly were interested in was looking at rural naloxone use. The odds were higher in rural settings versus urban settings, approximately 23 percent higher, the administration of naloxone.

That is part of the training. Intermediate EMT is 120 hours to 500 hours of training, basic life support, basic medications, and of course, driving the ambulance. Paramedics are what we mostly have an image of when we think of EMS. They’re the most -- in the EMS world, they’re with EMTs. They’re the highest trained. They’re trained in 30 to 40 different medications, all -- most of all to keep the patient breathing. They’re also -- do managing patient care. The other two categories in the basic EMT is 80 to 120 hours of training. The do basic life support and they drive the ambulance.

What we particularly were interested in was looking for some reason but -- there we go. Breathing -- what we did is there were 262,000 records identified using this description of drug cases and what we found was what we would expect to find, is that naloxone was used primarily when the symptoms called for it. Breathing problems are 20 times more likely to use naloxone when there were no breathing -- when there was no symptoms at all. Changes in responsiveness, malaise, is only approximately two times, and change in responsiveness is the odds of naloxone use is 13 times higher. Malaise is only two times higher roughly, and then weakness. We didn’t have EMS using naloxone under the wrong symptoms. I think this is an important finding. It’s what you would expect to find. For some of the demographic variables, we found that males were less likely to receive naloxone at about the odds of them receiving that is about 10 percent less. We had a robust -- a fairly robust discussion yesterday about gender and this helps inform that a little bit in that males are receiving naloxone in the EMS environment at a lower rate. Some people, when we looked at this data and we talked it over, some of the people had experience with some males getting violent out of the use of -- after being administered naloxone because they just came off their great high and they don’t like that. What we particularly were interested in was looking at rural naloxone use. The odds were higher in rural settings versus urban settings, approximately 23 percent higher, the administration of naloxone.

There is something called the rural paramedic paradox and it basically says that as one moves farther away from medical facilities in urban areas, one needs to -- one needs higher level of EMS service capability to fill that gap and the other part of the paradox is that they’re less likely to get that higher level of EMS service because of the resources. There are very stark differences in rural EMS, geography, mountains, long distances, population density, call volumes, availability of training and education to EMTs and, of course, this all translates into longer transport times.

This is a map of the United States. The green counties are considered rural. Approximately 80 percent of the land mass in the United States is rural. Urban centers, however, have about 80 percent of the EMS workforce. That leaves only 20 percent of the EMS workforce to serve 80 percent of the land mass across the United States. It’s pretty surprising.

For our study, we defined drug overdose as either ingestion or a poisoning for either the dispatch complaint or the EMTs that filled out the system to populate NEMSIS. They either identified it as an ingestion reporting or the complaint came in as that. We used logistic regression procedure and the dependent variable wasn’t lives saved or anything like that. It was whether or not naloxone was issued when we roughly defined these drug cases. We looked at a small, relatively small portion of NEMSIS. We looked at EMS certification level, some basic demographics, urbanicity, and primary symptoms. The red is not showing up on the graphic for some reason but -- there we go. Breathing -- what we did is there were 262,000 records identified using this description of drug cases and what we found was what we would expect to find, is that naloxone was used primarily when the symptoms called for it. Breathing problems are 20 times more likely to use naloxone when there were no breathing -- when there was no symptoms at all. Changes in responsiveness, malaise, is only approximately two times, and change in responsiveness is the odds of naloxone use is 13 times higher. Malaise is only two times higher roughly, and then weakness. We didn’t have EMS using naloxone under the wrong symptoms. I think this is an important finding. It’s what you would expect to find. For some of the demographic variables, we found that males were less likely to receive naloxone at about the odds of them receiving that is about 10 percent less. We had a robust -- a fairly robust discussion yesterday about gender and this helps inform that a little bit in that males are receiving naloxone in the EMS environment at a lower rate. Some people, when we looked at this data and we talked it over, some of the people had experience with some males getting violent out of the use of -- after being administered naloxone because they just came off their great high and they don’t like that. What we particularly were interested in was looking at rural naloxone use. The odds were higher in rural settings versus urban settings, approximately 23 percent higher, the administration of naloxone.
It was highest in the suburban. The level of service -- this is kind of what we were expecting to find is that basic EMTs, compared to basic EMTs, intermediate EMTs had a 5-1/2 times more likely to administer naloxone. This was a key finding. This sort of validated what we knew but that difference between a basic and intermediate EMT level really does affect the odds of administration. These numbers need to be put into better context with the overall burden. The blue line, these two numbers are independent. The two lines are independent and they're on both -- there's two axes, two Y axes. If you look at the blue line, that represents urban -- that represents burden in urban, suburban, and rural environments. I'm going to try the pointer. But you can see that in the urban environment, the burden was substantially lower than in the rural environment yet the naloxone administration, we set that at 1 because it's a statistical reference point, it was the naloxone use was higher in the suburban environment but proportionately not what we would expect to find given the burden. So this large gap represents the differences between how urban -- excuse me, how the suburban populations and rural populations receive naloxone. It's a fairly big difference.

As mentioned before, NHTSA published the Scope of Practice Model which serves as the guidance for basic EMTs to administer medicine. This is the specific blurb out of the Scope of Practice Model that I'm sure Drew will be addressing in his session, but these are the pharmacological interventions that a basic EMT can do: assist patients with their own prescribed medications and administer over-the-counter medications, and oral glucose and aspirin. As we've talked, there was another robust discussion on intranasal naloxone versus intravenous naloxone. It sort of misses the point here. The summary of the articles that I read, intranasal was almost as effective as intravenous, but the point of this is that basic EMTs in many states cannot administer this pharmaceutical. How many states? At the time we did this study, there were 12 states. Currently there's about 24 states. This is a rapidly changing policy environment. But the rural implications for opioid overdose is basic EMTs are more common in rural areas. So we have sort of -- that's the reason why we have the big gap. Drug overdose is a bigger problem in rural areas also. EMT service is starkly different in rural areas. We have volunteer fire departments in many communities, lower levels of training, geography, population density, all those things factor into the rural environment that makes the urban -- it's so different. This study suggests that rural communities suffer more from naloxone restrictions inherent in the scope of policy -- Scope of Practice Model, sometimes a single EMT is dispatched in rural areas. That is rare. Teams go out in basic and advanced life support, but in the cases where there's low resource environments, that has been known to happen.

So what do we do next? The manuscript provides support for changing -- addressing this issue in a couple different ways: Changing the Scope of Practice Model, and for states to develop local policy laws and policy regulation laws to allow intranasal naloxone use for EMTs, basic EMTs. As I mentioned, many states -- well, not many -- 12 states had this exception, 24 currently do now. Corey Davis would be really the expert on the precise number. He keeps track of it almost on a day-to-day basis. So -- and the other option is to get the additional training for basic EMTs. There some pushback within the system for that. The -- you know, some basic EMTs can't pass the test. That is a true barrier that's hidden in these numbers. Drew can talk a little bit more about that. And CDC's action in response to this article and this finding is to try to -- it did a press release which is fairly rare on articles, and the recommendations in that press release were more training for basic EMTs to get the additional certification, and also to concentrate training efforts in rural communities.

That concludes my presentation. We'll save questions for the end. Thank you.

[applause]
Presentation – Michael Dailey

DR. DAILEY: Good morning, everybody. I’m Michael Dailey. I’m the chief of the Division of Prehospital Operational Medicine at the Albany Medical Center in the Department of Emergency Medicine and I have been involved in naloxone for basic life support for providers and now law enforcement and volunteer fire responders over the course of the last five or six years. It’s been an interesting adventure and this been an extremely exciting meeting where I’ve gotten to meet a lot of the people whose work that I have emulated and borrowed and in, some cases, enjoyed taking to the next step. So thank you. I’m really glad to be here.

First of all, I have no academic conflict of interest, no financial conflict of interest. I am an academic physician. I can’t quite make the same statement Mark just did, and I will also discuss the off-label use of naloxone. We’re going to start by talking a little bit about the New York experience where we were, what we did, and where we are now, and then we’ll go over a brief legal review where again, I’m working with the experience from others.

The background itself, I don’t have to explain the impact of opioid overdose to this group. This group understands it better than most. However, we did have to do some explaining of this in New York as this program began. In a lot of areas, in New York State in particular, we are a home rule state where local municipalities and local organizations can form their own systems for EMS care, which, in some cases, leads more to a quilt rather than a system. In general, across the state we have -- I’m sorry, across the country there are basic life support advanced or midlevel providers, as Mark alluded to, and paramedics. In New York, we actually have an additional level of advanced life support provider, the critical care technician, which falls between an advanced or intermediate provider and a paramedic and is designed specifically for our rural communities. The goal is to try to move advanced level care into these rural communities, recognizing the time stipulations on

volunteers. Even with that, in our rural communities across New York, we are just about all basic life support providers.

The Scope of Practice Model does include naloxone administration at the paramedic and advanced level, and in many areas of the country, as I said, paramedic and advanced providers are not accessible. Certainly this is very true in New York, particularly across the Adirondacks and across what we would call our southern tier along the Pennsylvania border. And we believe that if we were going to start bringing naloxone to these basic providers, we’d probably reduce fatal opioid overdose. The reason that we wanted to make sure to bring this to our EMTs, our basic EMTs, is because across the state, they are almost always the first people to arrive at the scene of an event. We decided that we would start with an intranasal approach because we didn’t want to have to also teach these providers how to use syringes and we wanted to try to avoid the potential for accidental occupational needle sticks, which we found was particularly important. This is a well-established off-label route and actually, the work that I must comment on is the stuff that’s been done in Boston and the experiences that Boston EMS has had with using basic EMTs to reverse opioid overdose over the course of the last ten years. In conversations with them before we went live with our program, we discovered that they had had no injuries to personnel and they had had positive outcomes for their patients, and those were two of the things that we found most important to assure the safety of both our patients and providers in New York State.

Among the reasons that we needed to do this as a pilot project within New York State was that we couldn’t use the community access naloxone programs as they were written into code in New York because actually EMS providers were not eligible for participation in the community naloxone programs. There was local control of each individual decision to join us in this program, county involvement in the administration of the programs, and there was oversight from both state and regional programs as
we proceeded.

The picture itself, I highlight three areas
of New York State. You’ll see Suffolk County, which
is sort of the tail of Long Island, was one very
active participant in our basic EMT program. The
area I represent is the regional -- the region known
as the Hudson Mohawk Region, which is to the right,
and then the Monroe Livingston Region to the west
was also involved. The pilot covered three
disparate groups of providers, urban basic life
support fire department first responders which are
EMTs working for a career fire department. In
general across Suffolk County, we had EMTs working
for police departments. So these were actually law
enforcement officers who also happened to be EMTs in
Long Island. And in my area, we actually had
volunteer ambulance organizations who participated
as well. So three disparate groups of EMTs all
participated in this training. We used a 90-minute
standardized training which actually, by the time we
got it going, our instructors were doing it about 60
minutes. It had a lecture, 25-minute standardized

which is that this is a skill that was well within
the scope of practice for the basic EMT. Among the
other ones that I thought were really notable is
that these providers all felt very comfortable at
administering medications intranasally, and they
were confident in their knowledge of naloxone.

What did we learn in New York? Well in the
process of this pilot project, we trained 2,000 EMTs
and from those 2,000 EMTs, we actually had 223
opioid overdose reversals. We had never had a pilot
project we’d done with EMS before where we had one
reversal or one implementation of that pilot
activity for every 10 people we trained. We had a
couple of protocol violations. Most of those
involved patients who were in cardiac arrest that
were not supposed to get the drug. We’ve ultimately
moved past that in some of our other programs. We
had a couple of people who were breathing normally
who should probably not have gotten the drug. There
were no adverse events to our patients, however.
There were no significant hazards to EMS personnel
and there was actually one interesting case of

video, skills practice, and a question and answer
period. The trainer guide was used to make sure we
had equal training opportunities across the state
and we then did pre and post-testing of all
personnel that participated in order to assure that
we were moving forward in the right direction. We
also did quality assurance review of each one of
these cases.

What was nice in looking at the pre and post-
test questioning on this is that prior to this
process, we had really -- sorry. Prior to this, we
really had good results in terms of recognition of
opioid overdoses and the fact that people were
reasonably comfortable at treating opioid overdoses.
This was on a 10-point Likert scale. It worked out
really well and it was nice to see that we had that
level of training within our EMS providers already.
Frankly, we expected that. What was very nice,
though, was our post-test means which showed a
steady increase across each one of our objectives
and in particular, there are a couple that really I
thought brought to bear where we really should be,
naloxone in the emergency department. As we look across the results for them, in general these patients did receive some referral to drug rehab; however, the number of patients that actually ended up in these programs was very difficult to find out. Suffolk County did some discreet follow-up on these individuals and found out about 10 percent ended up involved in rehabilitation programs.

Our conclusion itself, this was a successful pilot. We had 1 in 10 trained EMTs used the drug and did a reversal. The training for providers, we felt, should be expanded and has subsequently been added to the scope of practice in New York State.

We built out a law enforcement program that you heard a little bit about yesterday and you'll hear more about law enforcement shortly, and there will be some first response fire personnel that will be involved as well. Something that I think is very important and we certainly have seen in some of the programs is that it is extremely important to have medical oversight and appropriate implementation of naloxone in these programs. We can't just put

regulations, and policies from 50 states including the D.C., Guam, and Puerto Rico which was an incredible undertaking. Protocols looking at the route and dose of administration were also reviewed as part of this. The interesting thing here is that this is something that will have to be followed by medical directors across the country as well to assure we're adequately treating our patients and not over-reversing, as we heard a little bit about yesterday.

Every jurisdiction in the United States allows paramedics to administer naloxone, as you'd expect. Almost all allow mid-level personnel. These are the advanced EMTs that we talked about before, to administer naloxone. And at the time in 2013, 12 jurisdictions allowed EMTs to administer naloxone. That was actually before New York was allowed. This is what it looked like in 2014, almost what it looked like. There was a little bit more of a patchwork on there than there should be, but this is continuing to evolve. One of the things, I think, that is most important about a continual evolving process like this is that we don't look at any one slide or any one study as being the be-all and end-all. What we heard yesterday is that we're up to 66 percent of our states that are allowing basic EMTs to administer naloxone. That is a very significant change from where we were just a couple of years ago.

Among the most important things for us to remember is that the NHTSA Scope of Practice Model is a model and unfortunately there are some states that have actually legislated this model as policy and that may actually be a key to why this becomes a problem. Drew will speak a little bit more about the Scope of Practice Model but we'll have to follow and see how this changes over time. Since this time, we've had additional jurisdictions continue to expand and the other thing that is important to remember is we don't, in this data right now, have a true understanding of first responders in each state because there will also be additional community access programs that are going to involve first responders.
So at the end of the day Narcan, or naloxone, is being brought to our patients by our advanced EMTs and by our paramedics but across the country, as Mark said so eloquently, there are not responding paramedics in many of our communities. We need to look and make sure that we indeed get naloxone to our patients that are overdosing on opioids, and in the rural environments, this will very frequently be bringing this down to the EMT level and then getting it safely to our patients. One of the ways we can do this is updating the National Scope of Practice Model with its next rendition and I suspect that will probably be included. We'll hear about that in a minute.

Lots of thank you's to a lot of partners across the state and across the country. In particular, I want to thank the thousands of EMTs, both our providers and instructors, in New York who really demonstrated that treating opioid overdose is a BLS, or a basic life support skill, and have subsequently moved it on into our law enforcement and volunteer fire communities. Thank you.

the table today. Anybody have that question? All right, all right, very good. So the short answer for that is that we have had a federal leadership role in support of emergency medical services systems since the late 1960s and it’s one that we continue to enjoy today. We continue to enjoy that in collaboration with our other federal partners, some of whom may be here today from ASPER at HHS, from the Department of Homeland Security, and from other federal agencies so it’s a very collaborative federal effort. So what I wanted to do today was to do a couple of things. I wanted to do a quick review of some updated data in terms of naloxone administration, to describe briefly the EMS education agenda for the future and the Scope of Practice Model and how that fits into it, discuss what I think is an importance in terms of dealing with a teamwork approach to the opioid overdose problem in a community of which EMS is but one component, and discuss kind of the idea of some collaborative partnerships at a community level.

So the National Emergency Medical Services Information System, as Mark has said, is the national repository for EMS data that was developed to help states collect standardized data elements and submit that data to the national EMS dataset. Using NEMSIS, it is possible to describe EMS trends and compare data at a national level. So the 2013 dataset includes over 24 million EMS activations submitted by 48 states and territories now, and this just describes the number of activations involving the prehospital administration of naloxone. So this is about a year later from Mark’s data and it’s also captured just a little bit differently. Some of the parameters in terms of capturing it are a little bit different from Mark’s data and he and I have chatted about that. So it’s not exactly comparing apples and apples when you look at the data but it shows that in 2013 there were 113,153 activations, or patients, to whom it was administered captured in the National EMS Database, but a total of 135,000 some administrations. This was 86 percent of those were at the paramedic service level. We can’t capture that exactly by the level of EMS provider,
the specific level of EMS provider, but we can say
it was provided by an EMS paramedic service. It
could have been someone else in that service
providing it but it was captured by an EMS level
service.

The EMS Education Agenda for the Future was
adopted in the year 2000. It was a very
collaborative effort among all of the national EMS
organizations. The final product is that of NHTSA.
It’s a vision for an EMS education system to help
assure more consistency and reliability on a
nationwide level, but it also recognizes the need
for flexibility to educators, to states, and to
others so it’s very difficult to have a single
approach on a nationwide basis that recognizes that
flexibility. And we’ve made considerable progress
with implementing the EMS education agenda since the
year 2000. This just points out the elements of the
EMS education agenda, a systems approach, starting
off with the National EMS Core Content which is
similar to other allied health professions which
describes the overall domain of everything related

so that’s gradually transitioning to the ones that
I’ve just mentioned today.

Let me talk a little bit about what Scope of
Practice Model is and isn’t. First of all, it’s a
model. It’s intended to help states and to
courage consistency of provider levels. It is not
mandated of states. So many states have now adopted
that and it is proceeding well. But secondly, it’s
intended to establish those provider levels and to
have some uniform levels of nomenclature across the
nation. It does not authorize an EMS provider to
practice. The state retains that authority. It
doesn’t retain it, it has that authority to regulate
EMS provider practice levels and the levels in their
state and their practices.

It also establishes a floor. So here’s what
the minimum level that every EMT should know. It
does not establish a ceiling. The idea is that
there’s a progression from EMT to EMT to advanced
EMT and that there will be a natural progression so
that if something is on the advanced EMT level, that
the EMT will -- may know that as they are proceeding

on to the advanced EMT level, but that certainly is
a state decision. It also it intended to promote
flexibility. It’s pretty broad so it’s not intended
to address every psychomotor skill or every
medication. That would be an impossibility in a
national scope of practice model. So it’s intended
and it’s stated in there it’s intended to provide
flexibility and adaptability. So this is updated
every 5 to 10 years. It’s impossible in a scope of
practice model to have a model that addresses every
single contingency. The idea is to keep it broad,
to keep it flexible for the states to have
adaptability for the states who are the regulators,
but to have it consistent enough that they can adapt
and have some consistency, rather, over a period of
years so there can be consistency in the terms of
the names of EMS providers for purposes of national
certification, for purposes of state law, and state
rule.

It’s also important to recognize that the
Scope of Practice Model is but one item of an EMS
system and if there is something adopted in the

if there is an opportunity for them to play in that way. And I think there are ways and opportunities that have been demonstrated for that to happen. For instance, if we look at where the overdose is occurring, what substance is causing the abuse, the things that you see on this slide, but we look at it not just from a law enforcement perspective, not just from a fire perspective, not just from an EMS perspective, but we look at it from the "we" perspective, and then we look at where are the resources at the community level to help drive the response. Those resources might be EMS. They might be fire as Dr. Bailey has indicated. They might be EMS. They might be, in Alaska, the community healthcare worker. They might be the sanitation worker in some communities, but really kind of think outside of the box in terms of the resources at a local level and we take more of that approach. I think it would be a way to get EMS to the table in a better level by bringing EMS to the table and enhancing their resources.

So the other thing that I think is really important is that we look and continue to look at measurement and evaluation and are we making a difference on the prehospital arena and the prehospital utilization of naloxone, and that...
there’s a need for uniform data, uniform measures, additional research, and long-term patient outcome and perhaps the development of a national out-of-hospital evaluation strategy for opioid overdose management. So, are we making a difference? How is it that we’re making a difference? Where could we make more of a difference?

So overall, I think patient first, ensure that all of our goals are patient-centered goals and that we focus at a community level, and at a federal level on getting the right care to the right patient by the right people at the right time and the right people can be really very variable on a community to community basis. So thank you very much.

[applause]

MS. PATEL: Well great. Thank you all for presenting such informative information. We have quite a bit of time here to ask some questions or hear from you all so if you have a question or comment, could you please come up to the microphone, introduce yourself. Thank you.

DR. JONES: My name is Steve Jones. I

near real-time surveillance for where are overdoses occurring, what are the circumstances, and I don’t know -- I think in some areas that information is available but it’s a potential goldmine for actually being able to know where the problems are and marshal the resources to do that. And the last thing, and I’m sorry for having so many points but you guys provoked me.

[laughter]

When I looked at the NEMSIS data, it was paradoxical. I talked to Michael about this. You get a faster response time for rural areas than urban and that doesn’t seem to make sense so if that could be sorted out, that would be of great interest. But I’ll come back to say it’s a great panel and thank you for all you’ve contributed.

DR. DAWSON: If I could just respond quickly about the NEMSIS data, first of all, as you’re looking at the OLAP cube on the website, that data is pretty much national data. But if there is a collaborative effort between and among the emergency response agencies on a local level, then that data

becomes much more rich so that you can look at response times, you can look at a considerable amount of additional information on a local level that we can be prohibitive because of data use agreements from putting on a national level. So you can make that much more robust. And to your point, I think that if you can look at all of that on a community-by-community basis, that you can then define what is the most appropriate response. You can look at law enforcement. You can look at fire services. You can look at emergency medical services. I think that that may vary on a community-to-community basis because that’s just kind of the nature of the beast and it’s not that one is better than the other, it’s just that that is variable from community-to-community because each community is different and you define the best resources for the problem for that community based upon good data.

NEMSIS is only one part of the piece that deals with emergency medical services but there are other databases but you don’t know that unless you

retired from the CDC. I -- this is a wonderful panel and I want to thank everybody involved in it.

It’s important information that’s not so widely known.

And I think that we all agree that the best situation is if the naloxone is available at the scene before -- even before first responders arrive.

I think, however, that the data on that are not so clear to people and I would say -- I would ask if somehow you or others could produce the data on how long it takes EMS to arrive on the scene. I went to the NEMSIS website and came up with 16-1/2 minutes but I didn’t really have good control over the data but I think if you could get that information in every state for rural and urban, for EMS and also for fire and police, it would make the case very clear that there’s significant waiting time between somebody calling 911 and there actually naloxone arriving if it’s an opioid overdose.

The other thing that I would suggest and ask for, and I loved your public health surveillance idea, but potentially you could have a real-time or
all sit down at the same place at the same time
talking about the same problem and address the
issue.

DR. DAILEY: Mike, we’re watching in New York
the response interval between law enforcement and
EMS and we see that law enforcement is first on the
scene greater than 80 percent of the time. Most of
the time it’s only five minutes or so but we have
times out to almost 30 minutes where law enforcement
is on the scene waiting for EMS so keeping
relatively local control on this to make sure that
we can get the right resources to the right patient
at the right time is going to be very important.

The other interesting take home from this is you can
look at that big dataset that we’re talking about
either by looking at implementations of naloxone or
by looking at call type for overdose. But I’m not
sure what ultimately will give us the best bite at
the apple. You have to look at both. In one case,
looking at the data from hospital discharges, we had
81 cases I showed you from Suffolk County. Of
those, only 79 were ultimately diagnosed with an
opioid overdose at discharge. Two of them looked
like they were appropriate utilizations pre-
hospitally [spelled phonetically] and we went back,
their discharge diagnosis, it turns out, was
actually, in both of those cases, Tylenol overdose.
Unfortunately missed the fact that the Tylenol came
from the Lortab they’d overdosed on. So there will
always be some problems with data entry restricting
how much information we can get out.

DR. FAUL: I just have a quick comment about
the response times. There’s a journal called “Pre-
hospital Emergency Care.” They publish frequently
on response times. It’s sliced up in rural, urban,
suburban categories. That’s been meta-analysis on
it. There’s a lot of variation, as Drew said.

MR. BRASON: Thank you all for your excellent
information. I’m Fred Brason from Project Lazarus.
From a community-based perspective, which is what we
do and Drew, I thank you for your comments, we do a
lot of that community by community by community. We
run across varying degrees of obstacles and issues
and I’d like your comments and thoughts, especially

Dr. Dailey, on working with law enforcement. You
know, even though our state, like in North Carolina,
the EMS director has said, you know, and put forth
training for law enforcement, at the local level we
run into the obstacle where EMS says “It’s our job,
not law enforcement,” and the medical director for
the local EMS will not allow local law enforcement
to carry and to administer. Yet, at the same time
some of those communities, the EMS policy is if
they’re called out on an overdose, they do not go in
the home until law enforcement shows up. So they
could be sitting out front with somebody overdosing
on the other side of the door and until law
enforcement gets there, they do not move. So those
are some of the different dynamics that we come
across and I just wonder from MHECA, how their
perspective might be in sort of opening that door,
either with a standardized training or something
that can allow that community interaction to where,
you know, it is okay for the local deputy to carry
and to administer. And I’m not sure, Dr. Dailey,
how you dealt with some of that in the New York

Communities.

DR. DAWSON: I think one of the opportunities
to do that and I see Dr. Carol Cunningham in queue
here, but one of the opportunities to do that might
be starting with the State Office of Emergency
Medical Services in terms of emphasizing the
importance of that dialogue from the State EMS
Office kind of on down and we’re certainly happy to
have that dialogue with them. The other is, and I’m
sure you’ve done that, but have you approached it
from the standpoint of getting everybody in the same
room at the same time?

MR. BRASON: Absolutely.

DR. DAWSON: I’m sure you have. That hasn’t
-- that’s where the rub has been?

MR. BRASON: Yes. I mean, yeah, we mobilize
everybody because there’s nobody out of the loop but
even still, you know, some come to that conclusion
this is our responsibility and not law enforcement
yet, you know, it’s proven that in many cases,
especially in some of those rural areas, law
enforcement is the first one there.
DR. DAILEY: I think just briefly from the experiences that I've seen in New York, the thing that I would look to the most would be leadership within law enforcement to take this on and have conversations with their medical directors. I've never met medical directors that didn't want to get people breathing and have their heart started. And one of the programs in particular that I can point to is the First Response Defibrillation Program that New York State Police instituted somewhere in the mid-2000s where basically at this point, we've had 200 documented saves by our troopers with their defibrillators. The first one was actually done at the New York State Fair by a trooper named Ross Riley who, unfortunately has since left us, but that element of care at the trooper level has really grown into an interest on the part of leadership in the state police and making sure they're affecting are across the population of people that they're responsible to protect and serve.

And you know, at this point, we've trained 3,200 New York state troopers in the use of naloxone. We've implemented it almost 75 times, I think 72, 73 times, very successfully and it's just one more tool in their toolbox as they're sitting there on the scene waiting for EMS and they've been fantastic participants as have our local sheriffs.

MR. BRASON: Absolutely.

DR. DAILEY: I think just briefly from the experiences that I've seen in New York, the thing that I would look to the most would be leadership within law enforcement to take this on and have conversations with their medical directors. I've never met medical directors that didn't want to get people breathing and have their heart started. And one of the programs in particular that I can point to is the First Response Defibrillation Program that New York State Police instituted somewhere in the mid-2000s where basically at this point, we've had 200 documented saves by our troopers with their defibrillators. The first one was actually done at the New York State Fair by a trooper named Ross Riley who, unfortunately has since left us, but that element of care at the trooper level has really grown into an interest on the part of leadership in the state police and making sure they're affecting are across the population of people that they're responsible to protect and serve.

national Capitol Contracting, LLC
200 N. Glebe Road, Suite 1016 | Arlington, VA 22203
Tel: (703) 243-9696 | Fax: (703) 243-2844
www.nccsite.com

And you know, at this point, we've trained 3,200 New York state troopers in the use of naloxone. We've implemented it almost 75 times, I think 72, 73 times, very successfully and it's just one more tool in their toolbox as they're sitting there on the scene waiting for EMS and they've been fantastic participants as have our local sheriffs.

MR. BRASON: Great. Excellent. Thank you.

DR. BANTA GREEN: Good morning. Caleb Banta Green from the University of Washington. I just want to say an amen in terms of partnering with EMS. We've had terrific relationships with them from a public health and visibility perspective. Also, eyes on the ground, for sure, about what's going on. I do want to share one thing. Naloxone administration is obviously a really important marker and a way to measure overdose. In Seattle, working with Dr. Coffin, we reviewed a lot of charts and what we found was from an ALS and urban area, naloxone was only administered about 62 percent of the time in documented opioid overdose cases. So it's part of the story, but it's not all of it and it also differs by opiate type. The other thing I just want to mention that came up yesterday is this idea of getting people into treatment, and I'm somebody who's worked in treatment and evaluated treatment for two decades and I love treatment, but I think we also need to not pin the success of naloxone about getting people into treatment as the sole measure. One, we're going to fail, and two, it's -- there's some problems with that. One of them is that people say they don't want treatment. Some don't want treatment. They want to keep using. Other people don't want the treatment that's out there. There may not be a good match for them in a lot of different ways so we have a lot of treatment that's failing people and we need to be very mindful about what we're talking about in terms of treatment axis.

Thanks.

DR. MALLEY: Hi. I'm Alex Malley from Massachusetts. This was a great panel. I think sometimes we take our EMS system for granted and it's really important to include it especially when
we think about rural areas and you made that case.

My question’s actually for Nisha Patel about the
recent grant, which I think is fantastic that HRSA has recognized this problem in rural areas. There was a restriction in the grant to allow funds to only be used for FDA approved devices and I think that was reiterated to people who applied to the grant and frankly it has generated difficulty for us, that restriction. So, I think especially Dr. Dailey’s presentation really spoke to the usability and the acceptability of the intranasal device.

Though it is improvised and imperfect it actually is the best fit in some cases as determined by really local and even statewide, you know, medical directors and EMS services for that matter.

So I’d be really interested to hear what HRSA’s view on this requiring an FDA approved device in this grant program and particularly if you guys really thought about the implications of that.

Because when we’re talking about protecting people from needle sticks the only available FDA approved device is the Kaléo auto-injector, which you know,

restrictions with the legislation as well that required that and so we’re looking into that as well. But that is great feedback and something that we are examining.

DR. BANTA GREEN: Great, thank you.

DR. CUNNINGHAM: Carol Cunningham, the Ohio Department of Public Safety. Thanks for a great presentation. Just to highlight some of the statistics that I gave yesterday on -- you know, EMS is really -- they’re going to do the right thing.

We’ve had the basic life support providers go ahead and change their scope of practice so the statistics that we’ve given today have changed significantly.

The national scope model is a model so really the states who are restricted to that were states who adopted that as their scope. Most states adopted it as Drew mentioned, as the floor rather than the ceiling so we’re able to change that.

The second thing that I’d like to mention is, you know, we talk about response times and we talk about having naloxone available. We also have to be cognizant of two things. Number one, naloxone is used for other things. It’s used in hospital emergency departments; it’s used in operating rooms every single day for patients who are not addicted to opiates who have to recover from surgery. Second of all, we have to pair this with an ongoing crisis that we have in drug shortages that happen periodically here in our nation. So as much as we would like to know that naloxone is available for everyone, there are periods of time where it’s not.

In our state -- and I do believe that we’re the only state who has this -- we have within our naloxone legislation it requires that pharmacists and wholesale distributors of naloxone prioritize their supplies to EMS, emergency departments, hospitals, and urgent cares for that reason. It’s not that we don’t want to have it in the community. We actually do but during those times of shortages we want to make sure that the people who are actually delivering emergent care have the naloxone.

And why is that important? Again, I’ve probably drilled it probably how many times in this meeting. It’s so important that anybody who is eligible to
get naloxone have training in CPR and airway management even at the layperson level for those periods of time where naloxone is not available or is not working. And I think when we added that piece of legislation some states kind of raised their eyebrow but on Memorial Day weekend, when the holiday heroin hit Ohio, that legislation helped us significantly.

In Marion county they had within hours 10 opiate overdoses and their local EMS agency ran out of naloxone on a Saturday where you aren't going to get any kind of deliveries over the weekend and through collaboration with our public health and all the other players that we had at the table to make that decision and have that amendment it was a drug rehabilitation center that resupplied my EMS units to get them through the weekend.

And again, a Mike said, the police model is great where they have the AEDs. You would never, ever think of giving someone an AED without ranging that with CPR training. So, you know, I can't hone in enough. I think we have untapped opportunities.

DR. SIMMONS: I'll try. I have a question about liability for EMS providers, primarily basic EMTs who might be carrying naloxone but are not authorized to use it. There's been at least a handful of people -- basic EMTs -- who are not authorized to use it who have gone on the getnaloxonenow.org website, have called me and asked, you know, questions about how to get it. They want -- they did take the training, they want to use it. So what are the liabilities issues?

Also, I was struck by the comment that Fred made about people arriving on the scene and not able to use their skills and their resources like naloxone. So, you know, if -- so just a question about liability and also, you know, we do have, you know, first responder online training that can be used to rapidly, you know, scale up education in rural areas and it's very underused. So I'm open to anyone who wants to discuss that as well. Thank you.

DR. DAWSON: I think the quick answer is that if someone is licensed by their state at whatever level then they are subject to the requirements of that state in terms of what their licensure agency is. So if they're an EMT, a paramedic, a first responder, and they're licensed by their state then they are subject to the requirements of that state. So it's not within their realm to decide to add something to their scope or regardless of whether they received the training or whatever. So they are subject to that and there may be ramifications if they exceed their scope of practice however well intended. If they are not licensed by their state it may be dependent upon the individual states' Good Samaritan laws and so forth. But if they're licensed by the state they're subject to be the state licensing rules and regulations.

DR. SIMMONS: Could I just ask, what if a basic EMS, firefighter, someone, had naloxone and provided it to a family member who was present who then utilized it? Would they be held liable for doing that if a lie was saved as a result?

DR. DAWSON: I think I probably don't want to get into conjecture about a particular case to be
honest with you. I think it’s probably getting into legal limbo there, but --

MS. PATEL: All right, great. Thank you to all of our speakers and I think we’re going to be moving on to our next session as our speakers come up and Mark’s going to be facilitating this one.

Thank you all.

[applause]

DR. PORTER: Hello everybody. Okay, it’s time to start the next panel, please. This panel focused on law enforcement. We have two excellent presenters. Tara Kunkel is going to be our first presenter and it’s on saving lives in new ways. Law enforcement role in preventing overdose deaths.

Presentation – Tara Kunkel

DR. KUNKEL: Good morning and thank you for having me this morning. My name’s Tara Kunkel and I’m actually a visiting fellow at the Department of Justice Bureau of Justice Assistance and I’m going to focus today on the Department of Justice Law Enforcement Naloxone Toolkit and how it came about.

I also want to thank SAMHSA and our public health partners for their participation. So what’s in the toolkit? We brought together about 80 resources from over 30 contributing agencies, primarily law enforcement agencies who had adopted programs. We aim to include samples and templates such as standard operating procedures and training materials that agencies could adopt and incorporate and make their own.

So here’s sort of a view of the online toolkit and those of you that are online today can pull it up while were talking. You’ll see on the left the areas that the expert panel encouraged us to incorporate into the toolkit. We are going to be updating the toolkit in the fall and I’ll make a pitch at the end and I’ll make it now that if you have materials you’d like to see incorporated into the next rollout please send it my way and my contact information will be at the end. We’d love to incorporate it in version two of this. For an agency that knows exactly what they want, say they’re looking for copies of training programs or PowerPoint templates that they can modify and make their own -- they can easily go in and search. If they want a law enforcement agency that’s of a similar size or nature like a state agency versus a tribal agency they can go an actually look by contributor. A lot of people do find that they relate more to agencies of same size or type. If they know they want all the materials from Quincy, Massachusetts they can go and pull out all the Quincy materials. If they know that they want to focus on Podcasts they can search under Podcasts. So it’s pretty user-friendly is somebody doesn’t want to go through and read it all the way through by going through the left side.

One of the things that all of the contributing agencies agree to do is allow other users to modify them as long as they gave them credit. So they can fully download them and incorporate them and be ready to go or make slight tweaks with the permission of the agency, which is great. In terms of accessing the material we’ve made it fully downloadable in its original version and how we’re pushing it out to local, state, and tribal law enforcement agencies. The URL is here at the bottom of the slide and you’ll see it throughout my presentation.

A little over a year ago in February then Attorney General Eric Holder issued a memo to federal law enforcement agencies encouraging them to review their practices and policies to determine the extent to which they needed to incorporate naloxone into their practices. At the same time, we were fielding a number of calls from local, state, and tribal law enforcement agencies who wanted to know what resources were available, what funding was available, so last July we brought together a group of experts. A number of them are in the room today to figure out what we should incorporate into the Law Enforcement Toolkit.

That toolkit was released in October and it’s an online free clearinghouse of information and resources for agencies interested in adopting programs. I’ll let you here review the slide of the law enforcement agencies that were involved in this.
FDA: Exploring Naxolone Uptake and Use

Day 2

so you can actually as opposed to downloading a PDF
and trying to monkey with modifying it can download
it in a Word version or an actual PowerPoint so it’s
easily modifiable. There’s also -- here’s just an
example of the types of materials. For those that
want more of a general education can download a
document like this, “Five Things You Need to Know
About Naloxone to Save Lives.” And it’s all really
target to a law enforcement audience. And this is
one of the most frequently downloaded components of
the actual toolkit. There’s a button in the toolkit
for agencies that are interested in training or
technical assistance. We have made funds available
to meet those needs. So, let’s as an example say
that somebody wants a presenter for a statewide
conference or a national conference. They can just
go and click on the button need assistance or have
questions, make that request and so far we’ve been
able to honor all of the requests for training and
technical assistance that have been submitted.

So I encourage you or any of your partner
agencies who need that type of assistance to make

there. There happens to be a category called
category three that funds community and statewide
programs and within that we’ve had and funded law
enforcement naloxone programs. So if you’re looking
for funding I highlight that one because it’s not
one people would think to look at in terms of
finding resources to fund the programs.

And as I previously mentioned, there’s a
place on the site to submit questions. The most
frequently submitted question to date is around
storage of naloxone in areas where temperatures are
very high or very low or both throughout the year.
So that is the most frequently submitted question to
date so I think we’ll be incorporating much more
information about this in the next version that we
do.

In terms of the toolkit used to date it was
released in late October. We’ve consistently
received on average around 3,000 page views each
month. About a third of the visitors to the toolkit
are returning visitors, which is great. And we get
about approximately 250 PDF downloads or downloads

that request. The focus is on short-term engagement
so we’re not able to fund long-term requests through
this but certainly meetings or one-time engagements
of a speaker or expert coming on site, so far we’ve
been able to meet those requests.

One of the questions that we get through the
toolkit is about funding options for naloxone
programs for law enforcement. We know from speaking
to our expert panel that a lot of the initial
programs have been funded through asset forfeiture
dollars that prosecutors have. A lot of prosecutors
have been willing to provide their funds to support
these programs for law enforcement community groups
so we’re seeing that. There are two federal funding
options available through the Department of Justice.
One is through the Byrne Justice Assistance grants,
which are formula funding to locals and states.
There’s also -- and it’s a lot of people don’t think
to look here but I always try to highlight this in my
presentation -- there’s a solicitation called the
Harold Rogers Prescription Drug Monitoring Program
solicitation. There are multiple categories in
each month and this had been consistent throughout
the release so that’s really exciting. The average
visitor stays a little over 10 minutes on the site
but we’ve certainly seen extremes in each direction.
And if anybody in the audience again has information
to contribute to the toolkit one of the areas we’re
starting to get a lot of questions about are use of
naloxone by corrections officers, and so I think in
the next version we’ll be trying to pull in
additional information that might be geared a little
bit towards that audience in particular. I’m going
to skip that.

We’re in the process currently presenting on
the toolkit at all of the major law enforcement
conferences. I was just at the National Sheriff’s
Association two days ago. We’ll be at American
Probation and Parole in two weeks, IACP -- the
International Association to Chiefs of Police -- so
there’s been a lot of interest in the toolkit and
all of our partner agencies and the major law
enforcement agencies and educational outreach groups
have been very supportive of getting the message out
about the toolkit. And if you have any questions or
comments or materials you’d like to submit my
contact information is here on the slide. So, thank
you.

[applause]

DR. FAUL: Okay, for our next speaker, I’d
like to introduce Robert Childs. He’s the executive
director of the North Carolina Harm Reduction
Coalition.

Presentation - Robert Childs

MR. CHILDS: Well, thank you all for having
me here today. It’s a great honor to be around such
naloxone access legends and great folks here who
invited me to come and talk today. My name’s Robert
Childs. I’m the executive director of North
Carolina Harm Reduction Coalition. We’re the only
comprehensive harm reduction provider in the state
of North Carolina. We do legislative advocacy work
around the south working on naloxone access and
other harm reduction issues. One of the really cool
parts of our program is early on we figured out we
need to engage law enforcement and have them
well as also other members in the state working to
increase access. New Jersey has a lot of programs
in the south; North Carolina has a bunch more since
I last put out this slide. There are a lot of
people doing great work, Massachusetts, Illinois,
but as you can tell mostly right now it’s in the
eastern third of the United States but there’s more
and more programs. Like, by the time I made this
list it was completely obsolete because we have a
bunch more programs. Colorado called me after we
finished making our map and said, “We have two new
programs.” So, there’s programs being added every
day and we try and keep up to date as
possible but, you know, there’s going to be more and
more every single day and that’s what’s been
happening. I make that map basically out of Google
alerts, press releases, and people who contact me so
there may be more programs that I didn’t mention and
I apologize for that. We do the best we can with the
information we can get. But, you know, there’s
a lot of people trying to do the right thing
expanding access to naloxone and having law
involved in each step of the process in expanding
access to naloxone and having them as part of the
solution in overdose prevention. Today I’m going to
talk about law enforcement naloxone programs in the
United States. We’re going to do a little bit of
close up on North Carolina and see how North
Carolina is rolling. We’re going to talk about
their attitudes. We currently run a law enforcement
training program all around North Carolina as well
as in Georgia and some in South Carolina, and I’m
going to talk about some of the attitudes of the
officers towards naloxone. I’m going to talk about
one of the big issues which is EMS and law
enforcement cooperation or making sure we reduce
overdose mortality, and then talk about
implementation of the projects.

So, in the United States today we have about
570ish programs that are operating. Right now there
are several larger programs mostly operating here
you can see them highlighted in red. But we have a
lot in New York and under the great leadership of
Sharon Stancliff in the Harm Reduction Coalition as
enforcement engaged.

Our most successful U.S. program is under
Lieutenant Detective Pat Glynn out of Quincy, Mass.
They’ve had 419 administrations and 402 rescues over
the last several years. When we talked to Pat, he
said like a lot of the times that, you know, that
wasn’t a save or say if somebody came back to life
the person was already had not been breathing for a
very long time. They believe it’s more to do with
that, but when they do get there in time they’re
seeing incredible amount of rescues, which is
fantastic, and he’s a national hero.

Down in Carolina we have a lot of great
leadership on the local level. This is the police
chief of Waynesville who’s worked on getting every
single member of his county to carry naloxone. And
we’re hoping to roll that out. They currently have
all their naloxone and we’re hoping that they deploy
this month. We have programs all over the state.
We only started in 2013. And right now we have
about 17 departments but we have 29 that are
planning on starting by the end of the year. We
work on training them, talking to them, and making
sure that they have the resources they need in order
to implement programs and also that they can develop
EMS cooperation so that they can get good programs.
Some departments such as Fayetteville, that you can
see here, Chief Harold Medlock that led the
department, they were able to get that program up
and running in about a month which was fantastic and
they had a reversal within one month. They had one
more last night and they had one more this morning.
So the program is working like butter. We're really
excited about that.

In Greenville there was some heroin that was
laced with fentanyl. They had four overdoses that
we reversed by law enforcement. They recently
started their program and they got to use it and
it was fantastic they're able to do so. So it's
really great. As for attitudes in Carolina, for
North Carolina law enforcement we found that 98
percent of law enforcement wants to carry naloxone.
Eight-eight pretty much 89 percent of law
enforcement think, that all their peers should carry

As for who should carry naloxone, there's a
lot of -- we've seen nationally a lot of battles
between EMS and law enforcement. It basically comes
down to who, you know, who should be carrying it.
It should be ideally everyone should be carrying it
if you're responding to emergency situations in

places which your resource, you may not have as many
resources such as the American south and rural
America.

You know, you may want to prioritize who
shows up first. On a regular basis in some places
it may be law enforcement, in some places it may be
fire. Paramedics should always carry it. First
responders who hopefully always carry it. But, you
know, it's really -- it's about saving lives, right?
If we're here to save lives we should give people
the tools so they can do it, right? The reason why
most people got into law enforcement is to help
their community, increase public safety, and support
its families, right? And they can't do that if they
don't have these tools. And you know, that's
something we really support.

But the most important group that isn't
identified in those slots up there are people who
use drugs and family members because those are the
folks who are going to be at the scene. And in
North Carolina it can take 22 minutes for EMS and
law enforcement to show up. You know, we need

naloxone. So, they not only want to carry it
themselves, they want their peers to also carry it.
And 95 percent think Good Samaritan laws and
naloxone laws will reduce drug overdose deaths,
which is fantastic. They buy into the laws, they
love the laws, and they encourage their peers in
other states to buy into these laws, which has been
fantastic because once you train these individuals
they get pumped about a locked zone. They get
pumped about naloxone, they get pumped about Good
Samaritan laws, and they have helped us advocate in
other states to help pass such laws, which is
fantastic.

One really important thing is EMS and law
enforcement cooperation; as been identified
sometimes that's the biggest trouble. In North
Carolina we're blessed. We have an amazing
gentleman whose name is James "Tripp" Winslow who is
the head of EMS who early on saying, "All law
enforcement and EMS should work together to expand
law enforcement naloxone programs in North
Carolina." He quotes, "Allowing law enforcement to

If we're here to save lives we should give people
the tools so they can do it, right? The reason why
most people got into law enforcement is to help
their community, increase public safety, and support
its families, right? And they can't do that if they
don't have these tools. And you know, that's
something we really support.

But the most important group that isn't
identified in those slots up there are people who
use drugs and family members because those are the
folks who are going to be at the scene. And in
North Carolina it can take 22 minutes for EMS and
law enforcement to show up. You know, we need

naloxone. So, they not only want to carry it
themselves, they want their peers to also carry it.
And 95 percent think Good Samaritan laws and
naloxone laws will reduce drug overdose deaths,
which is fantastic. They buy into the laws, they
love the laws, and they encourage their peers in
other states to buy into these laws, which has been
fantastic because once you train these individuals
they get pumped about a locked zone. They get
pumped about naloxone, they get pumped about Good
Samaritan laws, and they have helped us advocate in
other states to help pass such laws, which is
fantastic.

One really important thing is EMS and law
enforcement cooperation; as been identified
sometimes that's the biggest trouble. In North
Carolina we're blessed. We have an amazing
gentleman whose name is James "Tripp" Winslow who is
the head of EMS who early on saying, "All law
enforcement and EMS should work together to expand
law enforcement naloxone programs in North
Carolina." He quotes, "Allowing law enforcement to

person who uses drugs to be able to have it. In North Carolina, our program, North Carolina Harm Reduction Coalition, makes sure that people who use drugs, people on methadone, and the people who love then have access to naloxone. We’ve had 600 rescues over the last two years because we’ve been making sure they get it which is extremely important.

As for implementation, for the keys to success people need accurate information. I’m so glad that the toolkit is now available. It’s utterly important that people be able to get it. They also need statewide OEMS support and local EMS support. It’s going to be really difficult for them to run these programs if they don’t have it. In North Carolina, again, we’re blessed with Tripp Winslow who has issued a statement proclaiming saying all EMS should support it. He had me come in and talk to all the EMS directors to talk to them why it’s important for law enforcement to carry it which is fantastic.

They need access to sample trainings and policies and forums. North Carolina our group provides that to them and they also have access to a national toolkit, which is excellent, and we’ll actually write it for them so they can easily implement it without a problem. They need access to their peers. So say for example what we’ve done in North Carolina is we have a peer-to-peer training program. So we have a couple awesome hot cops who go out of their way to do amazing things. We have some in Fayetteville, we have some in Waynesville, we have some in Carrboro, we have some in Pitt County, and they all help each other out and problem shoot and will help other members out to problem shoot. There are a lot of super committed members of law enforcement who really want to see everybody in their community served with dignity and they also want to make sure that they have comprehensive overdose prevention plans. They’re willing to share that information for free just because we’re trying to help reduce overdose mentality and it’s utterly fantastic that they’re there and they have a support system for each other and each state and community needs to do that.

You need buy in from the upper levels of law enforcement. If you don’t have your command staff and your captain and your chief all bought in, it’s going to be extremely difficult to move these programs. And you also need sample contracts of partnerships with the city and state if that’s required in your region. We’ve made a couple available to members in North Carolina so they have that. Some of the other keys to success are to share your success: Press releases, informing your peers. I can’t update the national list if you don’t put out a press release because I will never know that you started a program. Also, identifying a storage plan for your naloxone at end of shifts is incredibly important. You need a media campaign, you need the willingness to all the community to call 911 in the first place otherwise you’re not going to get to use naloxone, so it’s really important to have Good Samaritan laws especially those that provide immunity from arrest and charge. In North Carolina we only have immunity from prosecution which means you could still be arrested and charged and we’re seeing laws -- Cory Davis does an amazing job of talking about what’s going on nationally, but you really need those other immunities so people aren’t afraid to call 911. And you also need to partner with harm production programs in order to find out, you know, how to order naloxone, potentially, how to put out the word. Our organization goes and talks to them about how Fayetteville police, you know, in North Carolina, they’re carrying naloxone and looking to help out. They’re not going to be prioritizing arresting. They want to help people and as we conceived in the last months they’ve had three rescues, two of which in the last 24 hours because we’ve been putting up signs at methadone clinics and talking to people who use drugs about they’re trying to, you know, do the right things in those situations. But if you’re not comfortable talking...
to law enforcement, calling 911 we’re going to give
you naloxone just in case, right? So it’s important
to do both.

Some of the barriers are the pricing of
naloxone. It can be expensive especially for larger
departments. We also see that, you know, we have to
be creative sometimes in how we acquire it for the
departments but it’s really important that they be
able to afford naloxone if they want to do these
programs. And also one of the barriers is we -- in
North Carolina we have a lot of law enforcement who
want to use syringe-based naloxone because it’s
cheaper but they don’t have access to it and are not
allowed to carry it according the OEMS, so that’s
been a barrier.

We have some rogue rebels who’ve done it
anyway, but the majority do not do that. We also
have sometimes there’s a lack of buy in from upper
levels of law enforcement if the lower levels of law
enforcement want it and that is what it is. So the
other barriers are concerns of liability. The
amazing Corey Davis and legal research team did a

study to find how many people are being sued over
these matters and they found an amazing zero. So,
even though that’s one of the largest, you know,
questions that’s being put out is like, “am I going
to be liable,” there’s been zero grounds we can find
that that would be an actual circumstance. Weak
Good Samaritan law or no Good Samaritan law: So in
South Carolina we were able to work with some
advocates on the ground and pass a naloxone law but
we were not able to get a Good Samaritan law passed
and so people may be afraid to call 911. When I say
may, they are afraid to call 911 [laughs]. And also
an access to an MD willing to write a standing
order. These are all really important things.

Some of the resources that are out there we
saw about the Bureau of Justice document, Corey
Davis, Carr, Southwell, and Beletsky just did this
amazing paper on engaging law enforcement in
overdose prevention initiatives. If you’re
interested in this issue this is mandatory reading.
It’s bloody fantastic. Also, our agency has law
enforcement resources. If you’re also looking for

some videos on law enforcement talking about
naloxone, we have a lot of southern officers who we
put on video and you can access it there and you can
look it up and get those videos. I’m happy to share
any of them. If any of you need southern officers
to come and talk about the benefits of naloxone from
a southern perspective we have a speakers bureau of
law enforcement. We also have law enforcement who
have overdosed and can talk about it. We have law
enforcement who have chronic pain and can talk about
why it’s important to have naloxone. It’s really
important.

But what I did want to end this on which I
think it really important, is it’s really good that
law enforcement have access to naloxone. It’s
really good that EMS has access to naloxone, it’s
really good that fire have access to naloxone. But
the really important group of people that needs it
just as much are people who use drugs and people who
are on the ground around those people using drugs.
Because those are going to be the first responders
in a lot of circumstances and they can reverse the

drug overdoses instantly, which would be fantastic
if we had more universal policies to allow that to
occur. But with that, thank you for your time.
[applause]

DR. PAUL: Okay, we’re running on time. We
have 15 minutes for questions.

DR. STANCLIFF: I just need to add an
amendment. Thank you for the acknowledgement. We
also have the New York State Department of Health
Val White here, and Michael Dailey here from Albany
Med. We work totally closely with them as well as
the division of criminal justice services. Thank
you.

DR. RUIZ: Good morning, I’m Sarah Ruiz.
Massachusetts Department of Public Health, Bureau of
Substance Abuse Services. Thank you both Tara and
Robert. We have a similar experience in
Massachusetts to what Robert, you were just
discussing. I wanted to mention to Tara in
particular that I didn’t see when you talked about
resources and funding opportunities any mention of
public health departments. We actually have been
the full funders of the Quincy Police Department
since 2010. That doesn’t often get mentioned. I’m
always like “okay, you know we funded that, we
provided the medical direction and the oversight
since 2010,” we also -- and other departments -- not
just Quincy. We have other police departments that
were early on in our pilot phase.

Since then, since last year, we’ve had a
public health funded grant program in Massachusetts
in which we’re doing funding for 23 municipalities
and we’re ramping up and that’s also, you know,
state funding and public health funding. So that’s
definitely a resource that should be mentioned and
one that it’s possibly available in other states but
also it fosters that public health/law enforcement
partnership which has been just so valuable to us
for just coming together. There’s been a lot of
mention of coming together at the table with both,
with EMS, law enforcement, public health, and that
through our pilot program, through our community
funding, and through our now grant program that
really fosters those partnerships. I wanted to also
mention that the questions about -- EMS concern
about law enforcement starting up and really in
Massachusetts we basically just worked directly with
law enforcement in the beginning, you know?

It wasn’t intentional really, it’s just that
we wanted to equip law enforcement and we equipped
law enforcement and through, over time we -- our
collaboration with EMS grew and that is now a strong
collaboration but in some ways it can be just
started with public health advocates, with a medical
director and law enforcement, and if EMS objects,
you know, over time they come around through a pilot
program, through partnership, and that’s how it’s
worked in Massachusetts in terms of now being fully
adopted in the regulations.

It’s been a step-by-step process but starting
with pilot programs and just doing it. So I just
courage you to include that going forward and
that’s it, thank you.

DR. KUNKEL: Point well taken, thank you.
DR. EISENBERG: My name is Richie Eisenberg
from New York State Psychiatric Institute. I have a

question for Tara. Does the current or the future
toolkit plan on having the Good Samaritan law
included?

DR. KUNKEL: There is a section on Good
Samaritan laws and I think we’ll probably
incorporate -- NAMSDL recently wrote a model Good
Samaritan law. We’ll probably be incorporating
additional resources in that area.

DR. EISENBERG: Okay, thanks.
DR. KUNKEL: Yes.

DR. JONES: Steve Jones. You know, there’s a
tendency for people to -- or for public actions to
emphasize first responders and fund first
responders. And I think I totally agree with you,
Robert, it’s absolutely wonderful that the police
and fire and anybody else who may show up on the
scene of an overdose, that they’re equipped with
naloxone is a wonderful, wonderful thing. I think
however, that in this situation where there’s this
tremendous emphasis on first responders, in part
maybe because people are uncomfortable with
providing drug users with naloxone, it’s important
to get the data on how long it takes for those first
responders to get to the scene, because that will
underline that fact that even though it’s wonderful
that they have naloxone in their pockets there’s
still a delay and there’s still an increased risk of
a bad outcome. Thanks.

[applause]

DR. FAUL: Thank you. Are there any more
questions? All right. I’ve been asked to tell
everybody to sign up for lunch. Pre order that
would be helpful. And also that it’s break time.
We’ll re-adjourn at ten after 10:00. Thank you so
much.

DR. FAUL: Okay, let’s get started. I’m
Jennifer Fan from SAMHSA and I’ll be moderating this
panel on bringing new products to market. This
panel will be covering two intranasal products from
two companies as well as we’ll have a speaker from
FDA on the regulatory process for Rx to OTC switch
as well as the community perspective from Prevention
Point Pittsburgh.

Let me introduce the first speaker. Our
first speaker is Seamus Mulligan. He’s the chairman
and CEO of Adapt Pharma.

Presentation - Seamus Mulligan

MR. MULLIGAN: Thank you very much, Jennifer.
Good morning again, ladies and gentlemen, and thank
you for joining us here today and I must again
extend my thanks to the FDA for the invitation to
this conference. My name is Seamus Mulligan and I’m
the chairman and CEO of Adapt Pharma. You’ve all
had your disclosure note -- slide at the front of
your presentation. I suppose I should put my one up
here. I’m a pharmaceutical executive and as such
maybe I should wear an "X" on my back here for the
presentation.

[laughter]

But, you know, today Adapt Pharma is a
business whose sole focus is the development and
commercialization and distribution of a novel
naloxone spray. That commitment is evidenced by our
submission in May of this year of a rolling NDA to
the Food and Drug Administration. At Adapt, our
goal is to develop and easy to administer nasal

as many people as possible.
So many voices and groups are calling for the
wider availability and distribution of naloxone, an
elements that we heard yesterday ranging from HHS,
the American Medical Association, and a broad range
of community groups many of you represented here.
So that evidence shows the growing consensus towards
broader availability and distribution. Now,
interestingly -- and we’ve had a lot of data
presented over the last day and a half -- but I was
surprised I didn’t see something related to this;
Where does the death related overdose occur? In our
evaluation of the data we would estimate that
approximately 77 percent of opioid overdose related
deaths happen outside of medical settings. And
critically, 56 percent of opioid overdose related
deaths happen at home.

Now, this startling statistic actually, for
us really is one of the drivers and guides towards
the development of an effective and easy to use
naloxone administration that can be administered by
non-medical personnel in homes and communities

spray formulation of naloxone that’s accessible to a
broad group of patients and people all over the U.S.
We understand that this is a public health crisis
and that public and private entities need to work
together to address this crisis. Now we know that
HHS and other stakeholders have developed many
initiatives in the area to respond to the crisis and
we’ve listened to a lot of the -- of this --
activity yesterday and earlier today and recently
we’ve seen the announcement from HHS on the three-
pronged strategy including expanded use and
distribution of naloxone. Now, I’m going to state
the obvious, naloxone is established as a gold
standard treatment for the last almost 45 years.
However today the only approved -- FDA approved --
presentation is an injectable presentation. No
matter how we want to look at it that is the only
approved presentation. And it does, as we’ve heard
this morning, cause problems because of that. We
believe that the availability of non-injectable
forms of naloxone is an important component for
supporting broader availability and distribution to
across the country. So what are we doing? We know
the problem. What are we doing as a private company
towards providing a solution or contribution to the
solution? Well, today as a business whose sole
focus is the development of a treatment option in
this area, we have collaborated with NIDA with the
goal of developing a naloxone nasal spray that would
be effective as a treatment option and that could be
used by non-medically trained personnel outside of a
health care setting.

I’ll get to a bit more about the product, how
it works, and how -- and what it does, and the
following slides will describe the product. But let
me just, at the outset say we are currently the
subject of review with the FDA and as such the
information presented is for informational purposes
only. Now, based on my comments earlier about
access, ease of use in a non-medical setting we had
select criteria for the product. These included a
single spray device that could be administered
easily in a supine position, a low spray volume
0.1mL. We heard problems of delivering 1mL up each
narial. We’re looking for a very low spray volume.

0.1mL. No assembly, no priming, and that it was
portable. Effectiveness obviously is critical and
that means appropriate dose selection, time to onset
must be comparable to I.M., drug exposure must be
comparable to I.M., and without any new AEs being
seen.

So, what is the manifestation of these
various laudable objectives? Well today we’ve
announced the acquisition of the Narcan NDA and the
Narcan brand name. So Adapt Pharma has acquired the
rights to that name. We would -- we propose to
apply to the FDA to use that as our product name,
Narcan Nasal Spray? And why do you think that’s
important? Well, Narcan has very high brand
Awareness. You all know naloxone but if you search
on the internet you find -- or look at the
search records on the internet you will find that 50
percent of the searches are under the name Narcan
equally as they are naloxone, so we think it’s
important if we’re trying to drive broad access to
have something that has a high brand awareness.

Now, I have described the technology, I’ve
told you about the product, the brand, and the status.
What about the data behind the product? Today we
will announce and present some of the summaries of
the key studies conducted. As I mentioned earlier,
please keep in mind that these studies have been
submitted to the FDA as part of our rolling
submission but have not yet been the subject of
review or approval. Therefore, at all times this
data must be considered experimental. You can
assume I paid some high priced lawyer to get those
words right before I came here this morning. Now
the studies include two P.K. studies, or
pharmacokinetic studies, comparing doses ranging
from 2 to 4 -- 2 to 8mg of naloxone in 0.1mL nasal
spray compared to the reference of 0.4mg I.M.

naloxxone. Additionally, three studies designed to
study label comprehension and finally, the building
blocks of any NDA, the characterization studies
required to seek approval. These are the boring
bits none of you like to hear about but they have to
be done.

Now, the human use and comprehension study --
very important. Three studies we had with a total
of 175 patients. Importantly, in these studies
there was prior product training provided. We
studied every day Americans. Young adults,
juveniles, individuals with low literacy scores, et
cetera. We included stress simulations into the
program and also we look to the critical steps of
simulated dosing and the secondary steps which we
heard about earlier today of calling for medical
help. The end points were met concerning ease of
administration with over 90 percent successfully
administering Narcan nasal spray without
training. These studies are important when
considering the use of such products in non-medical
delivered effectively and your dose is done. The
mist is fine, there’s no amount of going down the
back of your throat. So it’s quick and effective
and a small volume. That by the way was a placebo,
water.

So, that’s the product concept and the
technology. What about the time line? Well, we’re
working with the Food and Drug Administration. We
have our NDA rolling submission filed; we have
received fast track designation. We will complete
the NDA filing very shortly and we would hope to be
approved and on the market later this year.

Again, I bring you back to my comment
earlier. This is our sole focus. We do nothing
else in life. Every day we wake up we work hard to
get this thing approved and out there and
distributed. The team at Adapt Pharma, including
myself, have many years’ experience in the
pharmaceutical industry and more importantly in the
drug delivery section of that industry. We expect
to leverage that to make sure we can get approved
and distributed as quick as possible.

So on the right you will see how the device
works. I don’t know if the video actually is
showing you but it’s a picture of how the device
works easily and simply. And I have one here as
well. I’m just going to show you how it actuates.
So show and tell is always a good way. One simple
actuation, easy to use, and that’s it. 0.1mL
delivered effectively and your dose is done. The
mist is fine, there’s no amount of going down the
back of your throat. So it’s quick and effective
and a small volume. That by the way was a placebo,
waters.
settings. I’m pleased to also report the data we developed in our pivotal clinical trials comparing Narcan nasal spray to 0.4mg in I.M. show the following results. The time to maximum concentration, or the T-Max for those kineticists in the room, was similar for nasal and I.M. T-Max was the same. And Narcan nasal spray plasma levels exceeded the 0.4mg peak plasma levels for over two hours. So, the nasal spray kept the drug levels about the profile of the I.M. for over two hours.

Data suggests that the comparative bioavailability of the nasal formulation based on our studies was about 50 percent relative to the I.M. And finally, the data would suggest that there are no new adverse events seen in the study. We expect, by the way, to include of a final dose selection of Narcan nasal spray within the initial dose range within the I.M., but again that is all subject to FDA review.

So, in conclusion, I’m excited to support broader availability and access and distribution of naloxone through the launch of Narcan nasal spray rapidly post FDA approval and in

the expertise in the room. I’m really humbled to be here today. This is something that I have a lot of passion for and our company does as well.

So my name is Steve Hebert, I’m the global therapy leader for Indivior for the rescue medications portfolio that we have. Basically, my job is to commercialize our intranasal naloxone, so, you know, this is obviously very important to me.

I’m going to share with you a little bit about Indivior for those of you who don’t -- who’ve never heard of us. Our mission -- this is a company I’m incredibly proud to work for first of all -- our mission is to transform the lives of people who are suffering from the chronic relapsing disease of addiction and their co-morbidities. And our name it comes from the combination of the word “individual” and “endeavor” and it’s really about understanding the challenges of the individual patient and to normalize addiction, to break through the barriers of stigma associated with this to normalize and medicalize the treatment of addiction and to help patients on their treatment journey. And you know, that we expect to focus on current users and distributors. We also expect to look at their friends and family and others that may witness an opioid overdose. We wish to collaborate with a range of public and private stakeholders to address the major challenges associated with distribution.

Let us not forget reimbursement is a critical issue.

And finally, we would price Narcan nasal spray responsibly to facilitate this broad access.

The net result at the end of this process we believe will help deliver the common goal of treating opioid overdoses with an effective and easy to use formulation of naloxone with Narcan nasal spray. Thank you very much.

[applause]

DR. FAN: Okay, thank you, Seamus. Our next speaker is Stephen Hebert from Indivior and he will talk about his -- Indivior’s intranasal naloxone product.

Presentation: Stephen Hebert

MR. HEBERT: Good morning, thank you very much for having us here today and thank you for all
FDA: Exploring Naxolone Uptake and Use

know, really grew so much in the past 15 years that it made sense, you know, with the overall perspective of the company to spin us out and to have the right investors, you know, the ones who are aligned with that we’re doing from our patient focus and from our risk and reward profile to be investing in the business. So we were spun out in December. We’re our own, separate company. We’re solely focused on treating addiction and its co-morbidities so that’s our mission. We’re a global company. We have over 700 employees. We have a pretty substantial commercial infrastructure and it’s really come from we’re the people who make Suboxone. So, there’s over 5 million patients treated with Suboxone today and really, you know, even before I started at the company I looked at it and I was like, I look at what Indivior has done in normalizing the treatment of addiction. It’s really should be a case study in how we can take a fragmented disease space which I think is very applicable to overdose as well and to bring together different types of stakeholders and patient advocacy groups and to really medicalize and normalize treatment. So, we’re very proud of this and I guess I would say too that, you know, over the last day, you know, I’ve heard so many great speakers. This is such a tremendous conference and, you know, when we think about the community groups and the harm reduction groups and all of the work that’s being done by the clinical folks in generating data and whatnot that we’ve heard about over the last few days and the advocacy groups, the thing that seems striking to me that’s missing is a partner in industry, you know? We have a -- bring a unique experience to the table where we can go out and educate physicians, we can go out and educate pharmacists and patients alike. We have the reach, we have a sales force, we have a medical group that goes out and does this. We can change the mind-set and create awareness around overdose and then to arm them with the right products to be able to do something about it. So I guess that’s one of the messages I want to leave you here today is that you’re not longer lacking a partner in industry.

So, I -- you know, we’ve been through the growing epidemic, you guys are all familiar with this. I mean 260 million opiate prescriptions for 50 million Americans. This is a staggering number. I mean this is 15 percent of the population. Twenty-five thousand opiate overdose deaths, I mean, combination of heroin and pain prescriptions. We’ve talked about this at length, but what we haven’t talked about I guess is the fact that this is not just a U.S. problem. This is a global problem. There -- according to the World Health Organization -- there -- on -- every year there’s 69,000 fatal overdoses worldwide. Now that’s important and particularly from our perspective of Indivior as a global company we are not looking at this just solely on the U.S. And I would say that, you know, we’re doing things in Europe right now. We just filed at the request of the French regulatory agency, the ANSM, and the French Ministry of Health, we filed a temporary use authorization application for our intranasal naloxone product to be used in France. If all goes according to plan we would expect then this to be available in the fall in France.

And now we’re targeting patients in those groups that are prison release. We’re targeting folks who are in addiction centers -- who are being released from addiction centers -- so these are people who are at high risk of opiate overdose. And we’re going to be -- we’ve talked about data over the last couple days -- we’re going to be tracking these patients generating data. This will be 5,000 patients or so that we’re going to be looking at. So, big developments both internationally as well.

Now, as we’ve all talked about the tragedy of this whole thing is when you put all these numbers together is that naloxone is highly effective. It’s been around since 1971 but it’s not available when and where it’s needed most. So, what if there was an alternative available that could be accessed by non-healthcare professionals anywhere at any time? Rally the lay people and that’s what we’re been talking about.
Now, our device looks similar to yours.

[laughter]

MR. MULLIGAN: I love competition.
[laughter]

MR. HERBERT: But I'd say that speaks to the simplicity of the device and I think that should resonate well with everyone here too. This is a simple and easy to use device and it can be accessed and used by anyone. I think that's important. And you know, and we've mentioned it before about keeping costs down and those types of things so if we can make it accessible and available to everyone I think that's important, and it's in everybody's best interest too to have multiple competitors. It's in everybody's best interest to have more companies out there not only from a pricing perspective but also from a supply perspective. Making sure that there are no out of stocks anymore, that we can help mitigate these types of things. So, I want to talk just real briefly about the co-development of this. This was originally co-developed with a small company called AntiOp out of the University of Kentucky founded by Dr. Dan Wermeling who's over in the audience today in collaboration with NIDA as well. So, I'd like to take this opportunity to thank both NIDA and AntiOp for their foresight and their vision in this and getting us to where we are today. So, what is -- what's so special about this product? And again, I know, Seamus talked about some of these attributes but the, it's a device-drug combo. It's needle-free. I mean, we've done research with patients in physicians alike, particularly patients. I mean -- they don't want to use needles. And even intravenous drug users don't want to use needles in these situations so, you know, having those barriers eliminated from a product perspective is very important. Ready to use. You know, we mentioned too the 0.1, you know, the 100 microliter volume that's formulated for your nose, so -- and then compact and portable.

I would throw another attribute up there. I know this is a lightning rod for this discussion but we can talk about this more as we go along, is that it needs to be affordable and we understand that.

And that's going to create access for everyone and that's really at the heart of what we're about.

For us, we submitted the complete NDA in May, so if all goes according to plan and there's a priority review and we're successful in obtaining approval for this product we would expect to be on the market as early as January. So, we've very excited about this and, you know, we're doing all of the work right now to launch the product. We're, you know, doing all of the education work. We're preparing our programs to go out to pharmacists and to physicians and this is going to be a big effort for us.

I mentioned before -- I'm going to switch gears just a little bit very quickly to just talk about what our vision is for the product -- you know, our mission being the treatment of addiction and really having that patient focus. Well, you take a product now that can actually save a life. You put that together. We've set as a company goal to reduce overdose deaths by 50 percent and I, you know, I'm sure there's a lot of people in the room that say that's not achievable but we believe that, you know, we shouldn't be timid about this. That we should be setting high goals for ourselves to obtain. Now we've gone to our board of directors with this and we're going to be measured on the outcome of this. So we're starting to think about community programs that we can develop that are going to facilitate the reduction of opiate overdose deaths by 50 percent.

Now, I'll talk about that a little bit more in just a second, but our vision for the product is that everyone understands the risks of opiate overdose and embraces their community responsibility and personal role in potentially saving a life from opiate overdose. People have to have that call to action and understand how to use it.

I'm going to jump through this real quick, but the basic idea behind this right now is, we all know that the treatment of opiate overdose today is, largely, reactive. It's in emergency rooms and ambulances, and other places like that. There's a
So, Indivior will work with communities. I want to work through the health care system that exists today, because there is no awareness in the general public, or very low awareness in the general public, about the risks of opiate overdose. And in -- I’ll tell you what -- not only patients, but physicians themselves have never heard of naloxone. If they’ve heard about it, they remember it from medical school, but they get it confused with Suboxone, or Naltrexone, or these other things. So, you know, it’s -- we’ve got a lot of education to do, and if this were to go OTC tomorrow, I think we’d find that this would not be as effective as some of the -- some of the people who are advocating for that might think.

So, working through the health care system is important. Just real quickly, where are the overdoses in the United States? This is a little outdated, but I wanted to show this. The hot spots there, the dark red areas are where opiate overdose deaths are at their highest. This is from 2006 to 2010. What we see here is that, while this is a national problem, it’s a community by community phenomenon. And we have to understand it at the community level, to really -- to really do something about this. Now, we’ve gone through, and we’ve looked at -- this is very top line, but we’ve looked at different counties. The United States has about 3,000 counties in it. There are 250 counties that account for about two-thirds of all the overdoses.

Now, we’ve gone through the coroner data, and we’ve tried to do this on a top line basis, just trying to understand the socioeconomics of what’s happening, and to try and do a geographic segmentation, so that, ultimately, we can have a program in a box that can be rolled out to different communities depending on what’s going on in those communities:

Who’s overdosing, how they’re overdosing, and how can we best address it? And I’ll give an example of the rural, poor areas, you know, in the -- in the Appalachian areas, and in the -- in the Rust Belt.

You know, the overdoses there are largely driven by prescription medications. It’s a high Medicaid population. Is there an opportunity now, to work with Medicaid? Is there an opportunity to work with pharmacies, to come up with a pharmacy program, to really reduce opiate overdose deaths in those areas?

Similarly, when you look at Baltimore, or some of the urban areas, heroin is the driver there. And what you see is that, you know, when we talk to a group called Staying Alive that’s part of the Baltimore Department of Public Health, or sponsored by the Department of Health there. That they were telling us that the overdoses that are happening in public places. They’re happening in abandoned houses. These folks are using heroin together. So, can we have -- we -- there -- that’s an opportunity, again, as some of you know, from examples in your areas, to arm them with naloxone, and to train them. Okay.

So, this is -- this is my last two slides. So, Indivior will work with communities. I want to work through the health care system that exists today, because there is no awareness in the general public, or very low awareness in the general public, about the risks of opiate overdose. And in -- I’ll tell you what -- not only patients, but physicians themselves have never heard of naloxone. If they’ve heard about it, they remember it from medical school, but they get it confused with Suboxone, or Naltrexone, or these other things. So, you know, it’s -- we’ve got a lot of education to do, and if this were to go OTC tomorrow, I think we’d find that this would not be as effective as some of the -- some of the people who are advocating for that might think.

So, working through the health care system is important. Just real quickly, where are the overdoses in the United States? This is a little outdated, but I wanted to show this. The hot spots there, the dark red areas are where opiate overdose deaths are at their highest. This is from 2006 to 2010. What we see here is that, while this is a national problem, it’s a community by community phenomenon. And we have to understand it at the community level, to really -- to really do something about this. Now, we’ve gone through, and we’ve looked at -- this is very top line, but we’ve looked at different counties. The United States has about 3,000 counties in it. There are 250 counties that account for about two-thirds of all the overdoses.

Now, we’ve gone through the coroner data, and we’ve tried to do this on a top line basis, just trying to understand the socioeconomics of what’s happening, and to try and do a geographic segmentation, so that, ultimately, we can have a program in a box that can be rolled out to different communities depending on what’s going on in those communities:

Who’s overdosing, how they’re overdosing, and how can we best address it? And I’ll give an example of the rural, poor areas, you know, in the -- in the Appalachian areas, and in the -- in the Rust Belt.
FDA: Exploring Naxolone Uptake and Use

So, together, we can reduce opiate overdose deaths. And at the end of the day, nobody should lose their lives from an opiate overdose death. So, that’s my talk, and I’d just like to say, thank you for having me. Cheers.

[applause]

DR. FAN: Thank you, Stephen. Our next speaker is Dr. Theresa Michele from the FDA.
So, once you’ve identified a drug that you want to consider for an OTC switch, what sort of development program is required for the change? So, the first step in any program is typically to establish the safety and efficacy through clinical trials. And since OTC switch products typically have many years of prescription marketing prior to consideration of the switch, they often rely on the safety and efficacy established for the prescription product, unless, of course, there’s a new OTC indication or a new patient population. Now, in the case of naloxone, since the indication would likely be the same in the OTC as in the prescription setting, additional clinical trials may not be required.

The biggest step, however, in establishing a product as safe for OTC use is translating that prescription label into consumer-friendly language and then testing whether consumers can actually use the product correctly and safely without the advice of a health care professional or without some special training program. Now, remember that that includes correct self-diagnosis, self-treatment, and self-management of the condition. This is why most over-the-counter products actually treat symptomatic conditions that are easily recognized by the consumer.

So, at FDA, when we look at switch programs, usually our first step is to consider what’s in the prescription label and ask the question, “What key messages are there that consumers need to understand?” A good place to start is the indication, dosing, contraindications, and the warnings and precautions section of the label. So, by way of example, I went through this exercise, looking at the prescription label for EVZIO. Now, please remember that this is an example only. It’s not intended to cover every issue that OTC development would potentially need to address.

So, first, the consumer must be able to correctly diagnose opioid overdose and recognize that naloxone would not be beneficial in other kinds of overdose. And also, to differentiate overdose conditions from therapeutic use of narcotic analgesics. Secondly, the consumer program would have to factor in that naloxone would most likely be used by a caretaker, a family member, or a bystander, rather than by the person experiencing the overdose. Another important, if not probably the most important issue, is that naloxone users would have to understand that the duration of naloxone effect is shorter than the duration of the opioid effect. And so, they must seek emergency medical care immediately, and that additional doses may be needed. In other words, consumers must understand that naloxone is not a substitute for medical care.

So, given that naloxone can’t be administered orally, dosing and correct use of the drug delivery device – be that an auto-injector, a nasal inhaler, or any other delivery mechanism – is key. Other issues include potential precipitation of severe opioid withdrawal, the need to monitor for cardiovascular effects, and also, for possible aspiration. Understanding that this may have limited efficacy with partial or mixed agonists, and that naloxone is contraindicated in persons who are allergic to it.

So, once you’ve thought about all of these issues to be addressed in an OTC development program, and you’ve written a consumer label to address the issues, the next step is to test how well consumers do using your label. In the OTC world, rather than randomize clinical trials, these issues are tested in consumer studies. So, this slide outlines the various types of consumer studies that FDA may request and what they assess. Label comprehension studies, which are the foundation of any OTC development program, are open-labeled, uncontrolled tests of consumer understanding of the drug facts label. These tests frequently involve 300 to 600 subjects, including subjects of low literacy, and often require an iterative approach of testing label revisions, and then retesting of key communications objectives. Self-selection studies assess consumer decision-making beyond label comprehension using an individual end point of the consumer’s decision of self-management of the condition. This is why most over-the-counter products actually treat symptomatic conditions that are easily recognized by the consumer.
whether or not the drug would be appropriate to use, based on the medical situation. These typically include 400 to 800 subjects. Actual use studies are clinical trials that are most often self-reported, open-label studies of safe use including 500 to 1,300 subjects. The majority of these, the primary end point focuses on rates of misuse and then explores why failures or misuse occur. Finally, human factor studies evaluate the interaction between the consumer and a device or other technology by evaluating the consumer’s ability to use the device directly, with the directions provided on the drug facts label. Now, the focus here is on the risk associated with observed errors. Each switch program is different, and not all studies are needed for every switch.

So, let’s see what this might look like, for naloxone. I laid this slide out just by way of example. Again, each product is unique, and this doesn’t necessarily apply in all situations, or cover every potential naloxone scenario. Also, there’s more than one way to design a development program, and this is not necessarily the only way.

The table outlines the issues to be addressed from the prescription label for naloxone, that you saw on the previous slides, and shows you what sort of study could potentially address each issue. As I mentioned previously, the label comprehension study is foundational, and needs to address all issues that a consumer should understand about using the product. Self-selection focuses on whether a consumer can figure out when to use naloxone. In other words, when is a patient experiencing an opioid overdose? And contra-indications to use.

So, while label comprehension may give some idea of how a consumer will use the product, better proof comes from the actual use in human factor studies that show how consumers use the product and handle the device. In the case of naloxone, since it’s an emergency situation use, this could potentially involve some scenarios of simulated use, for example, with a mannequin. In this case, we’re most interested in whether consumers can correctly seek emergency medical care with use, and administer the product correctly.

So, now that you have a general idea of what issues need to be addressed, and what a development program might look like, the next question is, what regulatory pathway can be used for that development program? Since most prescription products under consideration for over the counter switch, including naloxone, are regulated under the new drug application process, over the counter switches are likewise typically NDAs and follow standard NDA review timelines. Sponsors considering OTC switches for any product, and especially naloxone, are very strongly encouraged to come in and meet with us during the development program.

So, the next few slides address some frequently asked questions about potential novel switch programs. One question we get frequently in the OTC world is, “Who can request a switch?” Almost always, a switch is requested by the holder of the approved prescription NDA. Any application must provide full data to support the switch, which includes a development program similar to what we just went over. In theory, parties other than the prescription NDA holder can request a switch through a citizen’s petition. Now, although to my knowledge, this has actually never occurred. Like the NDA program, the petitioner must provide a full development program and complete data to support the switch. Just submitting a citizen’s petition saying, “We want this switched” basically doesn’t work, because FDA does not conduct the studies to support OTC switches.

So, regarding dosage forms, again, in theory any approved dosage form can be a switch candidate, although some dosage forms are certainly more user friendly than others. So, for example, a drug requiring systemic delivery like naloxone is likely to require some sort of consumer friendly device and packaging in order for consumers to be able to correctly administer the product themselves, without specific by a health care professional.

Another question that we sometimes get is, “How long does a product need to be marketed in the prescription setting before it can be switched to...
FDA: Exploring Naxolone Uptake and Use

So, in theory the answer is "Zero." But typically, products are marketed in the prescription world for several years before OTC status is sought. The benefit of prescription marketing is that it provides data on both intrinsic factors related to drug-specific adverse events, and extrinsic factors related to self-administration. So, naloxone has been marketed for many years. We generally have a fairly good understanding of the adverse event profile. Given this, a strong consumer development program could potentially aid with extrinsic factors for a specific dosage form.

Now, one of the problems that we have with novel switch programs, and the difficulties, is that consumers must base purchasing decisions on information in the drug facts label. By definition, this is pretty limited because there really isn’t very much real estate on the label. You’ve all seen these labels. They’re about this big; it’s a pretty small space. So, sometimes I think we’re asking this tiny little label to leap tall buildings with a single bound, and that’s kind of a lot to expect.

purchase, vending machines, or websites. Basically, anything that goes beyond the drug facts label might potentially be an NSURE pathway. I want to emphasize that FDA is by no means requiring the use of NSURE for novel switch programs. In fact, quite the opposite, since it doesn’t exist yet, but since we’re taking about innovation in this session, I wanted to give you a flavor of what we’re working on at FDA, to try to facilitate new product development, while still assuring safe use. And we are very willing to discuss application of NSURE to potential switch programs.

So, in summary, prescription to OTC switch pathways are available, including for novel switch programs like naloxone; however, in order to successfully switch the sponsor must demonstrate that the consumer can correctly self-diagnose, self-treat, and self-manage the condition, without the intervention of a health care professional. For products that have difficulty doing this with the limited real estate available on the drug facts label, the NSURE initiative could expand the potential for novel switches.

Finally, I can’t emphasize enough, for sponsors to come talk to us. The division of nonprescription drug products is very open to discussing potential naloxone switch programs. This is an area where cooperative efforts, such as those demonstrated so very nicely in this conference today are needed to combat opioid overdose. In case I haven’t said it enough, please call us. Here’s our number. Here’s our address. And if you have specific questions about the NSURE program, you can contact the office of medical policy. And here, I provide you just with some websites that give you our guidances on some of these consumer studies.

Thank you.

[applause]

DR. FAH: Thank you, Dr. Michele. Our last speaker for this panel is Alice Bell. She is the overdose prevention project coordinator for Prevention Point Pittsburgh.

Presentation - Alice Bell
MS. BELL: Hello. Yeah, I'm Alice Bell. I am the overdose prevention project coordinator for Prevention Point Pittsburgh. We have a needle exchange-based naloxone program. Let me figure out how to -- there we go. I have been asked to speak as an advocate for over the counter naloxone, and I -- while I do strongly feel that having naloxone available over the counter will dramatically increase access -- can dramatically increase access to a lot of people, I also want to present some concerns that I feel like will need to be addressed, if that were to take place.

So, in talking about naloxone access, who is most likely to use it, how best to make sure these individuals have access? Is over the counter our best strategy? And what problems need to be addressed, to make over the counter a viable strategy? With skyrocketing deaths from opioid overdose, and high potency fast-acting fentanyl in the heroin supply, it's essential that naloxone is immediately available at the scene of an opioid overdose. This has been discussed extensively in the past couple of days. And individuals who use illicit drugs are the most likely to be already present at the scene when an opioid overdose occurs. Ideally, naloxone should be in the first-aid kit of everyone lay and professional responder. In police cars, ambulances, homeless shelters, substance use treatment programs, schools, community centers, and home first-aid kits. The description of the other presenters on this panel of the products that they're developing, and they're envisioning the broad access -- that everyone has access to this, will be great. The number one priority, however, is to put naloxone in the hands of those most likely to be on the scene, and first to respond: Individuals who use opioids them self. How best to reach this population? By making naloxone available, free of charge, in settings like needle exchange programs, jails, methadone, Suboxone, and other treatment programs, hospital emergency departments, and free clinics.

Prevention Point Pittsburgh’s program, as I said, we have a syringe exchange-based program, and we have distributed, so far exclusively, intramuscular naloxone. We have reports, over the -- close to 10 years now of our program of over 1,300 overdose rescues. We don't have reports of people having reports using the intramuscular naloxone. Of the people who have participated in the program in the first nine years, through the end of 2014, we had 1,175 program participants who witnessed close to 5,000 overdoses. Seventy-two percent reported having witnessed one or more overdoses in their lifetime prior to receiving naloxone. Fifty-seven percent reported witnessing two or more overdoses and this is comparable to data that we heard from Anne Siegler's survey in New York City.

In 2015, in Pennsylvania, we implemented Act 139 which allows third party prescribing, which has been discussed. It allows naloxone to be prescribed to potential witnesses including friends and family, police, firefighters, staff of substance use treatment programs, staff of homeless shelters, et cetera. It also allows physicians to prescribe by standing order so a physician doesn’t have to be present for training and dispensing. And it provides broad immunity from liability for prescribers and for those who administer naloxone. And this has allowed us to distribute naloxone much more broadly starting in 2015. So, in the first five years of -- this year, we've been able to give naloxone to 457 people, compared to 157 in all of last year. Seventy-five percent of those who've received naloxone this year report no opioid use themselves. They're friends, family, or professionals who anticipate they'd be likely to witness an overdose. Among this group, 35 percent reported having witnessed one or more overdoses in their lifetime, so obviously that's a lot of overdoses witnessed and this makes this group of people -- group that's very important for them to have access to naloxone. But when you compare that with people who use opioids them self, 72 percent report having witnessed an overdose in their lifetime.

And so far, this year, we've had a 104 overdose reversals reported, 102 of them
accomplished by individuals who use opioids themselves, compared to two reports from others. This is consistent with data from New York and Massachusetts, where they have also found that the majority of people who have reversed overdoses have been drug users themselves. This is a graphic representation that just shows our program through the years and the dramatic increase and the amount of naloxone that we've been able to get out so far this year with the new law. And a steady -- steadily increasing number of reversals, with 99 percent of those rescues, so far, being performed by individuals who use opioids themselves.

We made use of the standing order provision, also, for pharmacy standing orders, which other people have discussed. Pennsylvania has two needle exchange based naloxone programs, one in Pittsburgh, one in Philadelphia. Pennsylvania is a very large, predominantly rural state, in between, where we have been seeing a dramatic increase in heroin use and there is a tremendous need for naloxone and very little availability. So, pharmacy availability of naloxone can dramatically increase the availability.

It's -- this has been rolling out slowly in southwestern Pennsylvania, individual pharmacies pairing with individual doctors. In Allegheny County, the director of health has issued a county-wide standing order. And Governor Wolf has said that the physician general will be issuing a state-wide standing order. So, that provides hope for people throughout the state to be able to have greater access.

So, how would over the counter increase access for those people who need it most? Well, there's certainly an opportunity for dramatically increased access in rural areas and easier access for those who aren't comfortable accessing syringe exchange and other community based programs, and those who are able to pay. And that's kind of the key issue. It would remove the need for standing orders, which have been cumbersome for pharmacists who aren't used to this process, and we get lots and lots of calls from pharmacists who are trying to figure out how to navigate the standing order process. Would make it much easier for agencies, substance use programs, police departments, et cetera, not to have to navigate the standing order process. And it could really serve to reduce the stigma if people can just go into a pharmacy and purchase it.

Some of the risks and concerns are that if naloxone is sold over the counter in pharmacies and people perceive that that's all that needs to happen, it's just available to everybody, why do we need community based programs? Then, if this replaced free community distribution it would actually reduce access for those who need it most.

If insurance no longer pays for it, then the cost to individuals could be prohibitive, particularly for those who most need to have it. And there's also some concern that there might be issues with stigma as we see with syringe purchase in pharmacies, where, while theoretically people can purchase syringes in a pharmacy, often pharmacists don't sell them to people who look like drug users, who actually -- or look like who they think might be drug users who are actually the people who obviously need it most.

So, I would suggest that we know how to develop broad access to essential medications by using a variety of mechanisms for distribution. If you have it available in pharmacies and doctors' offices and traditional medical settings where it can be paid for out of pocket or billed to insurance, and also available in schools, community clinics, syringe exchange programs, substance use treatment programs, jails, homeless services, where it's offered, free of charge, to reach vulnerable populations with limited resources. Over the counter access to naloxone could be an extremely important avenue to augment access, but should not supplant existing channels that are effectively reaching those most in need. To some extent.

Again, in Pennsylvania, we have a small program in southwestern Pennsylvania that is effective in a very -- on a very limited scale, but we need to increase these types of programs, expand funding for these types of programs, so that we have a more
possible? That may not satisfy every community.
And some of them, you hear, may not. But if we can
get out there to as broad a group of people as
possible and achieve maximum reimbursement as well
across those people, we think that's a positive.
But to answer your direct question, we have not
settled on a price in Adapt Pharma, at this point in
time. Our folks are getting the thing approved.
MR. HEBERT: Yeah, we haven't -- we haven't
set a price yet, either; however, I can say that,
you know, give you some ball parking. Our thinking
is in the range of the Amphastar IMS syringes.
DR. OLIVA: I just wanted to make one just
quick comment, or question, because I know for --
sorry, Elizabeth Oliva, from the V.A. We've had
some challenges -- especially if this is going to be
new, and people want to expand -- but for places
that are starting from scratch, it's been really
kind of challenging to develop demo kits for the
existing ones, before the EPIIO auto-injector came
on board, because they have trainers, which has been
super helpful with getting demo kits -- or
demonstrations to places. So, I don't know, as you
guys are thinking about this, it's really important
to think about how to make those sorts of training
devices, or demonstration kits, available for
implementation.
DR. STANCLIFF: Is either company working
with international, low and middle income countries
-- I was told to be bold -- because that's a, you
know, we got the WHO guidelines, but nobody can
afford to buy it.
MR. HEBERT: I'm sorry, I missed the
question.
MR. MULLIGAN: I think the question --
MALE SPEAKER: The question was whether
anybody's working with low or middle income
countries, in terms of registering and pricing
strategies, I guess?
MR. HEBERT: Yeah, so, I mean, we're
preparing, you know, dossiers for Europe and for
Australia and Canada. But that's not going to take
place until next year. Pricing discussions are all
-- that's all downstream in those countries. So,
general vision, a broad access, again, using a
vaccine model I would suggest would be an effective
way to accomplish this. Thank you.
[applause]
DR. FAN: Thank you, Alice. Thank you to our
panel for great presentations. We're running a
little late, so why don't we go into QA, and maybe
just one question, so we can get back on schedule?
And perhaps, our speakers can stay after, just in
case if there's any other -- any participants who
would like to ask question?
MR. BIGGS: Thank you, all. And I'm curious
if you guys had a dollar amount for this product
when it hits the market?
MR. MULLIGAN: I'm very surprised by the
question.
[laughter]
I'm actually dumbfounded. No, is the answer
at this point. We are focused -- at this point, we
are focused on the approval, and then, trying to tie
into that what is the best price to achieve our
objective of broad access to as large a group as
National Capitol Contracting, LLC
200 N. Glebe Road, Suite 1016 | Arlington, VA 22203
Tel: (703) 243-9696 | Fax: (703) 243-2844
www.nccsite.com
Beth Bigley, and I'm the director at the Division of Nursing and Public Health at the Health Resources and Services Administration, and I look forward to hearing from the speakers. Thank you.

The first speaker is Steven Bentsen. Dr. Bentsen is the regional chief medical director, and I will be talking about the Beacon Health Option White Paper: Confronting the Crisis of Opiate Addiction. Thank you.

Presentation - B. Steven Bentsen

DR. BENTSEN: Oh, thanks so much. Before I begin, I'd like to state that I have no financial ties to pharmaceutical industry or any conflicts of interest. I am regional chief medical officer for Beacon Health Options. And my region is primarily the eastern seaboard, eastern coast of -- down to North Carolina.

At first, I'd like to explain who Beacon Health Options is. Beacon Health Options is -- it was created this year, through a merger through Beacon Health Strategies and Bayou Options. We provide behavioral health solutions, utilization management, intensive case management, EAP services, to large regional health plans, employers, and labor organizations. We also provide the same services to a public sector Medicaid plans in a number of states. And we also are one of the world's largest EAP providers, and provide EAP services for Military OneSource.

About a month ago, it was timing with this meeting, we released one of our first -- our first white paper on health care issues affecting behavioral health. And that paper addressed the issue of opiate addiction. As you all know, it's difficult to really give a general, overall strategy how to combat this illness. Much of the treatment is regional based, city based, and even needs to be individualized. And what I will do is try to go through kind of our view of naloxone use, from a health plan, and from a utilization management and health and wellness company standpoint. We feel it's very integral to the treatment of patients, and should be integrated into the continuum of care for substance use treatment. Because one of the issues that we have with the use of Naltrexone is that it is used for an overdose, typically, within -- with a person suffering from a chronic disease, and what we --

DR. JONES: Naloxone

DR. BENTSEN: -- naloxone. I'm sorry, what did I say?

DR. JONES: Naltrexone

DR. BENTSEN: Oh, sorry. Naloxone, pardon me. It is typically used for high risk members who have a chronic disease. What we really want to focus on is engagement and treatment once this drug is distributed. And that is one of the confounding problems we have at this point, is integrating the distribution of the -- of the medication to members who need treatment.

And we -- where the slide went? There we go. I'd like to kind of briefly cover that have been covered previously. We all know that opiate addiction is headline news. You know, due to increased regulations of opiate prescriptions, we have seen a shift, as mentioned before, to heroin use. And heroin now is, typically, not injected, because the quality is significantly higher. It is used intravenously. And due to that, we see more members, individuals, migrating to heroin use. And also, because of -- in many cases, the heroin is less expensive than purchasing opiate prescriptions on the street. One of the overriding and -- what happened here? Hold on. There we go. And this is evidenced too by the deaths. Those of you, as we all know, they -- there was a flattening of deaths, with opiate analgesics, and a concurring increase of deaths with heroin.

So, what we've seen, as we have kind of limited the opiate prescriptions, we've seen a migration to heroin. But from a health care standpoint, we have not seen people enter treatment. So, I think that's one of -- one of the issues we're really, primarily, focused on this. How do we get people that are overdosing, that are overdosing, to engage in treatment? The big issue unique to addiction treatment: All medical treatments -- and I'm referring -- and I think
opiate dependency is a well-defined medical
disorder. It is a brain-based illness. We're still
dealing, I think, with an issue that it's a moral
weakness, or it's something that a person needs to --
- needs to overcome individually, or we have people
that are really receiving treatment, very -- at the
very end stages of their disease, when they have
legal problems, accidents, and really have to access
health care in acute situation.

It's striking that only 50 percent of family
members would help a -- help a -- help a family
member obtain treatment. And what's even more
striking, as was mentioned previously, that health
care providers rarely are making these referrals.
And one of the goals we have is to really educate
providers to provide knowledge where to obtain
treatment, and also to push knowledge about use of
Naltrexone in individuals that are at risk.

Excuse me, I'm trying to move the slides. I
would like to focus, also, on medication assisted
treatment. We feel medication-assisted treatment is
grossly underutilized, and probably is contributing
significantly to the overdose problem. Methadone is
highly underutilized. It's a medication that we
have a long history on, and we know that the
mortality rate with opiate overdose is decreased
significantly with members that access treatment of
methadone.

There are newer medications -- buprenorphine
came out in 2002, and also Naltrexone, injectable
I.M. medication is available. And we feel it's
grossly underused also. It's delivered once a
month. Most -- we're finding most health plans are
covering this medication, as they do see a
significant cost benefit with the appropriate
population, and that their -- the use of medical
services is decreased significantly. And that, to
me, is also one of the overriding reasons to really
kind of identify this population that is receiving
the nasal injectable, and having the mechanisms in
place to make sure people receive appropriate
treatment.

And this is an overall view of our chronic
disease model which is identified in our white
paper. And we define opiate addiction as chronic
illness, where we see the use of medications are in
the community resources. We feel that nasal
naloxone needs to be available within the community,
and we actively are participating in increasing
availability. We work actively within the
Massachusetts health plan -- I believe there's a
talk at 2:00 this afternoon about the Massachusetts
experience, so I won't go into a great detail. But
we're -- but we are kind of limited, in that we
really feel, as part of any chronic disease model,
we really should know what members are at risk.

Just as somebody who is a pre-diabetic has a medical
intervention -- an intervention before the illness
advances -- we feel that when that -- when the --
when the medication is delivered, that it should be
-- that information should be transferred to the
health plan that is -- that is monitoring that
individual's condition so we can activate intensive
care management services if needed or at a minimum,
really push patient education.

Unfortunately, patients don't know where to

go. They usually come into treatment when there's a
crisis. Family members don't know where to go. And
providers don't know where to call to access
services. So, we feel that this is vital -- when
these medications are delivered, that there is some
mechanism where, if a person has insurance, that the
insurance carrier is notified that medication is
there to do kind of a wellness intervention. But
that needs to be done in a very sensitive way, where
people realize this information will not be used
against them legally, will not be distributed, so --
and we also need to have some relaxing of the
privacy laws that pertain to addiction treatment
because we feel that limits kind of appropriate
communication of information to providers.

Finally -- excuse me. Finally, we really
feel strongly that this illness, the medicalizing of
this illness, as a brain disease, really will push
treatment. This illness needs to be conceived as an
illness affecting judgment and impulsivity, and
pushing treatment also helps us push best practice
care, including medication delivery, including
advancement of psychotherapies, and early interventions, and motivational interviewing.

We also feel that legislative implementation should include integration of health care stakeholders. We’ve had some legislation released recently that are requiring inpatient detox for everyone that presents to an E.R. with an opiate overdose. We feel that might be putting people at risk for increased overdose upon discharge. As stated before, many people may benefit from medication assisted treatment, and not abstinence based therapy. Thanks so much for your time. It’s a pleasure being here.

[applause]

DR. BIGGLEY: Thank you. Our second speaker, Eliza Wheeler will be speaking about the -- ensuring the access to naloxone to community based distribution. And it’s an overview of the cost supply and procurement issues. Thank you.

Presentation - Eliza Wheeler

MS. WHEELER: Hi. My name is Eliza Wheeler and I work in San Francisco for a project called the

were donated -- thank you, Leo [spelled phonetically] -- and we have some injectable naloxone, and we have some nasal naloxone. And folks come in for a syringe exchange, and they come in for all kinds of other services, as syringe exchanges often provide. And we ask them if they’d like some naloxone, if they’ve ever been trained before. If they have, we give them a refill. If they haven’t, we sit with them for five, ten minutes, or more, if they have questions, and we have a conversation around overdose and response, and we give them a naloxone kit.

We’ve been doing that for almost 15 years in San Francisco. And in an above-board fashion, which means with the assistance of the health department, but there’s been naloxone distribution in San Francisco since the mid-90s. We’ve saved a documented -- we’ve recorded a documented over 1,600 overdose reversals -- from drug users. So, we rarely receive reports of uses of naloxone from anyone other than drug users. So, nationally, what this looks like for

community based organizations like ours, who receive funding or money from a variety of different sources and then purchased the drug, naloxone, and then distribute the drug to people who are at risk for overdose or potential bystanders of an overdose.

What this looks like nationally is pretty incredible today as opposed to how it has looked for many years in the past. So, the way that we are in this room today is that drug users have always figured out creative ways to save each other, or try to save each other. They are the ones that came up with ideas that sometimes are creative yet may be not always very effective, like throwing people in cold baths, and things like that. But they also discovered that there was a drug called naloxone.

And the first program to have -- to harness that creativity from a drug using community, and realized that we should be providing this drug to the very people who witness overdoses -- was the Chicago Recovery Alliance. That’s Dan, front row. None of us would be here without the work that he did in the mid-90s through that syringe exchange. What we’re
all talking about here is because of that idea. And now -- thank you. That's right. You can purchase, "Yes we Narcan" shirts with Dan's face on it from the Seattle needle exchange if you like online. So, we previously -- we published a paper about a week ago, I guess, in the CDC's MMWR, looking at what is happening nationally in terms of distribution programs. So, we had responses from 136 organizations that provide naloxone, 84 community-based programs, 18 health care facilities, 10 veterans administration health care systems, 18 state and local health departments, and six pharmacies. So, even since this survey that we did last summer, this has changed dramatically, in terms of the pharmacies, and clinics, and programs that have started up, even since last year. So, collectively these programs since 1996, when Dan’s program started, have collectively trained 152,000 and change people, and had 26,000 reported reversals. And I know Sharon went over the data so I’m not going to spend too much time, but I do want to show -- when you look at this map, I think, for me, the takeaway is the inconsistency of the distribution of programs and access to naloxone for lay persons across this country. And the reality of what this looks like on the ground, is you have some amazing state leadership in some of the states such as New York and Massachusetts and New Mexico that have implemented state-wide programs that provide access. And in other places, zero leadership at the state level and just very small non-profit organizations, sometimes individual people, who are working with groups or coalitions to try to get access to naloxone out in the community. So, again, I’m going just highlight the points here, where -- who we’re reaching, who these programs are reaching, are people who are using drugs -- mostly actively using drugs. Some people who are in treatment or about to leave treatment, but mostly actively using drugs. And those people are responsible for the majority of overdose reversals. The use of the drug naloxone in the case of an overdose emergency.

So, we’ve seen incredible increases. We did a previous survey of organizations, nationally, in 2010 that was published in 2012 in the MMWR. And that was -- that was one of the first papers that kind of looked nationally at what was happening with naloxone access for lay persons. So we’ve seen an incredible increase. We now have 30 states that have at least one access point where someone -- a lay person can get access to naloxone.

Okay. So, this is the reason I am here, I suppose, to talk about the issues that we face in terms of actually getting the drug. And we’ve heard this over and over again -- our friend from Utah, Jen Plumb, talked yesterday in public comment, about how, sometimes -- so, she’s in a medical facility, she has -- they have the will, they have the way, they can’t afford it. Programs face barriers in terms of actually acquiring naloxone in a lot of different ways. So, this is -- I know this is a hard to read slide. So, we couldn’t get it to look better. I’m not a PowerPoint wizard. So, this is just a slide looking at all -- of all of the organizations that are purchasing naloxone, or acquiring naloxone, and then distributing it for free to people in the community -- how are they getting it? So, that first set of bars -- and so, you have the light blue bar, which indicates that the -- those are the number of programs that rely solely on this modality for acquiring naloxone. And then the dark blue bar is programs that require multiple different ways of getting naloxone -- different funding sources, different mechanisms.

So, the takeaway -- so, the first set is state and local health departments are purchasing the naloxone, right? The second is non-health departments, state, or local government agencies. So, that includes the Veterans Administration and other governmental agencies that aren’t necessarily health departments. What you see in the third group, and then as you go further down, you have the private programs relying on private donations often from families who have lost people to overdose, individuals. We get $20 every week from one of our
needle exchange clients that goes into the pot of our program, who -- he just feels like it's an important service that we're providing. So, these are programs that rely solely on those types of donations.

And then we also have programs that are relying on in kind of donations of the product. So, people can get donations from the product from a foundation -- places -- big health departments sometimes purchase the drug and then deliver it to the programs that are doing the distribution -- places like Massachusetts, New York, have systems that operate somewhat like that. So, you have a variety of different, very confusing ways that people are actually getting naloxone.

So, how -- and I'm already almost out of time. Okay. So, how do we actually purchase it?

So, for programs that are limited by a fixed budget -- so, my program has a fixed budget, that I get from the San Francisco Health Department. It's out of their general fund pot of money. It does not -- it's not flexible. I am charged with distributing a relationship with Hospira to access naloxone. They have been one of the only companies that have stepped up to help community based distribution acquire in an affordable manner.

So, just a couple -- another quick points before I wrap up, and I knew I was going to run out of time. That -- just to kind of understand where we're -- in context to the presentation on the first day that showed that the naloxone market for the U.S. was about 3.2 million. The distribution programs provided access to lay persons over a total of 140,000 vials or doses of naloxone, including the intranasal version, and the injectable version, in 2013. So, we are a very, relatively small segment of this -- of the groups needing naloxone.

So, just to focus -- is that -- so, the way this works is that we are subject to a bunch of different barriers. One is the prescription status of naloxone makes it so that it non-profit organizations have to have some sort of medical/legal infrastructure in order to even purchase naloxone because we can't just, as lay people, sign up for a contract to purchase a pharmaceutical. We have to work with a provider; not all programs have one of those.

So, I use the example of North Carolina Harm Reduction Coalition. And Robert who spoke earlier who had a great standing order legislation passed in their state. They had money to purchase naloxone, they had an infrastructure for distributing it, and they approached over 200 physicians asking them to work with them and write a standing order and were rejected by all of them until they found one that would agree, even with authorizing legislation.

So, we faced barriers working with medical professionals. We faced financial barriers. There's no designated funding for what we do that's consistent. And we don't have a -- we don't have a consistent, long-term strategy for acquiring affordable naloxone.

I'm really out of time and as I have a million more things to say as people who know me know. But, I do want to just [laughs] dedicate this to one of our long-standing needle exchange
participants. One of the first people trained by the DOPE project in 2003 was saved about six lives; long-term drug user in San Francisco who passed away the other day from kidney failure and the long-term effects of drug use. She saved a lot of lives since, so -- thank you.

[applause]

DR. BIGLEY: Thank you. And the slides will be available. So our last speaker is Krystalyn Weaver who is the director of Policy and State Relations at the National Alliance of State Pharmacy Associations. And she’s going to talk about the community pharmacy perspective.

Presentation - Krystalyn Weaver

DR. WEAVER: Thank you. And thank you for having me here today. Thanks to Gary Worth [spelled phonetically] for facilitating NASPA’s involvement in this meeting. I’m honored to be with all of you, and just really humbled by the great work that you’re doing in our communities across the U.S. I don’t have any personal conflicts to disclose. I will disclose that Kaléo is a member of

National Capitol Contracting, LLC
200 N. Glebe Road, Suite 1016 | Arlington, VA 22203
Tel: (703) 243-9696 | Fax: (703) 243-2844
www.nccsite.com

1. care team and to assist in making their communities healthier. Also, pharmacists uniquely have access to prescription records from all of the patients’ providers; hopefully, ideally.

We know patients go to multiple providers, but you can see situations where patients may not realize that they need to tell each of their prescribers what other drugs they’re taking. And so they just continue to take them all as prescribed and potentially could unintentionally overdose due to misuse or really using it correctly but just in the wrong combinations. So, pharmacists are a good access point there to check for those types of interactions.

We’re used to using the prescription drug monitoring programs. I practice on a very part-time basis, but it’s a normal part of my routine to check the PDMRs which we know is a challenge for some of our prescribing practitioners due to time constraints. And it’s not as integrated as we want those to be yet. And it’s a really a priority for the profession of pharmacy. In 2014 we passed

policy that stated more than what it says here but that “APhA supports laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.” So, we’ve really embraced this idea as a profession that we want to increase access to these really important products.

But there are some barriers. We heard from some other speakers about different ways that pharmacists can increase access through collaborative practice agreements or local standing orders that are issued by local collaborating prescribers.

There are also other ways that we’re seeing through state-wide protocols where the same protocol applies to all pharmacists in that state and even prescriptive authority for pharmacists related specifically to naloxone, and then a third is this idea of dispensing without a prescription which has its own barriers.

The advantage of these state-wide types of programs: It streamlines education needs so that we
can help pharmacists understand what the legal requirements are and any certification they may need per the standing order. It helps to alleviate the need the approach prescribers. We heard from the last speaker they approached 200 [laughs] prescribers and had trouble finding a collaborator which is just a challenge for community pharmacies to engage in.

And then the last challenge is that the wording really matters in the law. If you're involved in any type of advocacy related to pharmacists prescribing of naloxone, it's really crucial that that authority allows them to generate a prescription or else they're not able to submit it to an insurance company.

That interaction, you know, dispensing without a prescription is nice. But, we can't submit that to insurance to have it adjudicated. So, an example of that is in Oklahoma where it's pretty much a cash-only practice. And I think other speakers have addressed those other legal challenges there.

And collaborative practice is authorized in 48 of the 50 states. Soon, we hope to be in 50 states. But it's very restrictive in some places; highly variable state-to-state. So, those shown in blue here are by my definition [laughs] of broad authority where I think we could implement a naloxone program; meaning that pharmacists are allowed to initiate therapy. Community pharmacists are allowed to participate in a collaborative agreement. Some states limit it to institutional settings. New York it's limited to teaching hospitals only, which is very unique. But there are no restrictions on what drugs can be included in the collaborative agreement and the laws and regulations are silent regarding the relationship between the prescriber and the patient.

So, some states require that in order for a patient to receive services under a collaborative agreement; in this case receive a prescription from a pharmacist for naloxone, the physician, or other prescriber would have to have a pre-existing relationship with that patient which doesn't really

This is a map that I've created, and as others have said, state law changes all the time.

I'm excited to hear that Pennsylvania may have something forthcoming so I can update this map. But I wanted to show how prevalent the opportunity is to partner with pharmacies on a state-wide basis.

This map does not reflect places where local pharmacies can dispense naloxone per a protocol specific to that pharmacy. These are state-wide opportunities. In green are places where a state-wide naloxone protocol is in place or pharmacists have prescriptive authority for naloxone. In blue are states where we have collaborative practice agreement authority.

If you're not familiar, collaborative practice agreement is a formal relationship between a pharmacist and a physician where the pharmacist assumes responsibility for specific patient care functions that are not in their typical scope of practice but are appropriate per their education and training. And this often includes initiation or modification of therapy.

help to expand access because they could've just gotten it from the physician in the first place.

So, when we're looking at these public health needs, it's critical that the law is either silent or doesn't -- or allows for there to be a broad collaborative agreement put into place.

In yellow, you'll see new activity in 2015 where prescriptive authority or state-wide authority for naloxone has been proposed. And I'm really excited to say that at this point in the session, all of these have been either approved by the House and the Senate, or whatever is equivalent in that state, or have already been signed by the governor, so really seeing a lot of progress.

And it's not that I left off the ones that didn't go through. This is what I found in our legislative database and they're all progressing through. So it's a hot topic and I think states are really starting to recognize what many of you have expressed; that pharmacists are a good option for us.

So, some of the access challenges and maybe
increased in price. And it’s just not a great
business model for these settings and increases
barriers in that way.
Also, the counseling time is really
significant. I spoke with a regional clinical
manager and by her estimation, it takes about at
least 15 minutes for the pharmacist to spend time
with the patient to teach them how to use it,
counsel them on when it should be used, and things
like that. And that time, you know, you don’t get
back in a community pharmacy. I’m sure you’ve all
gone and seen how busy they are. So, if there’s not
a reimbursement mechanism, management of the
pharmacy usually isn’t super supportive of that
pharmacist walking away for 15 minutes which is a
big challenge for us. New Mexico has a really great
model where their Medicaid Department is
compensating the pharmacy for not only the product
but also the time spent in counseling which just --
it, you know, is a great encourager of that
counseling time that’s really necessary.
Of course, with the auto injector we have the

Some solutions: I think we need to have more
model collaborative practice agreements for that’s

Insurance coverage policies -- we’re told that it’s
being covered in some places but may have some weird
pre-authorization requirements like a first-fail
policy which makes no sense to me [laughs] in the
context of naloxone. And of course primary non-
adherence is a problem for both of them.
Related to billing either of them, we’ve
heard some Medicaid programs are -- reimbursement
for drug products is a pretty weird system in the
U.S., where we have all these crazy calculations.
And if the calculation for what the product is being
reimbursed at doesn’t get updated as often as the
price changes, sometimes pharmacies have to dispense
it at a loss. So, they’re paying X amount for a
product but they only get paid, you know, $10 less
than what they paid for the product. So they want
to help patients but it’s really tough when they’re
operating at a loss and they’re trying to keep their
doors open.

Some solutions: I think we need to have more
model collaborative practice agreements for that’s

MR. BIGG: Eliza, I want to thank you for
organizing all of us un-organized people and sharing
that information. But, can you unequivocally say
today in the United States of America -- are there
programs that are not initiating opioid overdose
prevention efforts and not expanding their opioid
overdose prevention measures because of the cost of

Prevention efforts and not expanding their opioid
dered to some of the variability state-to-state. That’s one of the
biggest challenges for pharmacies at a national
level to get on board and participate in these. And
I maybe would propose that we look at quality
measurements related to co-prescribing. Once that
is developed as a maybe a consensus based that it’s
a great solution, we could look at quality measures
that analyze the drug plans at that point.
So, I’ll stop because I’m out of time but
tank you very much.

[applause]

MR. BIGG: Eliza, I want to thank you for
organizing all of us un-organized people and sharing
that information. But, can you unequivocally say
today in the United States of America -- are there
programs that are not initiating opioid overdose
prevention efforts and not expanding their opioid
overdose prevention measures because of the cost of

challenge of the cost which we’ve talked about.
Insurance coverage policies -- we’re told that it’s
being covered in some places but may have some weird
pre-authorization requirements like a first-fail
policy which makes no sense to me [laughs] in the
context of naloxone. And of course primary non-
adherence is a problem for both of them.
Related to billing either of them, we’ve
heard some Medicaid programs are -- reimbursement
for drug products is a pretty weird system in the
U.S., where we have all these crazy calculations.
And if the calculation for what the product is being
reimbursed at doesn’t get updated as often as the
price changes, sometimes pharmacies have to dispense
it at a loss. So, they’re paying X amount for a
product but they only get paid, you know, $10 less
than what they paid for the product. So they want
to help patients but it’s really tough when they’re
operating at a loss and they’re trying to keep their
doors open.

Some solutions: I think we need to have more
model collaborative practice agreements for that’s

required -- example of one is there from Washington
state model legislation to iron out some of the
variability state-to-state. That’s one of the
biggest challenges for pharmacies at a national
level to get on board and participate in these. And
I maybe would propose that we look at quality
measurements related to co-prescribing. Once that
is developed as a maybe a consensus based that it’s
a great solution, we could look at quality measures
that analyze the drug plans at that point.
So, I’ll stop because I’m out of time but
tank you very much.

[applause]

MR. BIGG: Eliza, I want to thank you for
organizing all of us un-organized people and sharing
that information. But, can you unequivocally say
today in the United States of America -- are there
programs that are not initiating opioid overdose
prevention efforts and not expanding their opioid
overdose prevention measures because of the cost of

challenge of the cost which we’ve talked about.
Insurance coverage policies -- we’re told that it’s
being covered in some places but may have some weird
pre-authorization requirements like a first-fail
policy which makes no sense to me [laughs] in the
context of naloxone. And of course primary non-
adherence is a problem for both of them.
Related to billing either of them, we’ve
heard some Medicaid programs are -- reimbursement
for drug products is a pretty weird system in the
U.S., where we have all these crazy calculations.
And if the calculation for what the product is being
reimbursed at doesn’t get updated as often as the
price changes, sometimes pharmacies have to dispense
it at a loss. So, they’re paying X amount for a
product but they only get paid, you know, $10 less
than what they paid for the product. So they want
to help patients but it’s really tough when they’re
operating at a loss and they’re trying to keep their
doors open.

Some solutions: I think we need to have more
model collaborative practice agreements for that’s

required -- example of one is there from Washington
state model legislation to iron out some of the
variability state-to-state. That’s one of the
biggest challenges for pharmacies at a national
level to get on board and participate in these. And
I maybe would propose that we look at quality
measurements related to co-prescribing. Once that
is developed as a maybe a consensus based that it’s
a great solution, we could look at quality measures
that analyze the drug plans at that point.
So, I’ll stop because I’m out of time but
tank you very much.

[applause]

MR. BIGG: Eliza, I want to thank you for
organizing all of us un-organized people and sharing
that information. But, can you unequivocally say
today in the United States of America -- are there
programs that are not initiating opioid overdose
prevention efforts and not expanding their opioid
overdose prevention measures because of the cost of

naloxone? Yes or no?

MS. WHEELER: Funny, we discussed that I was
going to say that, didn’t we? [laughs] Yes,
absolutely. So, we hear all the time from programs
that can’t start; have to scale back; have to stop
operating; have to prioritize people who they’re
giving naloxone to and other unethical types of
things that they’re sort of backed into a corner to
do sometimes.

And I know that, I mean, I ran out of time
and didn’t get to talk as much as I wanted to about
the impact of the price increases, and the lack of
access, and the complicated nature of actually
getting the drug itself when you’re a program that
has all the other -- you may have all the other
things in place to be able to start a program and
you can’t literally get the drug.

And so when we’re talking about a drug that
in the grand world of pharma is costing -- I mean,
even the Amphastar product, let’s say it’s costing
$50 per unit. And we give out two unit kits.

That’s $100 and change for our programs. And that
might not cost a lot in the big picture of pharma
but for us it’s unattainable. We cannot run a
program with drugs that cost that much money; we
can’t.

We need them to be cents, pennies. We need
the drug to cost virtually nothing for our programs
to actually operate to scale. And I understand you
all need to make money but you’ve got to figure it
out. So -- [laughs].

DR. BRATBERG: Great talk for the panel. I’m
also a pharmacist, and I think they’re pretty cool -
-
[laughter]

-- props to Dr. Weaver for a great talk,
outlining the benefits and limitations of pharmacy-
based naloxone. I just want to emphasize that in
our experience in Rhode Island, we’ve seen that 15
minutes would be an ideal and ideally reimbursable
procedure as in New Mexico. But, I think it does
take far less time, as some researchers have
documented, to educate people about naloxone
administration.

So, while we’d always like to have as much
time to discuss this, we’ve seen successes with less
time used. And we see corporate pharmacy partners
jumping onboard to provide naloxone and increase
access.

MS. THOMAS: Laura Thomas with the Drug
Policy Alliance, and last year we partnered with the
California Pharmacy Association to co-sponsor the
bill to create pharmacy naloxone access which was a
great experience.

We ran into a few challenges that I just want
to highlight. One was we faced significant early
opposition from our state medical association who
opposed any scope of practice changes but managed to
do this raising a number of irrelevant concerns
about naloxone just not based in any reality about
it.

Fortunately, we were able to pass it and put
it through. And we’re now in the phase of working
on the implementation which, because of the way the
law was written, pharmacists must go through a
training and certification in order to be able to
dispense naloxone directly from the pharmacy. And
so that’s been a bit of a challenge, is convincing
pharmacists around the state that they need to, you
know, pay to go through a webinar. We’re trying to
figure out how to make it more cost-effective for
them to participate in the webinar.

But just generating more up-take from a
pharmacist, I’m interested in thoughts on ways to
ensure that more pharmacists are actually
participating in the program. It’s, you know, one
of the things of the California Pharmacy Association
said a lot -- it’s one of their talking points but
it’s very true, that a lot of times pharmacies are
the most accessible health care facility in a
community which is really true. And it’s able --
people are -- they’re often open 24 hours which
their medical clinic might not be, for example.

So, you know, I think it’s a really important
adjunct to the kind of community programs that Eliza
runs and other sorts of programs. But, figuring out
how we get all those pharmacists onboard is going to
be a challenge, I think. So if you have any ideas
on that --

DR. WEAVER: Yeah, so I didn’t give much of
an overview of NASPA because I didn’t have much
time. But, NASPA -- our membership is CPHA and the
other state associations across the U.S. So, thank
you for your advocacy.

You’ve definitely set an example for other
states that are jumping onboard after California’s
example. And the wording there does generate a
prescription which, please, if you’re in your states
[laughs] make sure the wording generates a
prescription; it’s so crucial.

As far as getting other states -- more
pharmacists to participate, I think at the chain
pharmacy level, it’s an economics issue. So we’ve
got to get those financial incentives to make sense
for their business. I mean, it’s a business, you
know? And you’ll see lots of participation and
interest from pharmacists who went to school for six
years or eight years now to take care of people
which is what we want to do.

But, you know, if the management isn’t
1

certainly, you know, we worked a -- we did the
California legislation and the Vermont legislation.
And it was the same person on our legal staff who
wrote it. And she’s very available for people in
other states who are interested in looking at
legislation to create pharmacy access as an adjunct
to community programs.

DR. WEAVER: Wonderful.

MS. RUIZ: Hi, I’m Sara Ruiz, Massachusetts
Department of Public Health. Thank you to all the
panelists, thank you Eliza for your comments on
price. Price definitely impacts our program and
causes us to prioritize in ways that we prefer not
to.

I do have a question for Dr. Bentsen. I
heard you -- you were mentioning, this is what I
understood and wanted to ask for more information
and clarification, that notification of the health
plan when naloxone is administered? Is that what
you said and in to what situations? Just curious to
understand more of what you were suggesting.

DR. BENTSSEN: Oh, I think I’m really trying
to kind of conceptualize this illness for a number
of people as a chronic illness. And part of any
chronic illness is early interventions. And people
that, you know, some people obviously need this
medication not because they have an opioid addiction
but for other reasons just for safety.

But, it’s an opportunity for an early
intervention when this is administered and this is
given out. So, I really feel that if there’s some
communication within -- to the health plans, we can
reach out to members. And one of the goals we’re
having now even at managed care we’re not managing
care now. We’re really a wellness company. We’re
really trying to be preventative through early
interventions just like you would do with diabetes,
cardiovascular illness; that this needs to be
conceptualized at that same level.

So, if high-risk people are getting this and
they have insurance that there should be a mechanism
to refer that for a wellness intervention; at least
some acknowledgement of what the resources are for
treatment which most members don’t know where to go.
MS. RUIZ: [affirmative] Have you considered employing recovery coaches or advocates that could do that type of intervention? In other words, interventions you have in mind? I think --

DR. BENTSEN: We have intensive --

MS. RUIZ: -- that some thoughts would go into --

DR. BENTSEN: Internally we have intensive case managers that could do it. We could refer people -- as I mentioned we’re an EAP provider, we have EAP professionals. If people have EAP benefits that’s free to them; they have somebody to meet with and discuss what is going on in their lives.

Because usually when people get this, even family members when they obtain this, there are issues that really from a health stand point and wellness point that really need to be addressed.

It’s an opportunity to address these issues and to help people kind of cope with this illness that impacts not only the person but the family around them.

MS. RUIZ: Agree with that; thank you.

---

the pharmacists who aren’t quite as cool as they could be yet.

[laughter]

I do think there are a number of them; I know from trying to implement more over-the-counter syringe sales in California. You know, it was legal to buy 10, it was legal to buy 30. But then when we did practice buys, either people didn’t know, or just they didn’t want to, or they weren’t very nice about it, and that was my experience doing test buys. So, I think it’s a common experience for people accessing that.

And I’m wondering what kind of initiatives or capacity building, educational opportunities are happening to work with pharmacists, to have more cultural competence and deal with active drug users in a non-stigmatizing way?

DR. WEAVER: Well, I won’t concede that not all pharmacists are cool, of course --

[laughter]

-- because you might tattle on me, but I know what you’re saying. I was actually sharing with

---

MS. RUIZ: [affirmative] Have you considered employing recovery coaches or advocates that could do that type of intervention? In other words, interventions you have in mind? I think --

DR. BENTSEN: We have intensive --

MS. RUIZ: -- that some thoughts would go into --

DR. BENTSEN: Internally we have intensive case managers that could do it. We could refer people -- as I mentioned we’re an EAP provider, we have EAP professionals. If people have EAP benefits that’s free to them; they have somebody to meet with and discuss what is going on in their lives.

Because usually when people get this, even family members when they obtain this, there are issues that really from a health stand point and wellness point that really need to be addressed.

It’s an opportunity to address these issues and to help people kind of cope with this illness that impacts not only the person but the family around them.

MS. RUIZ: Agree with that; thank you.

---

some colleagues over this meeting that the needle exchange thing was not talked about in my education.

I can’t say that’s the way it is for all pharmacists’ training. But I remember being an intern and feeling very conflicted about -- I didn’t know how I was supposed to feel about it and what the right answer was which is just my personal experience.

My preceptor did not sell them unless we knew there was an insulin prescription or something relevant associated with it. And the law in Ohio is pretty ambiguous and kind of supported his stance on that. It may have changed right now; I haven’t been to Ohio for a couple of years.

So, I think education is probably very important. And I’m not an expert on this topic so I’m just sharing my personal opinions on this. But, I think the more we can get integrated with the schools and working with our associations on addressing these public health needs -- pharmacy hasn’t always been put in the forefront of public health.
I think that our vaccination progress has really helped to show other stakeholders the opportunity we have to utilize pharmacists for public health needs. And so with that evolving, I think the conversation is evolving. So, I think, you know, since I’ve been out in the world, I’ve seen much more information about it. Personally, I’m maybe more active than other pharmacists in this type of work. But, I think the more we can get out there the better. And de-stigmatizing it broadly will help to de-stigmatize it in the pharmacy community as well.

MS. MCQUIE: Thank you, and I really appreciate your presentation; it was great. Thanks.

DR. BIGLEY: We have two more questions, and it’s noon, so about quick questions and quick responses.

DR. WERMELING: A comment; the current financing model that you’re using is unsustainable. You have highly elastic demand and inelastic resources. There needs to be a different model for you than what is currently happening.

MS. WHEELER: I actually completely agree with you, Dan. And you know, I think when this type of intervention was originally conceived of it -- I don’t know if, I mean, maybe in the hopes and dreams of people it would get this big and be this widely accepted someday. But, I don’t know if we’ve ever had a tremendously good and well-thought out plan for how to really make it long-term sustainable in our model.

So, our model is separate from access through pharmacies and separate through access through clinics; a real public health model where we, you know, purchase the drug and then we distribute it for free along with education and support and wrap-around services of all different types. And that model is really important, and we reach a lot of people. And we are the evidence-based that we’ve been talking about in the last two days. We’re the people who have been doing this work and resulting in these reported reversals and all these lives saved.

And we don’t have a way to push forward under the current way that we do it. And you know, we’ve been brainstorming a lot in the hallways in the last couple of days being here. And you know, I was thinking about how the federal government sometimes assists with vaccine programs and with HIV-testing program; where, you know, they may contract with a non-profit group to provide the service of the HIV-testing.

And along with that money they provide the HIV-tests that then the community group goes out and delivers and does -- maybe we could think of something like that where we’re not responsible for negotiating prices with pharmaceutical companies and manufacturers and wholesalers as individual small non-profit groups with no buying power and no money; money that we get from people whose kids died. That’s ridiculous. Our model is ridiculous, and it’s not sustainable.

[applause]

MR. BRASON: I’ll be quick because it’s lunch. I realize that. From the pharmacy perspective, and I, too -- Fred Brason from Project
Lazarus, I too also think, you know, some pharmacists are cool, some not so cool. My sister's one, I think she's cool. [laughter]

Regarding the stigma aspect, a couple of different experiences, and I want to -- some interchange with you on how to kind of long term looking at this, one of the first requests we had from a mom because both of her kids were in rehab and coming home and she wanted naloxone in the house.

And you know, we provide the kit and then she had to go get the prescription. She found somebody to write it. But, when she went to the pharmacy, the pharmacy actually refused to fill it because they didn't want to get involved.

So, those are the kinds of things that we've been experiencing. And when we first had grant money to provide naloxone to those in medication-assisted treatment, we would provide the prescription but only 25 percent would go to the local pharmacy to get it filled; even though it was free. Reason was they didn't want to be seen in the pharmacy and how they might be treated and seen because of their issues.

So, those are some of the things that you know, when we have direct pharmacy dispensing for somebody to walk in and ask for it, it's going to be very, very difficult to do. And I wondered if you're talking to pharmacy schools, the customer service aspect in the box stores and so forth to see about how, you know, the approaches can be made and accepted and not stigmatized because you're going in asking for something like that?

DR. WEAVER: Well, I'm very sorry your patient had that experience, obviously. I don't think it's reflective of all of our --

MR. BRASON: It's not.

DR. WEAVER: -- profession --

MR. BRASON: It's not, but that's --

DR. WEAVER: -- of course.

MR. BRASON: [affirmative]

DR. WEAVER: But, I think some of the things you mentioned, the schools, working through the --
on the podium to help guide you, and if needed, I will try to provide some gentle encouragement towards the end of your time. First up is Leo Beletsky from Northeastern University School of Law. Sorry about that. Then, we will move on, and next up is Deborah Pasko from ASHP.

DR. PASKO: Good afternoon, everyone. My name is Deborah Pasko. I serve as ASHP’s director of medication safety and quality. ASHP represents over 40,000 members including pharmacists, pharmacy technicians, and pharmacy students. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety. I appreciate the opportunity to present the views of ASHP regarding the expanded availability and utilization of naloxone as a rescue agent for opioid reversal.

My comments today will focus on the current state of naloxone availability, including efforts to expand access, emphasize the needs of other than licensed health care professionals be permitted to access the drug after proper education, support certain routes of administration, many health organizations and first responders have chosen to make their own kits. Of an important mention here is the limited availability of the atomizer for nasal administration. The atomizer currently does not have an NDC number, and is not carried by most pharmacies -- only by durable medical equipment companies, and some online retailers. This is an important note to make, because when a patient caregiver receives their prescription for the -- and the auto injector is not used, the vital administration tool needed for teaching is not readily available.

The next point of concern is the patient population that may benefit from naloxone rescue. This includes a drug abuser that overdoses but also includes other individuals such as those that suffer from chronic medical conditions, requiring opioid therapy. One such patient population is oncology patients that may take large daily doses of opioids. If the patient experiences respiratory depression, or other signs and symptoms that would warrant enhanced education on the role of naloxone in opioid reversal, and on the proper administration techniques associated. My final point will support the need for states to allow pharmacists to prescribe naloxone.

In May and June 2015, an ASHP pharmacy student, with my oversight, completed an informal study about the availability of naloxone in the D.C., Maryland, and Virginia area. The student called 30 pharmacies, including large chain and smaller community pharmacies, and asked the pharmacist if they currently stocked naloxone on their shelf, and if they currently stocked atomizers. None of the 30 pharmacies contained naloxone on their shelf, nor did they have the atomizers for use, for inter-nasal administration.

Naloxone, as we heard, is available in many, multiple forms that can be -- excuse me -- administered through various routes of administration, including I.V., I.M., subq, or the nasal route, although not FDA approved.

Currently, given cost concerns related to naloxone administration, the caregiver may not know the proper after administration care that is needed. This is a key component needed in all training, for first responders and lay people alike. There needs to be broad understandings of the drug’s impact on not only drug abusers, but patients for opioids are part of a legitimate medication treatment plan.

Pediatric populations are also of concern, given drug abuse among teenagers. And we need to ensure that they can receive naloxone safely, as well. This brings me to my main point of this brief session, which is pharmacists can play a vital public health and patient safety role in naloxone therapy. Some have advocated that naloxone should be available without a prescription; however, we do not believe that this position is the best interest of patient safety. We believe that states have an opportunity to allow pharmacists to prescribe naloxone. California is an example of how well this process can work.

In conclusion, ASHP is advocating for the broad use of naloxone and availability to first

broad use of naloxone and availability to first
responders and the public at large. The drug should
remain as prescription only; however, states should
enable pharmacists to prescribe naloxone, and
provide the education necessary for its use. On
behalf of over the -- excuse me -- on behalf of over
40,000 members of ASHP, I would like to thank you
for this opportunity. Our organization stands ready
to collaborate with inter-professional colleagues
and national agencies to support the broad use of
naloxone. We also will ensure its safe use, and
train our pharmacists about naloxone and opioid
rescue therapy, so they can fulfill their vital role
and duty in such an important public health
initiative.

This was our official statement. I would
like to take the opportunity to respond to some of
the comments I heard in the past session. I heard
there are concerns from the health care community
that pharmacists need to better understand the
culture diversity and stigmatisms associated with
naloxone dispensing. I will take this back for
further comments and discussion within my
organization. Thank you.

DR. COMPTON: Thanks very much.

[applause]

Next is Gabriel Auteri, from Baltimore City
Health Department.

MR. AUTERI: Good afternoon. I’m Gabriel
Auteri, special assistant to the commissioner and
acting director of overdose prevention and treatment
for the Baltimore City Health Department, here on
behalf of Dr. Leana Wen, the Baltimore City Health
commissioner.

We in Baltimore city thank you for hosting
this important hearing to discuss a timely and
potentially lifesaving issue: The availability and
distribution of naloxone. Baltimore city has been
at the forefront of the fight against addiction and
overdose for decades. We have pioneered innovative
and progressive programs to address this issue. Our
city has sponsored needle exchange programs for over
20 years, training over 11,600 people in the
recognition and naloxone treatment of heroin
overdose events. Along with our behavioral health
partner, Behavioral Health System Baltimore, we
provide substance abuse and mental health treatment
across the city.

Despite these efforts, Baltimore, like other
cities around the country, is embroiled in the
epidemic of substance addiction. We have an
estimated 19,000 in our population of 620,000 who
use heroin. Many thousands more have other
addictions. Last year, 303 people in Baltimore city
died from drug and alcohol overdoses, 23 percent
more than the number who died in 2013. This is more
than the number of people who died from homicide in
our city. Recognizing the need to fundamentally
reexamine our citywide approach to drug addiction,
our mayor, Stephanie Rawlings-Blake, convened a
heroin treatment and prevention task force. Under
the direction of the health department, this group
has engaged community members, treatment providers,
and advocates, to develop a comprehensive plan to
address drug addiction in our city. Our report is
being issued later this month, but we recognize that
we cannot wait to begin saving lives.

That is why we have launched the Baltimore
citywide Overdose Prevention and Response plan. In
just three months, we have increased our naloxone
distribution by over 200 percent, with targeted
training and distribution including in jails and in
collaboration with our police department. We
successfully advocated for changes in state law to
allow for standing orders for naloxone prescription
and instituted liability protection for prescribers.

But our efforts are not enough. Opioid
overdose is a public health emergency. The federal
government must play a crucial role by removing
barriers to naloxone distribution and access. Here
are Baltimore’s four proposals: First, naloxone
must be available over the counter. There are
little to no side effects from taking naloxone. It
is not habit forming, and it has no potential for
abuse. As an E.R. doctor, Dr. Wen has used it
hundreds of times, and has seen how it literally
saves someone’s life within seconds. Naloxone is on
the World Health Organization’s list of essential
medications. People should not have to go to a
Third, naloxone should be co-prescribed with opiate prescriptions issued by all providers, including addiction and pain medicine specialists, primary care doctors, nurse practitioners, and dentists. The increase in opioid is directly linked to the increase in opioid prescriptions. Abuse of legitimate opioid prescriptions is the first step for many people toward opioid addiction. Prescribing naloxone to all patients who receive an opioid prescription will ensure all of these at-risk individuals have access to potentially lifesaving medication. It will also help to enforce to doctors that any amount of opioid medication -- even if it appears to be for an acute medication condition -- can be habit forming, and result in a fatal overdose.

Fourth, naloxone should be distributed to every individual who can possibly encounter another person with opioid overdose. It should available just as EpiPens and defibrillators are. There should be programs to distribute naloxone to every individual being released from jail, for example, and also, to every police officer, teacher, and citizen. Naloxone must be freely available and carried by every individual. We all have the ability to save another person’s life. While naloxone is by no means the only answer to the opioid epidemic, we -- and we also have to work to improve access to long term addiction and mental health treatment, we have to save people -- save people’s lives today, in order for them to have the possibility of making better choices tomorrow. As a profession, we need to eliminate barriers to naloxone access. These changes would make a huge impact in reducing our cities and our nation’s epidemic of overdose deaths. Thank you for allowing this testimony, on behalf of Baltimore city.

[applause]

DR. COMPTON: Thanks very much. Next is Joan Papp from MetroHealth System.

DR. PAPP: Good afternoon. My name is Joan Papp, and I am speaking to you today as both an emergency physician of our Cuyahoga County Safety Center, and as the medical director of Cuyahoga County’s Project DAWN, or Deaths Avoid With Naloxone Education and Naloxone distribution program. I’m also speaking on behalf, today, of the Ohio State Medical Association, and the Ohio branch of American College of Emergency Physicians, or ACEP, who both support increased access to naloxone.

In 2015, the Ohio Department of Health reported that 2,110 deaths occurred by unintentional drug overdose statewide, or nearly six deaths every single day in our state. This is the highest recorded number of overdose deaths in the history of our state, representing a 413 percent increase since 1999. Nearly three-quarters of these deaths are related to opioids, 46 percent, in part, to heroin, and 34 percent, in part, to prescription opioids. Cuyahoga County Project DAWN started in 2013 to combat this epidemic. And since that time, we have enrolled over 1,900 individuals into our program, and saved over 170 lives. We currently operate three community based walk-in sites, and provide access to naloxone. These changes would make a huge impact in our country, we need to eliminate barriers to naloxone.
Cleveland firefighters to carry and EMTs authority to carry naloxone, which has allowed EMS board expanded its gofer practice to allow basic in our state developing naloxone programs. The Ohio naloxone when they are responding to an overdose. This new law has led to over 30 police departments in our state developing naloxone programs. The Ohio EMS board expanded its gofer practice to allow basic EMFs authority to carry naloxone, which has allowed all of our Cleveland firefighters to carry and administer naloxone as well. And just last month, Ohio lawmakers took the next step by passing legislation to allow family members, friends, and those in a position to rescue an overdose victim, to receive a prescription for naloxone, and also to allow peace officers to carry and administer naloxone when they are responding to an overdose.

In early 2014, Ohio enacted a naloxone access legislation to allow family members, friends, and those in a position to rescue an overdose victim, to receive a prescription for naloxone, and also to allow peace officers to carry and administer naloxone when they are responding to an overdose. This new law has led to over 30 police departments in our state developing naloxone programs. The Ohio EMS board expanded its gofer practice to allow basic EMFs authority to carry naloxone, which has allowed all of our Cleveland firefighters to carry and administer naloxone as well. And just last month, Ohio lawmakers took the next step by passing additional legislation, which will provide even greater access to naloxone by allowing pharmacists and other authorized individuals to dispense naloxone under physicians’ standing order. This legislation is awaiting Governor Kasich’s signature, and will immediately become law, due to an emergency clause. Our citizens [unintelligible] has attempted to attack this epidemic from several other angles, as well, in addition to naloxone’s access legislation. Ohio has enacted legislation to close down pill mills, require PMP checks prior to prescribing opioids, and to require informed consent, when prescribing opioids to minors.

The MetroHealth System applauds Senator Sherrod Brown and other legislators who are taking the lead in addressing opioid management issues, with federal legislation as well. Our physician community is stepping up to address this problem, too. At MetroHealth, we rewrote our controlled substance prescribing policy to promote safer practices, and we have a fall conference planned to promote awareness of opioid addition and associated mortalities.

Locally, we believe our efforts are starting to make a difference. In 2013, the year our program started, the medical examiner’s office reported that although mortality had continued to grow from 161 heroin deaths to 194 deaths, the rate of increase had slowed significantly. The preliminary data for 2014 show that, for the first time since 2007, the result of this collaboration, Project DAWN and our partners have been successful in developing and passing several key pieces of legislation, guided by the Ohio state medical board on development of rules for office-based medication assisted therapy, and carried out a massive educational campaign in our community. Additionally, our law enforcement partners have trained nearly every northern Ohio police department on how to properly investigate heroin overdose cases.

In early 2014, Ohio enacted a naloxone access legislation to allow family members, friends, and those in a position to rescue an overdose victim, to receive a prescription for naloxone, and also to allow peace officers to carry and administer naloxone when they are responding to an overdose. This new law has led to over 30 police departments in our state developing naloxone programs. The Ohio EMS board expanded its gofer practice to allow basic EMFs authority to carry naloxone, which has allowed all of our Cleveland firefighters to carry and administer naloxone as well. And just last month, Ohio lawmakers took the next step by passing additional legislation, which will provide even greater access to naloxone by allowing pharmacists and other authorized individuals to dispense naloxone under physicians’ standing order. This legislation is awaiting Governor Kasich’s signature, and will immediately become law, due to an emergency clause. Our citizens [unintelligible] has attempted to attack this epidemic from several other angles, as well, in addition to naloxone’s access legislation. Ohio has enacted legislation to close down pill mills, require PMP checks prior to prescribing opioids, and to require informed consent, when prescribing opioids to minors.

The MetroHealth System applauds Senator Sherrod Brown and other legislators who are taking the lead in addressing opioid management issues, with federal legislation as well. Our physician community is stepping up to address this problem, too. At MetroHealth, we rewrote our controlled substance prescribing policy to promote safer practices, and we have a fall conference planned to promote awareness of opioid addition and associated mortalities.
FDA: Exploring Naxolone Uptake and Use

Day 2

Dr. Compton: Dr. Papp, I'm going to have to ask you to wrap up.

DR. PAPP: Okay. We have also incorporated naloxone training into our educational curriculum of our residents in training. And although -- I'll just wrap up. Although Ohio has continued to make significant strides, we still have a long way to go, as our state's mortality continues to climb. We need better funding for the work we are doing, greater access to naloxone that is affordable for both local programs and law enforcement. Thank you.

[applause]

DR. COMPTON: Thanks very much. Next up is Dr. Compton: [laughter]

and it really -- we really need to expand that. So, I was going to talk about that, but I changed my mind. I want to talk about money. And more specifically, I want to talk about, how do some of these newer, smaller, real grassroots, solo organizations, sometimes the only ones in their state, get money? How do they pay for naloxone? So, this is different than the amazing large-scale health department supported efforts. I mean, that's great. It's not currently politically feasible in some situations. There have been some really clever groups that have asked local health departments for some funding at the end of a fiscal year, when there's some spend-down money. Some lucky programs have access to some HIV set-aside funds. The number of big foundations who give money for Narcan is in the low single digits. So, this brings me to the grassroots, tiny family foundations. These -- I want to be very specific about what I'm talking about here -- when I say tiny family foundations,

Mays Dow-Simkins, Prescribe to Prevent Organization

Heartland Health Outreach.

[applause]

MS. DOE-SIMKINS: Hi, there. I want to start off with thanks for the time and energy that went into making this happen. I really appreciate it, and even though I'm so nervous I could puke, I'm not mad at you. I really appreciate it, so --

[laughter]

I actually have changed my mind a lot about what I was going to talk about today. It was initially, my intention to talk about the serious need for technical assistance. Traci Green and Sarah Ruiz talked a lot about how professional people in our organizations really require some considerable training and support to be able to actually launch and implement the Opiate Safety and Naloxone Network, PrescribetoPrevent.org, the Harm Reduction Coalition, both national and local.

Chicago Recovery Alliance had been providing implementation assistance, usually for free on our nights and weekends, for years and years and years,
But then, I changed my mind again. That's not actually how I want to conclude. Bill Marrone said yesterday that like, lunch and learns accomplish a lot. In this case, it's more like a dinner and prosecco with Traci Green, last night. Which, we had -- was over at this weird place, where we had to like, walk into a liquor store to get to a restaurant. It was a big liquor store -- it was really strange.

But anyway, back to my point -- so, these local community efforts attain Herculean results in short time periods with a relative pittance, and they're an incredible example of community resilience and community preservation. This is the stuff born out of passion, fury, urgency, and often times, a defiance of stigma. It's a refusal to allow a stigmatized death to mean that the lives and the names of people are erased from the collective community memory. It's an example of communities taking care of themselves, out of desperation: "We have to do something."

And you know, I've been involved in several community partners and stakeholders, such as law departments regularly work with a wide range of opioid misuse and overdose. Local health partners to identify opportunities for prevention of through surveillance, and convening community groups, can work together to use naloxone care providers, public health agencies, and to together to initiate this discussion on how health drug abuse, and CDC, SAMHSA, and HHS, for coming.

We applaud the FDA Center for Drug Evaluation and Research, National Institutes of Drug Abuse, and CDC, SAMHSA, and DEA, for coming together to initiate this discussion on how health care providers, public health agencies, and community groups, can work together to use naloxone to reduce the incidents of opioid overdose fatalities.

In the past decade, you guys know these statistics, but deaths from prescription painkillers have surpassed deaths from heroin and cocaine combined. And as public health professionals, it's really our responsibility to stop this trend. So, turning the tide on this epidemic requires a coordinated federal, state, and local partnership. Local health departments are on the front lines of responding to this epidemic, identifying hot spots through surveillance, and convening community partners to identify opportunities for prevention of opioid misuse and overdose. Local health departments regularly work with a wide range of community partners and stakeholders, such as law enforcement, hospitals, clinics, and community-based organizations. It's about bringing together the right people, with the right expertise, to make a real difference in the lives of those affected by the opioid crisis.
 enforcement, first responders, health care providers, community-based organizations, and families, to coordinate efforts to mitigate the effects of prescription drug misuse, overdose, and death.

Many local health departments train emergency medical responders, police officers, and community members on how to use naloxone to reverse an overdose. And in some jurisdictions, the local health departments provide the much-needed medications; however, not all communities have access to this life-saving drug. Many localities and states still lack Good Samaritan laws, which can help incentivize individuals to contact medical services or police when an overdose does happen. Similarly, many states and localities do not have policies in place to train first responders and distribute naloxone, leading to the 15,000 lives lost due to prescription drug overdose.

The provision of naloxone to third party recipients and first responders has already begun to save countless lives. You all heard about Project DAWN, but I -- I'll mention it briefly. In Cuyahoga County, Ohio, the opiate task force led by the Cuyahoga County Board of Health helped initiate Project DAWN. And you heard the statistics. It helped save hundreds of -- over a hundred lives, and over a thousand people have been trained, so that just goes to show how important local health department partnerships are.

In conclusion, local health departments are working within communities every day to reduce opioid misuse and overdose. NACCHO looks forward to engaging with federal, state, and local partners to help this opioid abuse epidemic. Thank you.

Dr. COMPTON: Thanks very much. Our next speaker is Anita Gupta from the American Society of Anesthesiologists.

Dr. GUPTA: Good afternoon. My name is Dr. Anita Gupta, and I'm representing the American Society of Anesthesiology. I am a physician, and a pharmacist -- hopefully, a cool one --

[laughter]
may result in death. It does not address the underlying cause of opioid overdose. We recognize the side effects of naloxone, such as negative pressure pulmonary edema, or extreme high blood pressure, can potentially occur and can be severe; however, these side effects are treatable, and preferable to an opioid-related death. And for this reason -- and many others -- the ASA sees the impetus to provide access to naloxone.

ASA also would like to stress the importance of health care professional involvement in naloxone distribution, particularly when a patient is co-prescribed naloxone with an opiate. A physician who evaluates a patient determines opiates are medically indicated, and counsels and educates the patient and his or her family member or friend about opiates should also be involved in counseling and educating the patient and his or her family or friend about naloxone, and prescribing the medication. We also believe that physicians must be educated so that they can better understand the risks of prescribing naloxone to people at risk of opioid overdose and provide advice on the management of opioid overdose.

In an effort to educate the public about reversing the effects of opioid overdose, the American Society of Anesthesiology collaborated with the White House Office of National Drug Control Policy to develop a wallet-sized card describing the signs and symptoms of an overdose and instructions for assisting a person suspected of an overdose, including instructions to administer naloxone and call 911. A PDF of that is available on our site.

In finality, I want to emphasize that naloxone is not the only step in combining misuse and the abuse of prescription drugs. This is only one small step in a positive direction that may mitigate opioid overdoses, and help improve public health. We’d like to kindly thank the FDA for convening this meeting to discuss how we can encourage the use of naloxone and to reduce opioid overdose fatalities. Thank you very much.

[applause]

DR. COMPTON: Thank you very much. Next up is Jef Bratberg, University of Rhode Island College of Pharmacy.

DR. BRATBERG: Greetings, everyone. Thank you for convening this important panel. I am Jef Bratberg, and I am a clinical professor of pharmacy practice at the URI College of Pharmacy. Three years ago, I helped implement a -- the first -- the national model of the large community pharmacy-based naloxone, using a collaborative practice agreement. Since then, I’ve helped develop several continuing professional development programs for both pharmacists and physicians, training hundreds of pharmacists in overdose education and naloxone response. And those programs at available at PrescriptoPrevent.org, and soon to be the College of Psychiatric and Neurologic Pharmacists. I get to promote, too.

Pharmacists are ideal locations for increasing community access to naloxone, with thousands of highly recognizable public locations, with extended hours. They’re the most accessible interface, between community-based programs, and people in the community, and the health care system.

You’ve probably received a public health prevention intervention at a pharmacy, without an appointment, and it was covered by insurance. Probably your annual flu vaccination. Pharmacists are sometimes the sole accessible health care provider in rural and urban areas.

The hardest hit by prescription and illicit opioid overdose and death. Pharmacists dispense the majority of those prescription opioids from community pharmacies, counseling patients on average drug reactions, including overdose. They provide medication lock boxes, and educate patients on drug disposal services. Pharmacists also, and pharmacists, provide harm reduction services to patients by selling -- if they’re good pharmacists -- over the counter syringes and sharps disposal boxes. An increasing number of insurers actually pay pharmacists to do comprehensive medication reviews, where patients’ opioid risk can be assessed annually, and naloxone can be prescribed, or initiated by the pharmacist or via the patient’s physician. In short, pharmacists are ideally suited
to identify patients at high risk of overdose.

Policies that permit pharmacists initiation in naloxone, like in my state, Rhode Island, are only available in a handful of states. And they depend on OMPT and destigmatized pharmacist intervention and/or changes in corporate policies to be broadly effective. Nearly half of the states don’t permit third party prescribing of naloxone by prescribers or pharmacists to carers, further limiting layperson community naloxone access through pharmacies.

Although guidelines and data support the positive outcomes of naloxone co-prescription with opioid prescriptions, this is also an opt to intervention, and we haven’t yet seen significant, positive impact on overdoses and deaths. In California this week, the governor signed a bill mandating vaccination for school entry. This occurred after a measles outbreak that occurred, largely a result of parental personal belief exemptions. This is probably could be called vaccine stigma. In a state like California, with robust clinical recommendations for immunization, naloxene’s availability as an over the counter product, this creates a financial barrier for patients, market barriers for manufacturers, and decreases the potential involvement in education provided by prescribers and/or pharmacists.

In that behind the counter model, naloxone meets the CSU, Considered Safe Use, criteria, and should be behind the counter, to ensure that patients and/or carers receive that hopefully REMS mandated overdose education, counselling on which product is best for that patient or carer. And we maintain insurance coverage, while also streamlining naloxone surveillance, so we know what outcomes are happening. We have that data.

A recent -- thank you for that opportunity to present my recommendations. I hope you find them valuable, and thank you, everyone, for this thing. [applause]

DR. COMPTON: Thank you very much. Our next speaker is Chris Stock from the George E. Wahlen V.A. Medical Center.

DR. STOCK: Thank you. Good afternoon.

annual public awareness and education campaigns, people still chose to opt out of this important public health intervention, and over 100 people got infected with measles. As you’ve heard, that number have died today, or in the two days -- at least, in the two days of this conference. So, mandates are needed. It’s imperative that the FDA rapidly adopt and implement mandatory supply, and demand interventions, to attenuate the overdose epidemic.

FDA can improve opioid overdose immunity, or herd immunity in the public, through expanded naloxone prescribing and dispensing, by first revising the long-acting opioid class risk evaluation and mitigation strategy to include all prescription opioids. Mandate -- not passive education -- mandated education for both prescription, and this time include pharmacists, and require naloxone to be co-prescribed for all opioid REMS. FDA should also inaugurate naloxone as the ideal candidate for behind the candidate or pharmacist-accessible only status. This can happen relatively fast. While I generally support

Thank you to the FDA, SAMHSA, CDC, NIDA, ONDCP, and other agencies who sponsored this pretty amazing conference the last two days. I have to say, the views that I’ll express are my own, and not those of the Department of Veterans Affairs. I’m a board-certified psychiatric pharmacist, a member of ASHP, who spoke earlier, CHPN, that’s been referred to several times, and INMERSA, all agencies that -- organizations that support expanded access to naloxone. Like Maya, I’ve been very impressed by the creativity, energy, and cooperative spirit demonstrated among all of the people here at this conference. The federal agencies, as well as community programs and private individuals and industry, as well.

Since I’ve been here the past two days, nearly five Utahans have died of drug overdoses. Over 500 will die this year. Approximately a fifth to almost a third of those may be veterans. Many have an opiate prescription in their hands, and are not known to have a substance use disorder.

Attending this meeting, hearing presentations, I’m
impressed by the programs and the progress that has been made since 2012. Three years, over 30 states have created mechanisms to put naloxone, life-saving medication, into the hands of people likely to present -- to be present -- when someone overdoses, and to improve their chances that the individual, and their brain cells, will survive.

It is my conclusion, opinion, and recommendation, that the current available data, that -- based on current available data -- that regulatory status of naloxone should be changed. I recommend that the prescription-only or legend status of naloxone be modified, and that a behind the counter or nonprescription status be considered.

I think several points here at relevant.

More than 30 states, many, many more community programs have developed workarounds to essentially make naloxone behind the counter, or nonprescription, already. But there are still states that don’t have that kind of access, and federal mandates, federal recommendations, would go a long way toward preventing overdose deaths in those states that don’t have these kind of programs.

I would also just point out the relevance of the World Health Organization guidelines that caution against creating prescriptions and barriers.

And I think that the FDA over the counter switch program and the NSAFE program has a lot of potential here for providing training, when there may not be a health professional available to give that training, or that presents a barrier. Think of a father who wants to have naloxone in his home to protect his teenage daughter, or his aging mother. He should be able to have naloxone, and get it without limits or restrictions. Let’s trust, but support and guide, with robust instructions, smart apps, online, telephone resources, that he can make the decisions to use naloxone correctly, when the time -- if and when the time arises.

Further, to encourage further uptake and use, the leverage of federal funding to state/local programs to enable distribution of naloxone.

Presenters have eliminated rich, robust data experiences now, three years later, in 2015
increasingly, states often led by pharmacy associations, have moved to standing orders, collaborative practice agreements, and other models that you heard about earlier today.

But what I want to add to that is a plea that we do evaluation of what is happening with those behind the counter models, on our way to over the counter, that NIDA fund the evaluations so that we're able to capture that data around what are the barriers to implementation. What are the ways in which we can increase uptake of these behind the counter options? Who is purchasing for whom? Do behind the counter models work? And for whom do they not work? And also, to ensure that we have -- that we move towards having consistent models across state lines.

Secondly, I want to, again, talk and echo the points that people are making about the need for funding. One of the things that the Drug Policy Alliance has been working on, unsuccessfully in California, is getting the state of California to invest any dollars in addressing what is now, in my opinion, the leading cause of accidental death. And it's been extremely frustrating trying to get a health department, a governor's administration, to put any money into it. But that's exactly what we need.

And so, my plea on that is for those of you from national associations who are here, those of you from the federal government who feel like you can, anything you can do to help us advocating at the state level for additional funding for naloxone is going to be very helpful.

And also, just for government agencies to be as creative as possible. Our California Department of Health Care Services has been working on some creative regulations to get naloxone into the hands of people leaving methadone programs. For example, we need to use every tool that we have available to us in order to ensure that, you know, all Medicaid formularies are covering naloxone. That all insurance company -- private insurance company formularies -- are covering naloxone. That it doesn't have co-pays. It's considered a preventive service. You know, what more can we be doing at the regulatory level to ensure that that's happening?

And then, my final comment is really about the role that stigma and criminalization plays as a barrier to naloxone, and is a barrier to preventing overdose deaths. While I realize that a recommendation -- that the FDA work to end drug prohibition -- may not go over, I do think that it's worth looking at the model from the country of Portugal, where, as a result of decriminalizing personal possession of drugs, they have seen drug overdose deaths drop dramatically along with associated HIV infections, and so on, without any resulting increase in overall drug use. And I think it's worth looking at what decriminalizing drugs and ending drug prohibition could do for ability to get naloxone out to people who need it. We spend a lot of time working around the edges of the criminal justice system, trying to get drugs to people -- naloxone to people.

And then, finally, just on the stigma, I want to, you know, acknowledge, as many other people have, we would not be in this room having this conversation if it weren't for the creativity, the resilience, the persistence, and intelligence, of people who use drugs. So, I want to say thank you for getting us here, and in -- you know, we need to use naloxone in our conversation around naloxone to change the conversation around who people who use drugs are. And move away from a narrative that says that people who use drugs are selfish, that they don't care about other people, and into one -- a narrative that honors the fact that it's people who use drugs who are saving lives with naloxone in this country, who are stepping up, who are taking care of themselves, their friends, their family, their community, and who are -- who are the heroes in this story. Thank you.

[applause]

DR. COMPTON: Well, thank you to all the presenters for fascinating, sometimes challenging, and really important ideas to share with all of us that have helped organize this meeting, and for the whole group here today. We're now done with the
FDA: Exploring Naxolone Uptake and Use

Day 2

**Panel 9: Measuring Progress and Impact. Give us a moment to change.**

**DR. SKOLNICK:** So, this is our last session of the meeting, “Measuring Progress and Impact.”

I’m Phil Skolnick, from the National Institutes of Health. We have distinguished speakers, and our charge is to end on time, so I’m going to be serious about cutting the speakers off at the allotted times. So, without further ado, I want to introduce Alex Walley, from the Massachusetts Department of Public Health. Thank you, Alex.

**Presentation -- Alexander Y. Walley**

**DR. WALLEY:** Great thanks, Dr. Skolnick. It’s a pleasure to be here. I’m going to get right into it, so I finish in time. So, I’m going to focus on community level impact. These are sort of the main things I want you to take away. Naloxone kits and overdose prevention education can help save lives. The harms appear to be few, and training should not be a barrier. There’s been a lot of talk over the last two days about different populations.

So, here’s a map of Massachusetts as of 2015. We’re about to add two more towns in western Massachusetts, North Adams and Pittsfield. These are the places where we have community-based organizations that are sponsored, or supported, really, by the Massachusetts Department of Public Health and the Overdose Education Naloxone Rescue Kit Program. The orange dots are Learn to Cope meeting sites. So, Learn to Cope is a group of family members, loved ones, carers, of people with opioid use disorders who come for mutual support once a week. The meetings are -- I think there’s over 17 now in the state. One’s in Rhode Island, actually, now. And they’re also naloxone rescue kit distribution and training sites.

At this time, through 2015 we enrolled and trained in the program 33,000 people, about 28 people per day in the state, and we’ve documented 4,700 rescues using program naloxone which is about five per day at this point. So, the program didn’t start out the way it is now. It started -- the officially sanctioned program started in 2006, 2007, with two public health departments. There was unsanctioned naloxone distribution before that and it really inspired the beginning of the program through community-based organizations. In 2007, 2008, the program was taken to other communities when it was taken on by the Department of Public Health and then further expanded in 2009.

So, this shows the towns that are color coded based on the number of absolute -- absolute number of opioid related overdose deaths by town. So, the darker the town the most absolute number of deaths. These are the towns, in yellow circles, where there were five or more deaths in each of those three years but there was no naloxone rescue program. So, the difference between the diamonds and the circles is what allowed us to do a natural experiment, which I’m thankful to the injury center at the CDC for supporting us in this R21 proposal. So -- and I want to thank Maya Doe-Simkins for this slide that helps me explain what we found, because it wasn’t easy to put together. So, I use it at every chance I can, and I hadn’t had a chance to thank her in person when I’ve shown it.

So, anyway, this is -- this is how you should conceive of what we found. So, imagine a town, one of those yellow circles, where there was no naloxone coverage. You would think that their baseline overdose rate would be 100 percent, meaning that’s their normal rate of opioid overdose death. If you -- if you take another town where we had between one and 100 people per 100,000 who had been trained in naloxone rescue and given a kit, if you were in one...
of those towns the opioid overdose death rate was reduced by 27 percent compared to those towns where there was no implementation or no naloxone enrollment. And then if you looked at another group of towns in years where the number of enrollments was over 100 people per 100,000 people, we found a greater reduction, 46 percent in the opioid overdose death rate. So, the statistically significant difference is between both the green and the fuchsia, I guess it is, compared to the blue. The difference between the green and the fuchsia is not statistically significant. But it is in the expected dose dependent direction. So, this is a slide just showing the same data in a table form. And couple things I wanted to point out here, which is that -- is that we found these differences, when we adjusted for community level factors. And I’ve listed those community level factors. If you don’t adjust for those community level factors, the effect you see is not as strong. And that just show that, really, communities are different and the naloxone, I think, doesn’t change your non-fatal overdose rate, right? It just changes your fatal overdose rate, whereas the -- so, people are still going to be going, you know, overdosing. We are -- in the education part, we’re doing two things that work in opposite directions as far as utilization. We are encouraging people to call for help, to call 911. That would actually drive the rates of utilization up, and then we’re also telling people how to prevent an overdose in the first place, which would drive their utilization rates down. So, that’s my best rationalization for why we didn’t find anything. So, just in summary, we found that fatal overdose -- opioid overdose rates were decreased in Massachusetts cities where overdose education and naloxone rescue kits were implemented, and the more enrollment the more benefit we found. But we didn’t see any clear impact on acute care utilization. So, we have a lot of adverse event information, because we collect -- they’re convenience reports of overdose rescues. So, as people come in for more naloxone we ask them, “Well, where did your other naloxone go?” And if they used it during an overdose, then we get this information here. And so, you can see that we do hear about deaths. Now, we reviewed each one of the deaths and I can tell you that in most cases, there are no signs of life at the time when the naloxone’s administered, so this is person who gets naloxone who’s already dead. We have overdose requiring three or more doses, so that’s something we look at. And that’s something we need to look more at particularly now we have more potent, more deadly, heroin and fentanyl that is available in Massachusetts. We also look at recurrent overdose. Now, recurrent overdose is somebody who’s revive with naloxone and then, without using again, overdoses again or becomes sedated again. And that’s a pretty rare event, but it is something that occurs, and it’s something that we address in our education. We have difficulty with the device. We use the inter-nasal device, which is off-label. And so, that does works in a lot of different communities. But when you’re comparing overdose rates from one community to another you really need to adjust for community level factors. So, in this case we looked at age, gender, race, poverty level, and the access to addiction treatment: Methadone, buprenorphine treatment, and detox services, as well as information from the prescription monitoring program that told us the number of prescriptions to doctor shoppers. So, the adjustment was important in what we found. Now, opioid overdose death wasn’t the only outcome that we looked at in this study. We also looked at emergency department visits, or really, emergency or hospitalization visits for opioid use problems. And in this case, we actually didn’t see -- we didn’t see a real effect from the program. And so, this is really our proxy for non-fatal overdose. I can’t -- I can’t tell you for sure why we didn’t see this but one thing to understand about OEND, or Overdose Education and Naloxone Rescue Kits, is, the naloxone -- what that does is it -- it
Withdrawal symptoms after naloxone. That’s something we actually didn’t track until sort of midway through the program, and I’ll show you some more detail on that, but it happens about half of the time. And then, negative interactions with public safety. When I had this slide just updated, and previously, that number was in the mid to high-20s, and so, over time, this number -- negative interactions with public safety -- has gone down. And then we have confiscations. And so, that’s something we have to work with other community organizations more on.

So, a little more information on withdrawal symptoms. So, this is program data, and what I’ve done here is, I’ve shown you the community cohort where we have -- in -- for this question we have 2,141 answers. We also have police and fire naloxone rescues -- 645 of them. And I thought it would be interesting just to show the withdrawal symptoms that the public safety are reporting, and compare them to what the community programs are reporting. And they’re very similar. So, about half the time, in both cases, the rescuers report explicitly that there are no withdrawal symptoms. So, none doesn’t mean no answer. It means they answered affirmatively that there were no withdrawal symptoms. The most common withdrawal symptoms are irritability, being angry. The general term: Dope sickness. We do see vomiting. Now, we don’t have any aspiration events that resulted in substantial morbidity, that we know about. But there -- vomiting is something that is not rare, I would say. There’s combative ness. Now, we ask specifically about combativeness. And you see that it is similar in the -- in the community as well as the first responder community. Now, we have reviewed all of the combative ones to see whether there was actual injury to either the responder or the person who was being rescued. And we haven’t had an instance of that. And so, that’s reassuring. So, there’s combative ness and then there’s physical violence.

and somebody getting hurt. That -- we’re not seeing that. And then, we have other things that overlap a lot with sort of general withdrawal symptoms.

So, that’s -- we have a lot of -- we’ve been tracking adverse events, and I think our -- this data is similar to what you’re going to see in other community naloxone programs, and I imagine you’re going to see in other first responder naloxone programs.

So, trained rescuers perform differently than untrained rescuers? So, we have this phenomenon where we actually don’t -- naloxone gets distributed secondarily. So, the naloxone that we hand out through the DPH program gets, actually, secondarily distributed to other people in the community, and then those people come back to us and report a rescue and say, “Hey, I want some naloxone.” And we say, “Well, you weren’t even trained.” And they say, “Yeah, but I used it to save somebody, and now I want some.” And so, we train them and we refill them. So, these are -- that’s how we get these untrained rescuers. So, it’s a -- again, not a systematic follow up of a -- in a cohort, but it is a convenient sample of people who have used naloxone. And what we did was, we compared how they -- what their actions that they took at the site of an overdose, compared to the people who’d been trained in the program. And again, you see things that are basically similar: There are no statistically significant differences in the different things that people do at the site of an overdose.

This is a new area that we are hoping to investigate more, which is about help-seeking. And so, what we’ve noticed is that the rates of help-seeking -- and what I mean by that is calling 911 at the scene of an overdose or acknowledging that EMS is already present. So, depending on the location, you’re not -- you may not actually be calling 911. You may be -- yep, yelling across the street to the state trooper, the police officer, or the ambulance, to come by and help out. So, in -- the general concept of help-seeking by people reporting rescues in our program, and you can see that we have this
where there never was a randomized controlled trial, but it’s now well accepted.

The research resources are, clearly, precious. Whether we should spend them on further demonstrating a mortality benefit with a randomized controlled trial, I think, is a question that we’ve gotten interesting insight into, during this -- these two days. So, specifically with the N-ALIVE trial, we see -- we see the case where the likely benefit works at the community level, a social network, and perhaps, it’s harder to detect at the individual level. And then, with the Seattle RCT that Caleb presented to us, the control group’s been contaminated, and that’s celebrated as something that, you know, is a good thing.

And so, in both of these cases the studies remain very valuable. There are going to be important things we’re going to learn from these studies because there are systematic cohort studies, and we really don’t have good systematic cohort studies that follow people closely with interesting assessments over what happens over time. And so, I think that’s really important, and I think that’s sort of where we need to go.

So, some evaluation questions. What is the secondary gain from naloxone rescue kits? So --

DR. SKOLNICK: I’m going to have to ask you to wrap up.

DR. WALLEY: Okay. So I’ll wrap up. Thank you. So, what is the secondary gain from naloxone rescue kits? You can see here, some possible outcomes that I suggest. What happens after a rescue? So, this is something that, often times, what we know stops at the naloxone administration. And we need to know what happens afterwards. And then, what should happen after a rescue? Should folks be connected to harm reduction and treatment services? How do you do that? Is there a way to incentivize treatment? How best to match training to venues and populations? A lot of the work that we’re seeing, over the last two days, has really given us insight on that. Monitoring for adverse events. So, we’re trying our best in Massachusetts to do that. But, you know, is that enough to really...
have this as another tool for our prescribers to utilize. Over 1,000 prescribers haven’t engaged in utilizing OEND for the veteran affairs. And they do this in a model of shared decision making with their patients. So, being able use a tool to discuss opportunities of strategies to risk mitigation, but as one other additional thing that they can offer the patient.

It’s really important that we’re working on resolution of barriers in our health care system. And we’re not a public health program. We’re rolling this out, in the context of a health care system, and the work force that we are providing health care. And we’re trying to identify high risk patients, and training on signs of overdose, the use of the kits, response to overdose. And this has to be integrated into a process of their work flow, of how do you engage a patient who may be coming for a blood pressure appointment and the ability to assess this as a potential risk of an event that they could be experiencing? And capture them in that opportunity to offer this as a life-saving product.

We are delivering this care within our health care system, both in outpatient, inpatient, rehabilitation programs, outreach programs, such as our homeless programs, that are literally going into the streets and identifying patients' needs for health engagement and how do we get them back into the V.A. to get the assessment and care that they need?

So today I’ll review a few tools that we are utilizing to measure progress and impact on a national network and local levels. We will end today with some lessons learned from our early progress report on key components of this wide scale implementation of a -- in a national healthcare system. In essence, our first priority is to have this intervention available to providers to prescribe to high-risk veterans in all V.A.s. So our wildly important goal is to make sure that wherever a veteran goes in our healthcare system they could access this. So we’ve spent this last year really focusing on how do you accomplish that when you have 150-plus facilities to try to
FDA: Exploring Naxolone Uptake and Use

Day 2

ascertain not only education, supplies, but
evaluation of the outcomes of national program
implementation requires that this is the first
priority we achieve. We need to get it into every
V.A. in order for us to understand our impact on
overdose. For monitoring the progress of
implementation to all the V.A. facilities there’s
been the use of these evaluation processes so that
we can make changes to our strategies along the way
and to be able to impact and adjust as we go.

The first tool I will share with you is our
national naloxone distribution report. We have
developed this as an audit and feedback tool so that
our healthcare leaders are able to identify the rate
of adoption across our system. In this fourth
quarter the reason I’m presenting to you, as the
national director of academic detailing, is that one
of my primary objectives was to educate the field in
order for implementation to rapidly be adopted and
so I had pharmacists who are often very cool in the
V.A. If you haven’t met a lot of V.A. pharmacists

we are cool. We actually were utilizing them to
meet with healthcare providers not only in
prescribers but the whole team -- how does the team
message this, so that every time the patient hears
about this it becomes a natural course of what is
offered to them. So social workers, nursing staff,
anybody who is having contact. So our academic
detailing program was really invading the healthcare
system in a way that we could give them tangible
tools, videos that showed how to be able to train
the provider on the language to use in the
encounter. How do you get the patient seeing this
information? So to date, we’ve had 115 medical
centers with over 5400 prescriptions that have been
released.

This is how much we’ve penetrated across the
U.S. You can see some of our states have very few
kits that have come out the door and others have had
many. We’re trying to learn from our best practice
models. We’re providing information from our
Philadelphia, Battle Creek, Cleveland, Boston, and
Indianapolis locations, and we’re celebrating our

successes.

We’re celebrating the number of reversals
that are taking place. So with 79 reversals
occurring we’re spreading the word across the V.A.
so that they see the lives that we can save. They
see what is possible and they say, “How can I adopt
this in my V.A.? How can we implement this faster?”
We centralized our reporting process for the
naloxone reversal reporting and this is an image
that you’ll see that includes collecting many of the
data that our previous speaker showed where we’re
trying to understand exactly what took place, what
product was used, was it by the veteran themselves
or did they administer it to person they came
across? A relative? We’re trying to understand
what drugs were considered the causing offender for
the overdose. We’re actually looking at follow up
that’s taking place. So what type of V.A.
engagement and care is taking place after the
patient reports this reversal? And these are all
spontaneous reports, so a lot of this is taking
place in the provider’s office when they’re engaging
care and typically when they’re trying to get
another naloxone kit. So how do we know what it was
used for is through that interview process and
trying to get as much information as possible? So
we did centralize this through our academic
detailing program office working with LMHO to be
able to aggregate this information and understand
where we were getting our greatest impact.

This was also a technique for us to outreach
to providers so we’re informing them through
electronic notification and email communication,

“Hey, you had a patient who had another kit ordered,
did you know that? Did you know that they required
another kit? And if you did, can you tell us was it a
reversal that took place?” And that was a way to
also encourage the behavior. We wanted the provider
to know that we were happy they were prescribing
these kits. That we wanted to reinforce the fact
that the insight of how is the provider doing follow
up after a kit is actually prescribed to a patient,
but to thank them for providing the service in their
very busy clinic with all the other things that are
going on so that they continued to look for opportunities within the healthcare system, within their panel of who else could they offer this to? We wanted them to have a positive reinforcement because let me tell you, their day is really busy. There’s a lot that they have to do and this was another new innovation that they weren’t comfortable with, that they didn’t know a whole lot about and that they were taking a risk of introducing that into their practice. So there were over 300-plus emails and communications and we had people calling us and saying “Gosh, thank you for what’s going on.” And that was important so that we could spread this as quickly as possible.

This is some data that shows you about the daily updates. We actually mine our information from our central warehouse so our electronic medical record reposita information nightly and then we query off of that to identify any time there’s a patient that is receiving a naloxone kit. You can see that there’s multiple kits. We’re tracking when a patient not only gets a kit from one V.A. but if another kit is dispensed from another V.A., say in a small catchment area where they use V.A. services at multiple locations, we can see as they go to other locations when that happens. We’re also tracking the number of issuing prescribers and this is actually a little bit older so I know there’s over 1,000 today; I was looking at it this morning. And then we’re looking at how many new providers are coming on board in the last 30 days to give us a sense of how is this spreading across our community of clinicians? Are they sharing the stories with each other? Are they showing successes that are taking place? And then you’re also going to see on this the last column, which is the veteran reversals. So, we treat heroes every day at the V.A. That’s one of the greatest things I get to say in my work and that’s why I work for the V.A. and you better believe that if they have the opportunity to save a life they’re going to. So we know for sure that some of these patients we had dispensed medication to, as naloxone, that was actually then that had the event.

But in some cases, they were using their own kit to save someone else. And so this is definitely a place where there are communities, they’re in drug use communities and they’re not going to not use their kit on their friend that’s beside them and we’re making sure that they get replacement when that happens because they’re still at risk of an overdose. So the issue is that we’re making sure that patients have the information, they know how to respond to reversal, the education’s taking place -- but we also want to know when the supply that they had because they’re at risk for an overdose -- if it’s not in their hand sit needs to be. So how are we making sure that takes place? Our central mail our pharmacy if they have an address we can mail it right to them with a new prescription so we have a lot of ability to communicate that information.

This resource center was developed on our academic detailing SharePoint and we also have an OEND SharePoint that is just excellent and has lots of penetration of information. All the best practices that are going on in the V.A. When we communicate to prescribers about what’s happening with their patients we often share this to them -- with them -- so that they have additional resources. This is where our dashboard and our reports are. We’re using audit and feedback so that they get this information.

So I wanted to tell you a little bit about what our detailers are doing in the last six months of the campaign. They’re providing education on implementation strategies, policy education; they’re identifying candidates for providers. So they’re pharmacists who are saying, “Hey, let’s look at your panel and see who may be at high risk. There’s patients who have benzos on their profile and they’re taking high dose opioids. How do we do risk mitigation strategies for them? Is a naloxone kit an idea for them?” And they’re actually demonstrating the use of the naloxone kit. They’re walking, in, bringing demo kits, giving tangible education because if you don’t have it in your hand you’re much less likely to prescribe that to someone. You don’t know how it works and you feel...
unsure about that, so it was very important that we
got demos out there as much as possible so that
people felt comfortable with that process. You can
see here from our graph, the increase in utilization
and new stations that were coming on board. So as
you can tell, we’re tracking which V.A.s are coming
on board each quarter -- really on a daily basis, a
weekly basis -- we’re looking at the kits that are
released every month, every week. And we’re looking
to try to make sure that we’re capturing the entire
population but we’re also seeing how that’s
spreading into rural areas, very high-risk overdose
locations, making sure that we have penetration in
those areas where we can make the biggest impact.

Other implementation considerations -- our
electronic medical record is a great way for
assessing outcomes. We are using no templates that
embed what we call health factors so that providers
can make assessments of what is occurring in the
medical encounter that you could actually identify
when someone’s getting into recovery program, if
they had an overdose event -- all of that can be
areas where we can really institute that question of
high risk and how to help patients think about who
they could prioritize a naloxone prescription for as
well as through other risk mitigation strategies.

This is real time data. It updates nightly
and so we’re educating primary care so that they can
use this as a population management tool. It will
be expanded to specialties eventually. We’re
working on those programming efforts but for now
this is another method for really suggesting who is
a candidate for this type of strategy. Our pilot
program implementation of OEND was used to inform us
on our next steps and I will go through a few
evaluation approaches that we’ve taken. Elizabeth
Oliva who presented yesterday is working on a
formative evaluation for the pilot and her
publication will be available to us in
implementation science. This is really looking at
barriers and facilitators and we hope to see more
information on that. We also have used feedback
surveys to administer. This is to really understand
if the training has been working for our patients,
what their perceptions of that are. In these
assessments we’ve seen that patients really identify
opioid overdose as an important information. That
knowing what to do during an overdose, they felt
confident about this and they understand the
importance of the training. We’re also seeing that
V.A.s are facilitating call-back programs to be able
to ask veterans in the past six months who are
trained with OEND, who have received a prescription.
This allows the staff to do an assessment of their
input, and we’re also looking at opportunities to
capitalize on our lessons learned.

So, really our electronic medical record is
able to capture a naloxone dispensing. It allows
mechanisms to be in place to capture various records
of what’s happening -- not only events that are
occurring with the patient but what other kind of
care they’re receiving, what other programing
they’re in for substance use disorder. Providers
may not be aware of OEND. We’ve actually modeled
the process. We’ve used pharmacists with their
prescribing privileges to demonstrate how they could
be embedded into note templates and we do have
facilities who have proceeded to use that type of
technique so that they can track very pointed
outcomes that are occurring with their programming
efforts. We also use quick orders so that providers
know exactly how to prescribe this. It defaults all
their instructions. It even connects to patient
education. We do that to empower this. To make
sure that they know it’s permitted. We also do
patient education groups. We embed this inside of
programming efforts and we use multiple healthcare
disciplines to roll this out.

I wanted to make sure I shared with you the
opioid risk reduction report. This includes
information about whether the last time somebody has
had a naloxone dispensed. This is a primary care
tool that is being used for our opiate safety
initiative. In general what it provides is
information specific to a primary care panel. It
demands risk factors, when they’re had urine drug
screening, it also includes information about if
they’re on an active benzodiazepine -- all kinds of
incorporate OEND in their clinic and actually walk through patients with them so that they can feel more comfortable and go forth and do it themselves. But we also need to do a more formative evaluation. We’re really at a stage where we’re just very early in the game. We’re just getting started and making sure that our priority to get it into the V.A.s is here. This is particularly important for patients who are prescribed opioids because the current basis of evidence is really in individuals with opioid use disorder and we have a large population that we’re prescribing opioids for as well. So, I’ll be happy to take questions after the next speaker. Thank you.

[applause]

DR. SKOLNICK: Our final speaker of the day is Chris Jones from the FDA.

CDR. JONES: We’re so close, can you feel it?

[laughter]

It’s very hard for me to sit still in the same place for two days, so -- so to wrap I wanted to provide some perspective that I think previous

certainly from the descriptive before and after pre-post naloxone programs by far have a larger number of studies than you saw on Alex’s slide. Those sort of first two boxes where there were a fair number of studies, certainly more than the other intervention classes here, and then of course at the time of this study -- which basically looked at literature published through December of 2014 -- you see one randomized control trial which is Alex’s. I mean, I’m sorry, one time series analysis, which is Alex’s paper for naloxone programs. No randomized control trials in the literature that we reviewed but that’s pretty consistent for any of the other interventions as well. It’s pretty I would say limited evidence base for the vast majority of interventions that are being put forward.

We also looked at the types of outcomes that were assessed and again, you can see here there was variation by type of intervention and we looked at patient behaviors, which are blue. We looked at provider behaviors, which are red, and then health outcomes, which are green. And you can see here in

caregivers, loved ones, et cetera. And of course this comes from Eliza’s NOSER that was talked about earlier but you could just see the rapid expansion especially in the last several years in distribution of naloxone in the U.S.

So, what do we know about the evaluations that have been done so far? And Alex mentioned this paper that I wrote with colleagues at CDC this past year and we looked at a number of different state or systems level interventions that could be used for prescription drug overdose -- primarily opioid overdose -- and we looked at a couple of different things. First we looked at the different types of studies that have been conducted for the different interventions and four of those that were in this study are included on this slide, so prescription drug monitoring programs, insurer PBM strategies, naloxone programs, and patient, public, and provider education. And we’ve lumped them into essentially three types of studies, so descriptive before or after pre-post type studies, time series analyses, and randomized control trials. Now you can see here

two speakers have really introduced the topic very well -- some from a very implementation perspective at the V.A. and from Alex’s experience over the last several years and thinking about how are they monitoring their impact in the community?

So, as we’ve heard over the last two days it’s really a rapidly changing legal and policy environment for naloxone. So states are passing laws, some of them are similar to other state’s laws, some of them have new provisions in them or have been tweaked in particular ways, and that’s certainly important context for evaluation. There’s certainly concerns about availability and cost and how that might impact implementation in various areas. And of course, looking at expanding how people are accessing naloxone, so pharmacy based programs, community based programs, co-prescription through general medical settings, et cetera, and those are all important for evaluation. Then in of course the broader target population of who should receive it: Patients, people in criminal justice, people in substance abuse treatment, family members,
the naloxone programs obviously as naloxone is an intervention to reduce a death health outcomes were often reported in the evaluations that people were publishing in the peer review literature, and then a lot of it was patient behaviors. And so what were those particular patient behaviors -- and much of this Alex mentioned briefly -- so thinking about are people changing their knowledge on how to recognize and respond to an overdose, increasing their knowledge on correct administration of naloxone, acceptance and use of naloxone. So those were common outcomes that were reported in many of the sort of program evaluation studies on naloxone programs. Some of the provider behavior -- decrease in the number of overdose decedents receiving prescriptions for substances implicated in their overdose, so sort of the idea that engaging people around naloxone may change prescriber behaviors or if there is a reported overdose they’re not going to continue to prescribe opioids or do something different in the treatment plan for that patient. And then studies looking at willingness and barriers that have implemented that, and then from the time series paper a decrease in overdose death rates in communities with naloxone programs and as you saw, there’s sort of a dose response to that decrease.

And I would note from a broader context of opioids that the vast majority of the literature is specific to heroin and so as others have mentioned there is a need to understand this in the context of prescription opioids. So, in looking at the literature -- and this was a recap for that full review that we did -- I think it applies to naloxone programs but it really applies to all of the interventions that people have been talking about. So for the interventions that we looked at including naloxone programs the overall quality of evidence is low and typically the vast majority of studies were descriptive -- before, after, or pre-post studies -- and some of the limitations then I think that we can think about as we are moving towards evaluation in the future and programs are being implemented thinking about what were some of those limitations? So lack of baseline data, lack of control or comparison groups and there’s been some conversation about challenges related to that, lack of randomization, inadequate statistical testing -- often times no statistical testing in a number of studies -- small sample sizes, self-reported outcomes. So you know you’re getting reversals reported but you’re getting them from people who are coming back. But you’re sometimes not getting from the other people who have been to the program. And short term follow up and especially lack of longitudinal data. For the vast majority of interventions it’s pretty short time frames that you’re looking at so really understanding over the long term what’s the impact. And of course, confounding factor for any of the studies this day and age is multiple interventions implemented at the same time and trying to control for or account for the other interventions that may have changes on behaviors upstream or downstream of the intervention.

So, with all of that said, I think it really is a great opportunity to have people who are
interested in this area. It’s clear there’s a lot of passion on this topic and understanding how best to provide this to the population. And so it really is from a researcher’s perspective a great time to be working in this area. So I wanted to sort of capture some of the primary research needs and I think Alex’s slides sort of started doing that. I’m glad he got cut off so I have something to say that’s useful.

[laughter]

But qualitative -- sorry -- it’s the end of the day I feel like I can be a little bit less serious.

So there clearly is a need for qualitative studies to understand how different policies and programs are being implemented. Especially as we broaden the spectrum of how people are accessing naloxone, we need to understand how is that being done. What are the most effective ways to do that? Even from a policy perspective. So, a law was passed. Did people know about the law? How did it get implemented? How did it get operationalized?

of substance abuse disorders really understanding the impact in various populations. And of course that comes with a lot of challenge, but I do think it is important to be thinking about that as people are designing research and conducting research.

Examining circumstances -- place and time of overdose -- we know that some heroin-related overdose deaths at least from the national mortality data sometimes are different than prescription opioid-related deaths as far as where they occur, the circumstances under which they occur. And is that -- can that be informative to how naloxone is offered or training is provided to particular populations? And again, the idea of following individuals over time, I was happy to see that New York was reporting yesterday about following people up to a year and I think, you know, we can build on that type of research.

So, there’s been some discussion too about, okay, so we have this great research questions what data sources do we use to actually answer the research questions? And I wanted to put forth a couple of ideas here. And some of those have already been mentioned and others are certainly actively working in that area. Poison control center data is one where one where naloxone is captured as a variable for administration in an exposure and so you are actually able to capture when an exposure occurs, what was the substance involved, and also, when was naloxone administered? But there certainly are barriers to accessing that data but it is a potential source and it certainly could be improved.

State based surveillance systems that are working. I think Alex is an example of trying to systematically look at the various ways naloxone is being distributed and capture information in a consistent way, so that’s sort of one possibility and helping to understand impact. You heard previous discussions today from EMS or pre-hospital data thinking about how that can be used as the source. Emergency department data or other claims data certainly has its limitations but may be a source to be used at least looking at outcomes in those types of things. PDMP’s may be an option, one,
to help look at just the overall trends and
prescribing and use of prescription opioids and
where that might be hopping in particular
communities and think about maybe those communities
need an infusion of naloxone and you could evaluate
how that has changed prescribing and use behaviors.
And certainly adding naloxone to a state PDMP for
those states who are able to do that or add a flag
for naloxone as being given to a patient so you can
look at what other prescriptions that patient is
receiving and how that might be changing over time.
And then just this question of proprietary data
systems: Are there data systems out there that
people are building or thinking about that could
be useful in this case?

So some of the considerations for
surveillance systems and thinking about -- trying to
measure impact -- I think there are several critical
questions that should be asked. So first, who
overdoes? And previous speakers have talked about
that. Of understanding is it the person who
received naloxone? Did they administer it to

regulatory perspective at FDA that's of importance
but I think more generally that is also important,
you know, did they survive? What were the adverse
events that that person reported? And then I think
following that, what happened with the patient?
Were they connected to some other medical resource
or substance abuse treatment? So trying to have,
again, some longitudinal information on those
patients. And what was the patient’s history with
an overdose education naloxone distribution program?
And then of course, was the patient connected to
other services? So I think those are some of the
basic questions as people are thinking about
surveillance that should be incorporated into their
surveillance work. And I think having some
consistent definitions will help improve our
understanding across the board of how these programs
are being implemented. So, really the next steps I
think as a community of people who are interested in
this topic is identifying the data sources that can
be used to track and measure naloxone impact.

And that may be creation of data sources to

somebody else? So who overdosed? What drugs were
involved? Again, critical to understand, you know,
the particular drugs that were involved, how that
might be changing over time. What product was
administered? So, you know, we're rapidly
introducing new products -- I would say not rapidly
because only one -- but hopefully in the future we
will be having new approved products that will be
into the mix of products that are already out there.
So understanding the types of, you know, I.M. or
I.V. or intranasal, auto injector, et cetera --
which product was administered. Who administered
it? Who was the person? Was it an EMS? Was it a
medical personnel? Non-medical personnel?

Those are certainly important questions.

Where was the naloxone obtained that was
administered? What type of training did the person
who administered it have? Had they been trained?
Had they not been trained? And you’ve seen some of
those from Massachusetts so far as far as how
they’re responding. What was the immediate patient
response including adverse events? Certainly from a

track impact. Looking at systematic and
standardized ways to track naloxone distribution and
use and impact on health outcomes. So again, are we
all asking similar or are we going to say one state
has asked these questions and another state has
asked these questions and we really can’t compare
because there was no standardized way of looking at
it? I think it's important to think about that from
a surveillance perspective. And then rapidly
sharing and translating research findings into
policy and practice improvements. It’s moving very
fast and it would be really great to have as much as
possible evidence informed policy or data driven
policy so that when a state is wrestling with where
-- which way do we go? What do we do here? We can
rapidly have a network to say “Actually, we have,
you know, this information that can be shared.” And
the last two says certainly have been an example of
lots of data that’s not in the peer reviewed
literature yet that is certainly informative for
policy discussions.

So in conclusion, certainly naloxone as we’ve
heard the last couple days, is a key part of a strategy to reduce opioid-related overdose. And I don't want to lose sight of it's a part of a strategy. There are many other pieces to the puzzle that have to take place to fully address this issue.

We are operating in a rapidly changing policy environment and rigorous research using standardized approaches is really going to be important to advance our work in this area and clearly collaboration among all stakeholders is critical.

That's it for me, thanks very much.

[applause]

DR. SEOLHICK: I'd like to thank the speakers for staying on time and now the presentations are open for discussion.

DR. SIMMONS: Yes, hi. Terrific panel. Janie Simmons, NDBI. I wanted to ask, I remember in the Learn to Cope -- Alex, I think it was your paper, but I know it was Learn to Cope; there were people who turned down naloxone. And I know my colleague Alex Bennett at NDBI is working with homeless vets, sometimes people turn it down.

schizophrenia. Patients often didn't want to take that medication for the monitoring issues and so there was a technique in our medical record to actually document that an offer was made and that the veteran determined that they did not want it.

So I think there is a technique for us to do that. We're pretty early in the game so I think it's something if we rolled out nationally it would be a way to kind of have a better comprehension of even why they refused would be kind of -- kind of a good thing to get. The other question I wasn't super clear on so you may want to repeat that again?

DR. SIMMONS: Well, I'm assuming that you can only track data on people who go to V.A. hospitals, right?

DR. CHRISTOPHER: Sure, yeah.

DR. SIMMONS: So just as a citizen I mean, what percentage of the population of veterans of U.S. go to V.A. hospitals as opposed to those that don't? So what -- how much of the population are they offered it, they turn it down. So, the V.A. data, are you able to count -- like all these wonderful other data that you're collecting -- are you able to count if people are turning down the naloxone once it's offered by a provider? And I also wanted to just quickly ask, I mean -- since you have such terrific data -- what percentage of the veteran population go to V.A. clinics so that you're able to track and what percentage don't? Thank you.

DR. CHRISTOPHER: Well, just to take the question regarding whether patients who turn it down is tracked, there are some facilities that are looking at that information especially in the group environments when they're providing group encounters and they're particularly interested in how many go away with the prescription after they do a group education. What we don't have in place but I think it's actually a pretty good idea -- we use a technique called clinical reminders that are often adjudicated and can track, you know, if an offer to a veteran takes place for a particular healthcare intervention. We did this with like clozapine for...
There’s high, high acceptability in the Learn to Cope group. Now, in other venues like detox for example or methadone clinics or primary care that’s a whole different story and you saw Ingrid -- both Ingrid and Phillip -- present on, you know, the primary care setting. I’m particularly impressed, you know, because they -- they’re really working through those issues and giving us very helpful information that’s going to allow us to increase the uptake rate or it’s a triage who we should be, you know, focusing our efforts on and who we should wait till later or wait on.

MR. BRASON:  Fred Brason, Project Lazarus.

And again, I just wanted to take a quick moment to thank Dr. Lurie and the FDA, and HRSA and SAMHSA and CDC and NIDA for putting this all together. I think we’ve crossed like the Grand Canyon in three years since our last meeting and this choir is kind of more in harmony than I think ever before so I greatly appreciate that.

Melissa, regarding the Veteran’s Administration and your program there, I’m curious about a couple of things. When I first approached the V.A. in Durham, North Carolina probably three some years ago when the V.A. was even first considering even doing any kind of naloxone program I was meeting with the Chief of Pain at that facility and just taking a tour and one of the pain docs there explained, you know, “Well, when I have a patient visit I kind of go through three things.” He said, “I tell the patient I want to hear what you have to say.” And then they inform the patient there’s something I have to say and then they inform the patient there’s something in the computer tells us that we have to say. Are we at the place now in the V.A. where the computer is actually telling the prescribers that naloxone is part of an opioid prescribing program for pain?

DR. CHRISTOPHER:  Well, I mean the answer to that question; I guess that’s kind of the perception of the provider. Sometimes there definitely is what we refer to as decision making tools that are embedded into the prescribing and electronic medical record process and different local V.A.s have, in fact, implemented techniques to try to integrate decision making tools so that it kind alerts a clinician that this is available to them as an option. So, some of the things I shared showed kind of something that’s actually outside of the medical record so that report, the -- what we call the “odder.” The odder is actually outside of the medical record and it’s mining data, but the tools that we use within the medical record are sometimes related to risk factors that are being triggered or identified in the particular patient that we’re seeing. So again, that idea of a clinical reminder or decision support -- we do have the technology ability to do that, it’s just at this time the evidence base around, you know, requiring that on every medical record and is that over alert concern is one of the things we’re always balancing to make sure that’s not ignored, that when we do institute thoughtful processes that they’re actually incorporated into the medical practice. So what your clinician from North Carolina was probably alluding to is that, you know, a lot of that is done at some local levels and sometimes we even do that at a national level where we’ll roll out, you know, a preventative health process in that manner.

MR. BRASON:  Good. One note that I saw on one of your slides when you were talking about a request for another kit or something, you know? It said there was also a request for a switch from the intranasal to the auto injector. We have spirited debate among us regarding certain devices and so forth, and that goes on every time we get together between intramuscular and intranasal and now the auto injector. Have you found with the pilot that you’re doing a preference among the prescribers or the patients?

DR. CHRISTOPHER:  Seventy point five percent of our prescriptions are nasal.

MR. BRASON:  25 percent you said?

DR. CHRISTOPHER:  Seven --

MR. BRASON:  Seventy-five --

DR. CHRISTOPHER:  -- point five. And 20 percent -- around 20 percent are the intramuscular device and then we’re up to nine and a half percent.
or so with the -- for the auto injector. Our auto injector from a release standpoint it was made available May let so we really haven't had a whole lot of time for that to be adopted and familiarized so we're still kind of in this step-wise process of getting demos in all the locations so I would say I expect an increase in that number.

Naloxone as a nasal is preferred by patients. I think a lot of patients are asking when they have an option they like the nasal product. I think where we see some folks switch is there is some dexterity concerns. Sometimes they come in with their loved one and they can't get it together, you know? So there's some opportunity to really tailor the selection. I like the idea that some of our homeless veterans in particular can fit the auto injector in their pocket and having to -- I don't know if you saw what Elizabeth Oliva brought, but it's a big --

MR. BRASON: Right.

DR. CHRISTOPHER: -- bank thing. It keeps it clean and it keeps it in the package but where do you put that on your person? So I think sometimes there can be preferences that patients present with based on the size of where they can store it, and so that's some of the things that we're seeing is that when a provider's now aware, "Oh, the auto injector's available or this is available." They may put another prescription request in so that the patient is more likely to keep it on their person.

MR. BRASON: Great, thank you.

MS. WHEELER: Hi, thank you all for presenting. Alex, of course, thanks for sharing the Massachusetts work. Melissa, I just had a comment for you. I work in San Francisco, as you know, and I've had the fortune to work with Elizabeth in the V.A. for the past few years and it's been amazing and just a quick anecdote. We have a young man come that I met at the methadone clinic a little while ago when we were doing Naloxone distribution there and he said, "Oh, I already have some from the V.A. from my provider, but I used it on my sister." So his sister was also using and he saved her, so he was also a hero, so -- and then he went back to get a refill. So what you're doing is working. I never -- ten years ago -- thought that I would hear that the V.A. health systems rolled out a national naloxone program, it's insane. I have to pinch myself.

And then my other comment was for Chris and I guess for the room too, and I don't know if this will resonate at all, but I think a frustration from our perspective sometimes with all of the demand for evidence around naloxone distribution is it feels sometimes like the bar is set very high for this particular intervention to prove it and prove it and prove it and prove it over and over and over again.

And we've seen a similar thing with syringe exchange where 25 years of evidence supporting syringe exchange still hasn't actually helped us, because the resistance is not about research in a lot of ways. We can only tell people it doesn't increase drug use. And yes, drug users are capable of administering naloxone so many times -- and yes, it saves lives. I don't think that's actually the real issue because the demand for evidence from us is not required of other interventions. PDMPs -- little to no evidence that they're effective. We put all kinds of resources into it. We say, "Hey, we need money for naloxone, we get back, "Great, we'll give it to cops." And so there's no evidence that that reduces mortality or doesn't increase drug use.

And I just think that the bar is set really high. I'm not opposed to research. I participate in research I believe in it but I just think it's something for us to think about in reaction those of us who work on the ground, I don't know if people have seen it, have created a video campaign called "I'm the evidence." Where we are the evidence, which is all video testimony of people who have used naloxone or been, saved saying we are actually the evidence.

DR. SKOLNICK: I think we have time for one more question and then we have a wrap up speaker, Dr. Leonard, so last question? Comment?

MS. RUIZ: Be quick, I had a -- thank you to all the panelists. I had another question for
Melissa. That you mentioned that you were going to do a six-month follow up with everybody that received a naloxone kit. I was interested in that opportunity and what questions you’re planning on asking and --

DR. CHRISTOPHER: So I didn’t get to go over that with not a lot of time. But, actually one of our V.A. facilities did kind of put together a case manager interview that they are using in one of the V.A.s in the south and so some of the information that has come out of that has really been more or less trying to identify reversal cases that are taking place and the clinician interviewing the patient for the comfort level they have with the training that took place at an earlier time -- have they used it, do they need a replacement, things like that. So I don’t have the full survey that they’re providing but I guess what wanted to kind of express in the presentation was that the evaluative processes are primarily at this point in our process really going into the implementation steps. So, what they’re learning from those types of interviews that was a bad idea and no one would come and people would see it as a slight and I said, “You don’t know these people.”

[laughter]

“They’re going to come.” And indeed I think looking at late in the afternoon, as many people are here as began, I think that has turned out to be true. I want to just go through some of our plans going forward and some of this you’ve already heard and I probably would have done better if I hadn’t left my piece of paper behind on that chair. Let’s see if I can hit them all the same. So, the plan after this is --

DR. BRASTON: -- save lives as well as speeches.

DR. LURIE: My god, thank you. My god, he does it all. It’s a small state, but what they do there -- remarkable.

[laughter]

So this whole program will be archived and placed on the web so you can go back and review Seamus Mulligan shooting the -- their device into the air and all of the many other visual highlights of this meeting. They’ll be a transcript that will be available about 45 minutes after -- 45 days after this meeting is complete, and we’re going to get the slides from the presenters who wish to share theirs and put them up on the web and most will, I believe. So you’ll be able to see all the important information conveyed in those.

I’ll just remind you if you wanted to submit any comments to -- about this meeting you can do so at www.regulations.gov. So, you know, in addition I got to say I’ve got a very long, long list of to-dos coming out of this meeting. It was pretty long to start with and then we went to the open public hearing session an hour ago and it doubled in length, so I do want you to know that we hear and we heard lots and lots of good ideas today and keep us busy for years to come. I wanted to thank everybody for coming. In particular everybody here in the audience, thank you very much for coming. I want to thank all the co-sponsors, CDC, SAMHSA, BID, HRSA, ONDCP for coming as well so thank you to all of
FDA: Exploring Naxolone Uptake and Use

Day 2

all of our colleagues at FDA, CDC, HRSA, and NIDA for working together to support and facilitate this meeting. I want to thank all of the volunteers including Georgiann Ienzi, Nick Oakley [spelled phonetically], Parinda Jani, Candace Wang, Lauren Diberry [spelled phonetically], Mary Bigley, and Nancy Deere [spelled phonetically] who helped to ensure that the meeting ran smoothly and effectively for all of us. Let’s give them another round of applause, please.

[applause]

Finally, I want to thank each of you, our speakers, moderators, panelists, and audience members for bringing your expertise, insights, commitment, and passion to this meeting. It is with great humility that I echo Peter’s sentiments and express our deep gratitude to all of the individuals on the front line. You have faced the challenges and tragedies of drug overdose daily. You have pressed forward to identify solutions, to implement solutions, to widely disseminate solutions, and in doing so you have transformed tragedy to triumph.

saving lives and providing second chances for loved ones near and far. You have catalyzed and propelled forward local, regional, and national dialogues, policies, and actions where none or few existed before. You have displayed uncommon courage, unflinching responsibility, and an unwavering commitment to not just those you know well, but to complete strangers and to our society as a whole.

We are humbled by your efforts and we are elevated by your compassion. During this meeting we have discussed the human, societal, and economic costs of opioid overdoses and opioid use disorders and to fully appreciate naloxone’s role in this landscape we have to place naloxone in the broadest context of healthcare, public health, and public safety.

Michael Botticelli addressed this broader context in his opening remarks yesterday when he discussed the critical importance of comprehensive, evidence-based, universally accessible healthcare treatment for OUDs, and when he emphasized that medication or treatment for OUDs should be a standard of care just as medication assisted.

For example broken down by red and blue and purple. It’s a slide with no relationship to political activity whatsoever and I thought it was very striking. And, you know, here at FDA you talk about what has happened in the last three years, we get letters at this point from both sides of the aisle asking us why over the counter naloxone is not available, and if that isn’t a sign of progress and acceptance I don’t know what is.

Finally, you know, the question was asked will we be back in three years. I do want to say one last thing on that subject which is you should definitely hold on to this. It’ll clearly be, you know, a keepsake for years to come because if nothing else you will never be invited to a meeting on naloxone again.

Okay. And so, with that, I’d like to offer Kim Leonard the chance to make some final comments.

Thanks.

[applause]

DR. LEONARD: Good afternoon. It is my privilege to join you at this Naloxone Uptake and Public Use Meeting where we are addressing such a vital aspect of health and healthcare for individuals, families, and communities. On behalf of SAMHSA’s administrator Pamela Hyde, myself, and my colleagues across SAMHSA, I thank Peter Lurie and
treatment is a standard of care for heart disease, diabetes, and many other chronic conditions.

And as we conclude our proceedings today, I want to restate and reinforce this point. Naloxone is one part of a comprehensive approach to OUD prevention, treatment, and recovery services -- treatment and recovery services that may include medication assisted treatment as a standard of care. Simultaneously, naloxone plays an equally vital and irreplaceable role in the prevention of unintentional overdose in individuals using medically prescribed opioids to treat pain or other medical conditions and in reversing accidental life threatening opioid poisonings.

It is clear from the discussions at this meeting and from the input of many other stakeholders that we must ramp up our efforts across the board in a number of areas including dissemination of guidelines that inform the clinical use of opioid medications for a variety of health conditions including pain management, expansion of accessible, affordable, high-quality OUD prevention efforts, and its use and success in reducing unintentional overdose morbidity and mortality. Over the past two days we have shared a wealth of data about the community and clinical use of naloxone, its value as a part of a comprehensive approach to overdose reversal and harm reduction efforts, and its use and success in reducing overdose mortality and morbidity across diverse communities and populations.

We have also shared best practices and lessons learned from communities and clinic based overdose education and naloxone distribution programs focused on high-risk populations including veterans and individuals with criminal justice involvement. We have explored the complex dynamics, interconnections, and sometimes contradictory relationships that exist between the appropriate use of medically prescribed opioids, the illicit use of prescribed and non-prescribed opioids including heroin, and the existence of co-morbid confounding health conditions. We have discussed the different formulations and the delivery devices for naloxone including those that are currently in development. We have called out economic, legal, and regulatory barriers to overdose prevention and rescue and we have articulated the importance of medical co-prescribing as the potential value of over-the-counter availability, of vital importance in the public health crisis as well as the panelist speaker sessions. We have shared ideas, evidence, and rationales for the ways and means we could use to accelerate, expand, and scale up research, policies, and practices to advance real time solutions to the opioid crisis.

The efforts of you and so many others on the frontlines have helped to open the windows of opportunity and to actually create windows of opportunity. For example, your work has informed opportunity and to actually create windows of opportunity. For example, your work has informed
reflect on the wealth of insights, information, and ideas that you have presented at this meeting, and will seek the ways and means to translate your ideas into action. In this context, the 2015 meeting has been a platform for discussions and will serve as a springboard for our collective efforts in the future. We look forward to your continued guidance and support in our collective efforts.

In closing, I want to commend you again for your commitment to mitigate the human toll and societal costs of opiate use disorders and opioid overdose mortality and morbidity. Every day you are saving lives, shaping lives, and improving the health and well-being of individuals, families, and communities. Thank you.
Index

A
access 9, 26, 35, 78, 80, 87, 88, 92, 93, 94, 104, 105, 109, 119, 143, 144, 147, 149, 150, 151, 153, 160, 161, 163, 165, 170, 171, 175, 176, 179, 180, 181, 185, 186, 187, 191, 193, 197, 206, 212, 220, 222, 223, 224, 228, 230, 232, 233, 239, 243, 244, 246, 247, 251, 253, 255, 266, 280, 282
Adapt Pharma 100, 101, 105, 106, 153
Alaska 47
Amphastar 153, 174, 191
ASHP 212, 213, 216, 251
Australia 155
B
Baltimore 124, 217, 218, 219, 220, 221, 224
Boston 25, 284
C
California 193, 194, 195, 197, 201, 216, 248, 255, 257
Canada 155
Carolina See North Carolina
CDC 11, 21, 49, 169, 237, 250, 264, 278, 297, 316, 328, 330
CDER 127
Centers for Disease Control
CDC 10
chronic disease 158, 162
Cleveland 224, 228, 284
Colorado 81

D
D.C. Washington, D.C. 33, 213
Department of Health and Human Services, HHS 7, 8
Department of Justice 70, 76
Department of Veterans Affairs See V.A.
DOPE 165, 166, 177
drug users 99, 118, 125, 147, 150, 166, 167, 168, 174, 202, 236, 323
E
E.R. 165, 220
emergency medical services. 40, 45, 52
EMS 2, 9, 10, 11, 12, 13, 15, 16, 17, 20, 23, 25, 26, 28, 29, 32, 33, 38, 39, 41, 42, 43, 45, 47, 49, 52, 54, 56, 59, 61, 62, 63, 65, 67, 69,
80, 82, 84, 85, 87, 94, 96, 97, 228, 273, 307, 309
EMT 13, 18, 19, 26, 28, 35, 41, 42, 44, 68
Europe 116, 154, 155
EVZIO 132, 154
F
FDA 13, 61, 62, 63, 100, 102, 104, 105, 107, 109, 126, 127, 128, 131, 133, 138, 139, 140, 141, 186, 214, 237, 241, 244, 248, 249, 250, 253, 255, 258, 278, 295, 309, 316, 329, 330
fentanyl 83, 144, 268
fire fire prevention services 6, 20, 22, 27, 29, 31, 32, 36, 46, 47, 50, 52, 86, 94, 98, 121, 270, 274
fire departments 20
firefighters 32, 146, 228
first responder 6, 68, 271
Food and Drug Administration See FDA
friends 110, 146, 228, 260
funding 45, 62, 71, 75, 95, 96, 151, 168, 172, 177, 230, 232, 254, 257
G
Georgia 79, 90
Good Samaritan 69, 83, 90, 92, 98, 239
H
Health Resources and Services Administration HRSA 8, 156
healthcare See health care
HHS 37, 101, 102
HIV 207, 232, 259
Indivior 3, 110, 111, 114, 116, 124
intranasal 19, 21, 25, 32, 61, 63, 100, 110, 111, 116, 174, 176, 309, 319
K
Kaléo 62, 175, 179
Kentucky 118
kits 144, 153, 187, 191, 211, 214, 225, 261, 267, 277, 279, 280, 284, 286, 287, 290
L
law 22, 27, 31, 36, 43, 46, 47, 51, 52, 54, 56, 58, 70, 71, 72, 73, 74, 75, 78, 79, 81, 83, 84, 85, 86, 87, 88, 89, 90, 92, 93, 94, 96, 97, 98, 148, 182, 183, 185, 194, 203, 220, 227, 228, 231, 238, 304
law enforcement 22, 27, 31, 36, 46, 47, 52, 54, 56, 58, 70, 71, 72, 73, 74, 75, 78, 79, 81, 83, 84, 85, 86, 87, 88, 89, 90, 92, 93, 94, 96, 97, 227, 231, 238
M
Maryland 1, 213, 255
Mass See Massachusetts
Massachusetts 4, 61, 73, 80, 95, 96, 97, 125, 147, 162, 170, 174, 197, 261, 262, 267, 268, 277, 300, 309, 321
Medicaid 123, 157, 188, 189, 258
methadone 87, 91, 145, 161, 258, 266, 316, 322
MMWR 169, 171, 297, 301
N
NAMSDL 98
Narcan 30, 32, 35, 105, 108, 109, 110, 169, 232, 236
narcotic 127, 132
nasal 101, 103, 107, 108, 109, 110, 133, 162, 167, 175, 186, 213, 214, 269, 319, 320
NASPA 178, 179, 195
National Alliance of State Pharmacy Associations NASPA 178
NDRI 312
needle exchange 143, 145, 148, 169, 173, 177, 202, 218, 275
NEMSIS 13, 14, 15, 38, 49, 50, 51, 52
New Jersey 80
New Mexico 170, 188, 192
New York 23, 24, 26, 29, 31, 33, 36, 52, 55, 58, 59, 80, 95, 98, 146, 147, 170, 174, 185, 306
NHTSA 12, 14, 19, 34, 40, 55
NIDA 103, 118, 250, 256, 278, 316, 328, 330
North Carolina 54, 78, 79, 80, 83, 84, 86, 87, 88, 89, 91, 92, 157, 176, 317, 319
NSURE 140, 141, 142
overdose

OUD

opioids

Oklahoma

Ohio

ONDCP

opiate

over-the-counter

opioid

overdoses See overdose

over-the-counter

P

paramedic

paramedics

PDMP

Pennsylvania

pharmacists

pharmacy

OTC

OUD

overdose

overdoses See overdose

over-the-counter

P

paramedic

paramedics

PDMP

Pennsylvania

pharmacists

pharmacy

OTC

OUD

overdose

overdoses See overdose

over-the-counter