Naloxone Access: Answering Questions

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Moderated by:

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Meeting Transcript

WELCOME

Susan Winckler: Hello, and welcome to our virtual public workshop to answer questions about Naloxone access. My name is Susan Winckler and I serve as the Chief Executive Officer for the Reagan-Udall Foundation for the FDA. And we are pleased to host this workshop today, along with the FDA.

If we go to the next slide, I'm going to [00:00:30] open our meeting, and address some of the housekeeping issues. First to note, we are recording today's workshop and we will be posting the recording along with the slide deck and transcript on our website a few days after the meeting. Second, if you would like to ask a question, please put that in the Zoom Q&A, and we will address those question as time allows. And for those of you who submitted questions with your registration, thank you. We [00:01:00] use that content to develop the main questions for our panel discussion. Note that attendee microphone and video will remain off during the meeting. And our speakers will not be addressing any pending regulatory action in their remarks.

If we go to the next slide. This is our agenda for the next two and a half hours. I'm shortly, going to turn the podium over to Dr. Patrizia Cavazzoni from the [00:01:30] Food and Drug Administration. Then, we're going to have a panel discussion about the current landscape of Naloxone access. And we are closing today's meeting with about an hour of public comments. For those of you who registered in advance to present public comment, which was required, we have you on a list, and we will unmute you when it is time to speak. So, again, a reminder will begin those at 2:00 PM Eastern time. And we do need you to check in [00:02:00] with the meeting host via a chat message by 1:15 Eastern so that we know, in fact, you're present. If you have not checked in by that time, we will not call on you for public comment.

Note that the public commenters, you'll appear by voice only not video. And we will have a clock to help you with that two minute timeframe. We regret having to do the two minute timeframe, but that allows us to hear from as many public commenters as possible.

So, if we [00:02:30] go to the next slide. It's time for me to get out of the way with the housekeeping remarks and let us jump into our discussion today. So, to open our meeting, I'm going to welcome of the podium, Dr. Patrizia Cavazzoni, who is the head of FDA's Center for Drug Evaluation and Research. Dr. Cavazzoni would you provide a few remarks today?

OPENING REMARKS
Patrizia Cavazzoni, MD
Director, Center for Drug Evaluation and Research,
U.S. Food and Drug Administration

Dr. Patrizia Cavazzoni: Yes. Thank you Susan.

Good afternoon, [00:03:00] everyone. And welcome to our public workshop on discussing Naloxone access. I would like to thank all of the speakers, panelists, and attendees for coming together today, and contributing to our explorations of the issues surrounding Naloxone availability. I would also like to thank the organizers of this workshop, the Reagan-Udall Foundation, and acknowledge their dedication in putting together this virtual gathering.

Over the course of the COVID-19 pandemic, we saw drug [00:03:30] overdose deaths reach a record high with CDC's provisional estimate of over 100,000 drug overdose deaths last year. The toll that overdose deaths have inflicted on our country has been devastating, and we continue to prioritize the urgent public health needs resulting from opioids, and the overdose crisis. FDA's approach to advancing solution that address the overdose crisis are grounded in the Department of Health [00:04:00] and Human Services' Overdose Prevention Strategy.

This strategy focuses on primary prevention, harm reduction, evidence-based treatment, and recovery support. Under this strategy, an integral part of our effort is making Naloxone more readily available and accessible. Naloxone is a life saving emergency treatment that reverses opioid overdose. It is a medicine with no abuse potential, and is not a controlled substance. [00:04:30] It can also be administered by individuals with or without medical training to help produce opioid overdose deaths.

Now, with this in mind, we understand the importance of having all forms of Naloxone available for community use. This includes injectable Naloxone, which is the least expensive option. We know that it is especially important for first

respondents, and harm reduction groups to have access to this low-cost product [00:05:00] as part of their community-based distribution programs. The FDA acknowledges the critical work of harm reduction groups to make Naloxone available in their communities. And the agency does not intend to interfere with these efforts.

While countless dedicated organizations at the federal, state, and local levels have themselves to make Naloxone more readily available, we understand that some barriers to access still exist. [00:05:30] In response, FDA has taken a number of steps over the last several years to support increased availability of Naloxone products. This includes our efforts to encourage drug companies to enter the non-prescription market by developing a model drug facts label for over-the-counter, or OTC Naloxone. One of the critical requirements for an OTC product. This was the first time the FDA proactively developed and tested a drug facts label [00:06:00] to support development of an over-the-counter product. With it, FDA intended to ease the burden for industry and facilitate a timely switch from prescription to over-the-counter Naloxone.

However, despite our efforts Naloxone is still a prescription only drug. We are aware of re the recent calls for broadening Naloxone access by switching Naloxone to over-the-counter. And over the years, we have explored [00:06:30] all options available under our authorities, and acknowledge that the transition to OTC remains challenging.

Specifically, FDA has heard the calls for improving the availability of all forms of Naloxone. This includes the intermuscular formulation, for example, the bio and syringe injectable Naloxone, which is a product that poses particular challenges for over-the-counter development. In FDA's statute, non- [00:07:00] prescription drugs are defined as drugs that are safe and effective for use by the general public without the supervision of a healthcare professional. This includes individuals who have never injected drugs, and must demonstrate the ability to administer medication with minimal instructions. As such, other Naloxone formulations, such as intranasal, and autoinjector formulations might be better suited for over-the-counter [00:07:30] transition. But even for these products, we still need data to support safe and effective over-the-counter use.

It has also been to our attention that the transition from prescription to over-the-counter status may, generally, result in a loss of reimbursement through health insurance. And that pricing of an OTC product may create new unintended barriers to access. This is an issue that we're actively examining [00:08:00] with our federal partners. And we also invite private payers to consider this important issue of Naloxone coverage.

Now, despite these challenges, we're forging ahead using all available evidence and tools at our disposal, we're committed to increasing options for opioid overdose reversal, and improving access. As part of this, the agency plans to continue working to advise industry, encourage the development of over-the -

counter [00:08:30] Naloxone, and bringing new products to market. We're also supporting development of novel opioid overdose reversal products, and engaging stakeholders across the healthcare continuum to explore effective solution that increase Naloxone availability.

During this pivotal time in our country, we realized that it's essential to advance the conversation on Naloxone access. Through [00:09:00] this workshop, the Reagan-Udall Foundation has brought together a range of stakeholders, including harm reduction specialists, physicians, pharmacists, and regulators to develop meaningful insights on the current landscape of Naloxone access.

Thank you again for joining. And I look forward to today's thoughtful discussion. I will now turn it back over to Susan Winckler.

Susan Winckler: Great. Thank you so much, Dr. Cavazzoni. And it's always important to [00:09:30] hear from the head of FDA's Center for Drug Evaluation and Research where Naloxone is regulated to open the meeting so thank you. Your appearance underscores FDA, and CDER's commitment to this topic.

So as Dr. Cavazzoni mentioned, drug overdose persists as a major public health issue in the United States. And we have heard a number of questions about access to Naloxone, a drug that [00:10:00] can literally save someone's life when experiencing an opioid overdose. And so, we are gathered today to host this workshop to bring you as many answers as we can.

So if we go to the next slide, as Dr. Cavazzoni mentioned, Naloxone is an FDA approved medication that rapidly reverses the effects of opioid overdose. It's an opioid antagonist, so it binds to the opioid receptors, and reverse, or blocks [00:10:30] their effect. And it's a standard treatment and incredibly helpful in this crisis situation. So, that's just some basics there.

And as Dr. Cavazzoni mentioned, it's known by several branded names. And Naloxone can be administered in a variety of ways, including a nasal spray, so up the nose, an autoinjector, or extracting a dose from a vial, and administering it with [00:11:00] a needle and syringe. So, when we talk about Naloxone, we're talking about all of those different ways that it might be administered, and as well as any of the brand names that might be used to refer to it. But we're all talking about that specific medication, which is Naloxone.

So if we go to the next slide, as I noted, we are going to walk through a whole host of questions with our expert panelists. [00:11:30] But, in addition to that discussion, there are a number of resources available from other agencies within the Department of Health and Human Services, including CDC and SAMHSA and additional material on FDA's website. So, links to those websites are being provided in the chat now, but wanted to make sure you knew there's information that will be shared here. And then, there are a number of other

resources about Naloxone, and expanding access from other [00:12:00] agencies as well.

So, let's go to the next slide, and let's jump into our panel discussion. So, as we looked at the questions that were submitted, we wanted to make sure that we addressed things from a number of different angles. So, we are going to hear from the state regulatory perspective. And so, I'm going to ask Josh Bolin, who is Associate Executive Director for Federal Affairs and Strategy at the National Association [00:12:30] of Boards of Pharmacy to go ahead and put on his camera. And Josh will be calling on you for some questions in this discussion in the next segment of our meeting.

I'll also call on... We know there are questions about pharmacy practice and what is it that pharmacist can do. And so Dr. Jeff Bratberg, whose clinical professor in the College of Pharmacy at the University of Rhode Island is joining us for our discussion.

An important player that we'll [00:13:00] learn more about in Naloxone access is harm reduction organizations, and just experts in this space. And joining us for that perspective is Dr. Nabarun Dasgupta, who is a senior scientist and inquiry prevent and research center innovation fellow at the University of North Carolina's Gillings School of Public Health. Dr. Dasgupta would you come on camera? And I'll also note you're the co-founder of Project Lazarus. Thanks so much for joining us today.

[00:13:30] Coming around to the prescriber perspective, Dr. Bobby Mukkamala is the chair of the board of trustees at the American Medical Association. And we so appreciate you joining us for today's discussion.

And then, rounding out our panel is Dr. Marta Sokolowska, who is the Associate Director for controlled substances at the Center for Drug Evaluation Research at FDA.

So you now see our panelists, and I'm going to tee [00:14:00] this up with a vignette about some of the questions. And then, we're going to start firing the questions away at our panelists. So panelists, a common question about Naloxone is whether it is a prescription drug, which typically described as available only after the intervention of a so-called learned intermediary, a physician, or another healthcare professional, or a prescriber, and available only [00:14:30] in pharmacies, that's one place. Or whether it can be sold without a prescription, which we often call being available over-the-counter for over the pharmacy counter, or in front of the pharmacy counter. But in reality, the distinction between requiring the intervention of a learned intermediary, or a prescriber, and being available without a prescription isn't as clear cut, as I might say, with one being here and one being over here. So, let's [00:15:00] unravel this knot.

Let's turn to our panelists. Dr. Sokolowska, I want to give you the first opportunity to speak. What is the current federal status of Naloxone? Is it available without a prescription, or does it require a prescription?

CURRENT LANDSCAPE of NALOXONE ACCESS
Josh Bolin, National Association of Boards of Pharmacy
Marta Sokolowska, PhD, U.S. Food and Drug Administration
Nabarun Dasgupta, PhD, MPH, University of North Carolina
Bobby Mukkamala, MD, American Medical Association
Jeffrey Bratberg, PharmD, The University of Rhode Island

Dr. Marta Sokolowska: Susan, thank you very much for the question.

So, at the federal level, Naloxone is a prescription only medication. So currently, as you have mentioned earlier, there [00:15:30] are three FDA approved forms of Naloxone, injectable autoinjector, and nasal spray. And all three currently require prescription, which can be a barrier for people who are not under the care of healthcare provider, or who are concerned about the stigma of substance use, or substance use disorder in general.

However, in response to the crisis, all 50 states, and the District of Columbia have some form of Naloxone access law, and most [00:16:00] states, as well as District of Columbia have standing orders, which allow pharmacists to dispense Naloxone and take the place of an individual prescription. Some states also have given pharmacists and direct authority to prescribe and sell Naloxone to consumers. Still, many pharmacists may be unaware of the standing orders and direct authority in these states, or unwilling to provide all forms of Naloxone to consumers [00:16:30] without an individual prescription.

We have heard from multiple stakeholders that make Naloxone more widely available as over-the-counter, or a non-prescription product would be an important public health advancement. One that we are all working on at FDA. We recognize that Naloxone is a critical tool for individual families, first responders, communities to help reduce the opioid overdose deaths. And we recognize the need of Naloxone [00:17:00] that... We recognize that access to Naloxone still continues to be limited in some communities.

Susan Winckler: Thanks so much. And so yes, federal perspective... Well, federal requirement, it does require a prescription. But there are some broader access pieces, which then tees up the question, does FDA have the authority to move a product from a prescription [00:17:30] only status to over-the-counter status?

Dr. Marta Sokolowska: So yes, FDA does have the authority to change a product from prescription only to OTC, over-the-counter. The process of changing the status of the drug from prescription to non-prescription is sometimes called the prescription to OTC switch. It is usually initiated by the manufacturer of a prescription drug.

And for a drug to switch to non-prescription status the [00:18:00] data provided must demonstrate that the drug is safe, and effective for use in self-medication as directed in proposed labeling. The manufacturers must show that consumer in general population can understand how to use the product safely, and effectively without the supervision of healthcare professional. FDA may then approve a switch of a prescription product to non-prescription status when it is determined that the requirements for prescription use are [00:18:30] not necessary for the protection of public health.

So, what does that mean for Naloxone? For a number of years, FDA has encouraged drug companies to enter the OTC market. In January of 2019, the FDA designed, tested, and validated one of the key labeling requirements necessary to approve the OTC version of Naloxone, the drag facts labeling, or DFL. To do this, a model facts labels [00:19:00] was developed with pictogram instructions to instruct users how to administer the drug safely and effectively. Testing of the written label confirmed that it could be read and understood by the general public. This was the first time the FDA proactively developed, and tested a DFL to support development of an OTC product.

However, now in addition to the DFLs that we have published manufacturers need to conduct product specific testing [00:19:30] of device instructions. These instructions need to be easy to implement and understand for the general public. Drafting such instructions might be challenging for intramuscular Naloxone formulation, for example, vial inserted formulation for those who do not have experience with injecting products. This may be more straight for relatively user friendly formulations, such as nasal spray, or autoinjector.

As we are considering [00:20:00] the prescription to OTC switch, we are looking more broadly on the implications of such a switch, and we anticipate that the prescription to OTC transition could impact reimbursement for Naloxone. As it may generally result in loss of reimbursement through healthcare insurance, pricing of OTC version, and it may create additional barriers that there are ongoing efforts to determine the reimbursement implications of a changing status. So it would not produce [00:20:30] additional barriers for patients to get the Naloxone. And we also invite a lot of stakeholders, both federal as well as private payers, to provide their insight on this important issue of Naloxone non-coverage.

So, in summary, with a template for one of the key components for OTC availability of the drug facts label now in place drug companies can use this information as part of the application to obtain OTC Naloxone. [00:21:00] And we are continuing to work with industry partners who are interested in development of OTC products to further this development, and get it available for patients as soon as possible.

Susan Winckler: Great. So, Dr. Sokolowska if I could paraphrase, yes FDA could move us from prescription only to over-the-counter status, but there's also a participation of

the manufacturer in helping with some of that, [00:21:30] what's needed to confirm that a consumer could use the product to show that consumers could safely use the product. Is that a fair paraphrase?

Dr. Marta Sokolowska: That is correct. We need to make sure that in general public, people will be able to read instructions, and administer the product safely and effectively.

Susan Winckler: Yeah. And so, FDA has done some work that we wouldn't usually see in saying, "Here's what the label might look like generally," [00:22:00] but because there are the different dosage forms that some of the work that we still need to see done and kind of show that's another step to get that across the finish line. Or as I keep making my hand motions to move from one side of my screen, to the other side of my screen.

Dr. Marta Sokolowska: Yes, there are multiple presentations of Naloxone products. And for each of these presentations, we need to make sure that the instructions are appropriate. So, again, general public can administer [00:22:30] it.

Susan Winckler: Right. Because it's very different if you're kind of using something intranasally, or an autoinjector, and then the other piece. So, there's some work to be done there, but there's some work being done. So, that answers the question at a federal level that yes, from a federal perspective, Naloxone is a medication that still requires a prescription.

So, let's shift [00:23:00] from federal perspective to state perspective. So, Director Bolin, I'm going to turn to you now. Can a state make a prescription only product available over-the-counter?

Josh Bolin: So states do not have the same drug approval authorities as the FDA. So, broadly speaking, once the FDA has made a product as being prescription only the states don't have that authority to move it to an over-the-counter status.

What has happened at [00:23:30] the state level, in some instances, is that some of them can move, for example, a controlled substance to a higher schedule. There's some differences from state to state along some of those. And then, you have some states, for example, that move like pseudo ephedrine to a prescription only product. So, sometimes you can become more strict, but not less. So, I think just sort of broadly speaking, that's that's where the states come down.

Susan Winckler: So, the federal law is a floor and the [00:24:00] states could make something more restrictive, but they can't go below that floor.

Josh Bolin: That is correct. And I think states, by and large, I don't think that many become more strict. I think it's just in certain instances, if there are certain controlled substances that they might want included in a prescription drug monitoring

program, or something like that, they can identify those, or flag those separately.

Susan Winckler: Okay. So, states are working with the prescription only requirement at the federal level. [00:24:30] But what flexibilities do states have to determine who can prescribe and dispense? So FDA says prescription required, what can states do? And I think we've heard mentioned that states are doing some novel things here with Naloxone. What can states do with that prescription requirement?

Josh Bolin: Sure. So, you have a large number of states that have issued some sort of [00:25:00] statewide standing order where they've just indicated that any prescriber, or dispenser can dispense without a prescription. There's, obviously, some variability within that. Then, you have other states that have taken steps to actually provide the pharmacist with the ability to prescribe medications. And that's something that's evolved over the last several years.

So, some have allowed pharmacists to prescribe certain medications, [00:25:30] or adjust drug therapy, administer vaccines, lab tests, things like that. And some of that comes within a standing order, or collaborative practice agreement. But then, we're starting to see more of a trend more towards a statewide protocol, or limited prescribing sections of law put into place, so that pharmacists can prescribe birth control, smoking sensation. And then, obviously, Naloxone is one that we've seen increase over the last several years.

Susan Winckler: Great. [00:26:00] Thanks Josh, that helps us with the kind of what can happen at the state level. So, federal floor, prescription required. State has some flexibility in who may prescribe, and who may dispense as well.

Okay so, I know some of those standing orders require a physician, or another prescribed to [00:26:30] engage. So Dr. Mukkamala, I'm going to be coming to you. So, what are some best practices that physicians think about whether or not to sign standing orders, or other protocols to expand Naloxone access? 'Cause we've said there's still requires a prescription, but there's some flexibility on who can prescribe. And now, part of that is a standing order. Talk to us about the physician perspective here.

Dr. Bobby Mukkamala: Sure. Yeah, thanks Susan. So there's multiple things that a physician [00:27:00] can do to increase access to Naloxone including, as you mentioned, signing standing orders with their local pharmacy. But in addition to that, doing that with harm reduction organizations as well. So, not just the pharmacy as the source. So, when we talk about best practices for Naloxone it means doing everything we can to ensure that people at risk of overdose and, frankly, their families, and friends, that they have Naloxone. And that's the ideal because when that happens, we won't be reading about another year with 100,000 [00:27:30] plus deaths. So, standing orders are simply one strategy, but an important one to increase that access.

And so, the AMA has strongly supported state legislation to authorize these standing orders that enable pharmacists to dispense Naloxone to an individual without a patient specific prescription. So, we've encouraged state physician leaders, whether that's a state surgeon general, or a public health official to sign county or, ideally, statewide standing orders for Naloxone. And, [00:28:00] of course, we strongly encourage physicians to prescribe Naloxone to patients at risk of overdose as well.

So part of our sort of all of the above approach also includes changing state laws to allow for wider distribution of Naloxone to beyond the pharmacy, and also urging Naloxone manufacturers to finally submit their over-the-counter applications which, as we've heard, is a necessary step. So the AMAs supports physicians signing such orders as part of their working relationship with local harm [00:28:30] reduction organizations. So, if physicians did so it would be much easier for these harm reduction organizations to make bulk purchases of that Naloxone.

And we also encourage physicians to work with their community pharmacies to increase that access as well. So, for example, we encourage our pharmacy colleagues to make the existence of standing orders more visible in their pharmacies, and to ensure that Naloxone is stocked in all pharmacies. So, all too often, we see there's a little 8 1/2 x 11 [00:29:00] sign tap... Or taped to the side somewhere in the back of the pharmacy about the benefits of Naloxone. And those signs are fine, but they need to be more clear, more visible, so that when an at risk person, or their family comes in to pick up a prescription for amoxicillin, let's say, and they see the sign, and they think about their, or their own loved one's risk, and act at that moment by going home with the antibiotic. But also going home with a potentially lifesaving dose of Naloxone. [00:29:30] So, they should know that their perceived barriers like, "I can't get that because I don't have a prescription," or, "I can't afford it" are not, in fact, barriers because it's covered by most insurances.

So, we also need to ensure that pharmacies have Naloxone in stock. This is a big issue. There are too many reports of pharmacies not carrying the medication because they don't want to attract "that population." And sometimes up to 50% of pharmacies, in certain areas, don't even have it in stock. So, we need to combat the stigma [00:30:00] forcefully if we're going to improve health equity, frankly. And I'm sure that many pharmacists talk to their patients about Naloxone, but Naloxone dispensing is not as common. So, pharmacists are busy, they're pressed for time like everyone and going out of one's comfort zone doesn't happen when we're busy. So, standing orders at the pharmacy counter are only effective when they're used. And we need to be honest that they're just not used very often.

On the other hand, standing orders with harm reduction organizations [00:30:30] are very effective. The purpose of Naloxone is the exact purpose of these organizations, and that's to save lives. So we're gratified the data show that millions of doses of Naloxone are purchased and distributed by harm

reduction organizations. But the takeaway here is that the AMA really encourages much greater awareness, and use of standing orders for Naloxone, both in the pharmacy setting and in harm reduction organizations.

Susan Winckler: Really helpful. And so, if I may paraphrase [00:31:00] there as well, kind of under scoring the AMA's support for physicians to say, "Yes, sign these standing orders and make it available." Partnering with pharmacy and with harm reduction organizations, that's a way. And then, in addition, encouraging physicians to talk to their patients about why you would want to have Naloxone available because, [00:31:30] if I understand correctly, you would even want Naloxone available when prescribing opioids because problems can occur, or just situations can emerge where one would need Naloxone as a prescription opioid user, is that right?

Dr. Bobby Mukkamala: Yeah, for sure that. But I mean, as we've seen the trend though, it's much more than prescription opioids now.

Susan Winckler: Correct.

Dr. Bobby Mukkamala: But absolutely, as long as we're limited, and it has to come through a conversation with the physician then yes, we need to [00:32:00] have more of those conversations. But the overall goal is to sort of get rid of that step. And, as we've already heard today, the wheels are in motion to do that, to just minimize the number of hurdles between a patient that's at risk, and the Naloxone that they need.

Susan Winckler: Wonderful. So, you raised the importance of the pharmacist piece because we've got that floor requirement of a prescription, and then dispensing largely from a pharmacy, or a harm reduction organization. And I'm going to get to you [00:32:30] Dr. Dasgupta as well. But let's turn first Dr. Bratberg tell us a little bit about pharmacist involvement in expanding Naloxone access.

Dr. Jeff Bratberg.: Yeah, thank you. I think it's important to start from the beginning. And I appreciate the comments about the involvement of pharmacists in standing orders. I was part of a group with the first statewide collaborative practice agreement for Naloxone in Rhode Island, one of the top states, unfortunately, for per capita opioid overdose deaths.

[00:33:00] And I think it's important for people listening to realize that this is a step outside pharmacists comfort zone. Pharmacists are used to receiving a prescription in the name of a person, and dispensing it. So, again, it's important to realize that through advocacy, and collaboration with public health experts, and physicians thousands, and thousands, and thousands of pharmacists and pharmacy students have been trained in overdose response, and Naloxone [00:33:30] access to, as we've heard, prescribe independently, or to work with standing orders, or protocols.

But realize this is still unusual. It's very hard. We went from punitive restrictions on opioids that have had a pendulum effect in restricting opioids to, "Well here's Naloxone, let's co-dispense this let's co-prescribe this." We've moved from assuring that the med is correct within person's name on it to third-party prescribing to caregivers, to families [00:34:00] where we say, "Here's Naloxone, you need to use this on someone else, and need to train..."

PART 1 OF 4 ENDS [00:34:04]

Dr. Jeff Bratberg: Where we say, "Here's Naloxone and you need to use this on someone else. I need to train you, or you need to train your family members to use it for you." These are unusual, hard things, not just for pharmacists, but really for all prescribers or healthcare workers. Who it's not unusual for are the people who are at the greatest risk, which are the people who use drugs, who are using an unsafe supply contaminated most greatly with fentanyl. What's not hard is understanding that OTC Naloxone's needed now. [00:34:30] Almost two million people have seen a YouTube clip in the last two days from John Oliver on Last Week Tonight, basically asking the FDA to remove Naloxone's prescription-only status and do it right now. And this follows up a year ago when the American Pharmacist Association passed policy to not only increase the availability of Naloxone, supporting it as both a prescription and non prescription medication.

And we applaud the AMA for citing our policy, and to ensure equitable access and affordability [00:35:00] of at least one formulation regardless of prescription status and to provide fair reimbursement to dispensers of Naloxone, because not only are these conversations difficult, they take a long time and they're unreimbursed. We are one of the only practitioners who give away our cognitive knowledge. Let me tell you, I just went to a doctor's visit with my son this morning, and I'm going to get a bill for it for advice. And that is not something that pharmacists are getting. And if we want greater access, reimbursement appropriately for our services is desperately [00:35:30] needed in both in this public health problem of overdose, but also other public health problems.

Susan Winckler: Jeff, that's helpful in illuminating that it's different, that for the other tens of thousands of medications, a prescription comes in with Dr. Bratberg's name or Dr. Dasgupta's name and the pharmacist's responsibility is to say, "Is that the right medication [00:36:00] for that in individual?" in that assessment. And here with Naloxone, it's different. It's a preventive and maybe dispensed not to the individual at risk, but to a caregiver, and then having the conversation about how to use it correctly. But I'm encouraged that you mentioned that pharmacists are... At least some are saying, "Yes, we want to lean into this and understand how to do it."

Dr. Jeff Bratberg: [00:36:30] Yeah, we have difficult conversations just as prescribers do. We've been, again, in Rhode Island, we've been filling this for 10 years. I think the other thing that we've advocated for is not only here mandated insurance

coverage, but not enough, right? Copays can be up to $80, and that's inhibitory, especially in commercial insurances, even though they are mostly covering Naloxone, some add zero copays. That's great, but realize that even though what we've done is we've mandated co-prescribing and we [00:37:00] have some of the greatest pharmacy based access, not only in our state, but several other states that have passed co-prescribing saying, "You're getting this prescription opioid. Here it is." And our laws as broad is it includes the highest risk populations. Those who are prescribed medications for opioid use disorder, are diagnosed with opioid use disorder, or who've had previous nonfatal overdose. Those are the highest risk and really anybody buying syringes or physicians who are prescribing syringes. There's opportunities to have [00:37:30] those conversations, multiple conversations to decrease the societal, familial, and self stigma that people who use drugs have that inhibit their access to Naloxone.

Susan Winckler: Thank you for raising syringes. Let's ask one more kind of federal state legal requirement question here. I'm going to first turn to you, Dr. Sokolovska, do supplies like syringes, which are required to administer some [00:38:00] forms of Naloxone, do you need a prescription to obtain syringes from the FDA perspective? So the federal perspective. What's that federal status?

Dr. Marta Sokolowska: Whether a prescription is needed to obtain a syringe depends on a state. This is not federal. Depending on the state and local regulations prescriptions for syringes just may or may not be required.

Susan Winckler: Okay. This is one where the floor from the federal is no prescription required. Josh, [00:38:30] what happens? I should say, Director Bolin. What happens when we transition from the FDA, no prescription required to the state level?

Josh Bolin: You could have different floors in different states. I think, historically, many states have previously classified syringes as being drug paraphernalia. Depending on how that state classification started, and there's been a lot of evolution over the course of the past decade or so, many states [00:39:00] have taken steps to actually provide exceptions because of the opioid epidemic and trying to increase access.

Many states do allow for syringes to be sold over the counter as long as certain criteria are met. For example, if you're selling to someone who's over the age of 18, or if it's being dispensed in limited quantities for example, like less than 10 syringes, those are some instances where states have [00:39:30] sort of walked back some of those regulations.

There are many states that actually allow pharmacists to use their professional judgment to dispense the appropriate needle or syringe to accompany a prescription for an injectable drug. There certainly is some differences state to state, but that's why discussions like this, I think, are so important because it gives us an opportunity to understand what's good model policy? What's

something that we can work on collaboratively and then try to get some more uniformity [00:40:00] from a state level perspective?

Susan Winckler: That's really helpful in kind of helping on the different levels of floor there. I'm going to turn us to a different vignette, unless, Dr. Dasgupta, I saw you unmute. You want to jump in? Okay. It's because I'm coming to the new vignette. We have clarity that Naloxone does today require the intervention of a learned intermediary from the federal [00:40:30] perspective, but how that learned intermediary role is played is up to the state. And so that's where we get standing order, and some of the other kind of broad prescribing ability authorizing pharmacists to prescribe, authorizing administration in harm reduction organization.

Let's turn to a second area. This is our vignette number two. Because Naloxone is in this kind of middle ground where we have broad parameters for who may be [00:41:00] that learned intermediary, or prescriber, and who may be the dispenser that, we've heard, creates some challenges regarding purchasing Naloxone and other items necessary to use the product. Let's go there and we're going to turn now to the harm reduction organizations, as Dr. Mukkamala said, Dr. Desgupta, harm reduction organizations exist solely to help [00:41:30] in this space. Naloxone is one of their important components. Why don't we return to our panel discussion? I want to turn to you. I've heard that in some cases, pharmaceutical companies require signed agreements with harm reduction companies to then distribute Naloxone. Tell us more about that.

Dr. Nabarun Dasgupta: Sure. Thank you. I have deep respect for the integrity of the pharmaceutical supply chain and FDA's role in securing it. [00:42:00] Thank you first to the public officials who convene this meeting and who protect our health. Safe medications are vital and an underappreciated part of public health. With Naloxone, however, the very rules that typically safeguard consumers are having the opposite effect and harm reduction programs know better than most the dangers of an unregulated drug supply. It is unregulated drugs, street drugs that are killing people. We are fighting unregulated drugs with an overregulated antidote. No wonder we're not making more progress. [00:42:30] There's an immense overlooked burden on harm reduction programs to actually procure Naloxone. You have the privilege today of hearing specifics from out upcoming speakers, but I'll summarize their experience. Literally every day, I hear another heartbreaking tale of inefficiency and hassle of administrative waste.

Pharmaceutical companies are reluctant gatekeepers because of Naloxone's prescription only status, a position they don't like being in. However, the threat of federal action [00:43:00] makes them overly risk averse. On a practical basis, it looks like this. Pharmaceutical manufacturers and distributors require a medical or pharmacy license to ship Naloxone to a program. They also require typically that the program ordering the Naloxone provide a DEA license number, even though Naloxone is not a controlled substance. I'll touch on that in a moment. If a program has multiple sites, the distributor often requires a separate physician license for each ship to address. They will only ship to

commercial addresses [00:43:30] even for a single box of Naloxone for a small program, which is infuriating during a pandemic, and makes especially no sense for mobile programs serving remote and rural areas. Last year, joining the affordable Naloxone shortage, a manufacturer wanted to make a donation to harm reduction programs.

They required not only a DEA number and a medical license, but also assigned affidavit from each doctor because the ship to address of the harm reduction programs didn't match the doctor's clinic address, right? In a broader sense. [00:44:00] These things make sense, have a place in the supply chain for Naloxone. These are things that are killing people. Another organization routinely donates Naloxone, and additionally requires a clinic profile from the harm reduction programs, which doesn't fit any of the harm reduction programs and results in denied requests. This happens like all the time. Even when cost is not a factor, these archaic workarounds have to be put into place to get Naloxone actually into the hands of people who can do the most [00:44:30] good. But aren't the state standing orders supposed to circumvent some of this like we were hearing? When we present those standing orders to Naloxone manufacturers, they point out that the standing orders only cover community distribution, not purchasing.

This is infuriating. In Pennsylvania, where the state provides Naloxone nasal sprayer programs, you'll hear from Alice Bell who has to have a halftime employee to just deal with the paperwork of obtaining Naloxone. 20 hours per week for one program, [00:45:00] just to procure Naloxone from a state that's already paying for a lot of the product. So ask yourself, who does the prescription requirement for Naloxone serve? We've heard from AMA and FDA that Naloxone is safe enough, in theory, that a physician involvement is not needed. The manufacturers don't like having to treat this lifesaving drug is prescription only either, and they've told us as much, and would much rather see the product used to save lives. So, let me be clear. A few generic Naloxone manufacturers have been immensely helpful in providing low cost Naloxone [00:45:30] in times of crisis and shortage. We are grateful to them, but as regulated industry, they can only release prescription drugs to doctors and pharmacies.

And so corporate compliance officers impose these additional requirements in case they're called out by FDA or state pharmacy boards. One solution would be to make community groups exempt from wholesale distribution regulations to distribute an emergency medication during a declared public health emergency. This is pretty logical, right? This doesn't solve all the problems with Naloxone [00:46:00] distribution, but it would alleviate community groups from having to have a prescriber. The DEA number requirement is really baffling. A DEA number is like a social security number, right? You can only give out in various circumscribed situations, when a physician retires or moves out of state programs spend months courting new prescribers. Can you imagine asking strangers for their social security numbers? Because that's what it's like. Manufacturers require a DEA number because their IT and customer account

systems are not able [00:46:30] to make a carve-out for a single prescription drug that has this hybrid regulation between state and federal authorities.

We've worked with multiple manufacturers for years, for years to solve this silly problem, but it's intractable. Even if the DEA number wasn't required, getting a prescriber is difficult. Most harm reduction program prescribers are an addiction medicine. They don't routinely even administer Naloxone. And most times the harm reduction programs teach the doctor more about Naloxone than the other way around. [00:47:00] This is the reality on the ground. So even if a DEA number was not required, having to beg a prescriber means that smaller groups with access to heart to reach populations. Those at the greatest risk of overdose are the ones that get systematically excluded.

Susan Winckler: I want to pull a piece that you shared, that's consistent with comments of Dr. Bratberg and Dr. Mukkamala, which is that idea that Naloxone is different and that different [00:47:30] creates friction, right? Creates friction with the pharmaceutical companies who are used to, "I only sell to Dr. Bratberg on the authorization of Dr. Mukkamala." They have a structure that's not thinking about this. It sounds like there may be an opportunity there for some education and saying, "Yes, it is different and for now you need to treat it differently and kind [00:48:00] of figure out a different path." I do want to get an authoritative answer. Dr. Sokolovska, I'm going to turn to you as the authority. Would you answer this question? Do you need to have a DEA number or be a DEA registrant to prescribe Naloxone? I'm pretty sure I know the answer to that question and our panelists know the answer to that question, but would you answer that question for us? Do you need a DEA number to prescribe [00:48:30] or order Naloxone?

Dr. Marta Sokolowska: Well, to clarify, DEA would be the best to answer this question, however...

Susan Winckler: Correct, but you are here with us today.

Dr. Marta Sokolowska: I'm happy to provide the input that I can. In our understanding, under the Controlled Substances Act, any person who manufactures, distributes expenses, imports, exports, conducts research chemical analysis with controlled substances must register with DEA unless they exempt. However, [00:49:00] Naloxone is not a controlled substance. It is not scheduled as it has no abuse liability, therefore it should not be covered under this requirement. Prescribers should handle Naloxone as if it were any other non-controlled medications, such as antibiotics. And you do not need DEA [inaudible 00:49:21] for prescribing of antibiotics. Decisions made by individuals, organization, or companies requiring a DEA number is likely not based [00:49:30] on federal require. Although a DEA number is not mandatory for medical providers who do not plan to prescribe controlled substances. It is common for healthcare practitioners to be DEA registered.

Susan Winckler: So, no.

Dr. Marta Sokolowska: No.

Susan Winckler: Because it's not a controlled substance. Okay. We'll capture that on a kind of what you should know. [00:50:00] That's a requirement that's kind of inconsistent. I want to ask a follow up question that relates a bit to this kind of controlled substances, things being different, a number of other pieces. I want to come to you, Dr. Mukkamala. Can physicians prescribe Naloxone without any special certification or do you need... There are some treatments in this space where you need a special certification. Where does Naloxone fit in the physician prescribing authority [00:50:30] and training?

Dr. Bobby Mukkamala: Yep. You're absolutely right. There are some things that relate to substance use disorder that require special training. Naloxone is not one of them. I can just as easily write Naloxone as I can write amoxicillin. buprenorphine, different category. That requires training. It's an opioid, and so a whole different category, but Naloxone is not in that category. It's more like amoxicillin than it is like buprenorphine.

Susan Winckler: Great. So, no special [00:51:00] training required. It's just kind of straightforward within their typical medical practice, training, and authority.

Dr. Bobby Mukkamala: Yep, you got it.

Susan Winckler: Great. I'm going to toss a question to Dr. Bratberg, and then come back to you, Dr. Desgupta, on some of the mechanics with wholesalers. But Dr. Bratberg, let me turn to you. We've heard, and you acknowledge, that Naloxone [00:51:30] access is somewhat disparate across the country. What contributes to kind of that distribution and access?

Dr. Jeff Bratberg: Yeah, I'm as concerned as everyone here and all of our listeners that here we have an essential medication that people have literally run into pharmacies thinking it's going to be there and it's not there, and people have died. That is a true anecdote. I've heard here in Rhode Island and countless other places. In fact, we've even written about [00:52:00] pharmacy overdose response programs because there's a trained first responder, of course, we're all first responders when it comes to overdose. Every overdose death is a preventable death, as long as Naloxone's available. It's important that some pharmacies are responding to overdoses in their bathrooms, in their stores, in their parking lots. And that happens every single day, but the Naloxone needs to be there. We have to say, "Well, why is it that some pharmacies wouldn't stock it?" Well, stigma's obviously [00:52:30] a huge issue, but I think there's also demand. There's a correlation in some of the studies.

I think my colleagues would agree with me of... Dr. Mukkamala mentioned buprenorphine. Some pharmacies don't stock buprenorphine, which is a highly effective medication, first line therapy to treat opioid use disorder. There are pharmacies that don't stock that essential medication. They also don't often

don't stock Naloxone. And I think that just shows that 80% of people with OUD aren't getting access to their medications [00:53:00] and therefore there's no demand. And we all know when we go buy things, if there's no demand for something, we're not going to have it on the shelf. The difference with pharmacies, they lose money putting that on the shelf. We talked about lack of reimbursement. There's a great federal law, or bill, that we should pass to help pharmacist providers in underserved areas. I think it's important. We looked that up, but we're also getting poor reimbursement on the drug itself.

Because of some pharmacy benefit managers, there are pharmacies that are losing [00:53:30] money doing the right thing, recommending, dispensing Naloxone, co-dispensing, and co-prescribing it or dispensing co-prescribed Naloxone, and they're losing money due to PBM efforts for that. That's just insanity, essentially. We now have a willing pharmacist. They've been educated, the education's out there, we've done all these things. They have learned it in school. The technicians are on board. We know pharmacy technicians can do this. They can prescribe in certain states, even Naloxone.

We're increasing the number [00:54:00] of people who can provide it. In our studies we've even seen in over 140 pharmacies, 85% of people were able to get Naloxone, but that differed by state and by region. I think we need to... We did have a shortage of affordable Naloxone and that never happened in pharmacies. It was just they didn't stock it because they didn't want to lose money on it, and because there wasn't demand. Again, it may not even be healthcare worker stigma or prescriber stigma, it's family stigma. It's societal stigma. It's these things [00:54:30] that say, "I don't want to carry this. If I'm even taking prescription opioids legitimately for chronic pain." People do not want to possess it sometimes or have their name on it or have their insurance company know about it.

Susan Winckler: Part of this may, too, being helping those within the healthcare system, harm reduction organizations and the general public, that this is an antidote that you want to have [00:55:00] on hand, that you are saving lives, and the stigma should not be with the opportunity to save someone's life when you can do that. Thank you, Dr. Bratberg.

I want to turn to Dr. Desgupta. I've got another one here that seems like another friction point. [00:55:30] How do harm reduction... We don't have anybody here from drug wholesalers, but that's who whole often holds the medication. It comes from the manufacturer to a drug wholesaler who then distributes it out to those who purchase, often pharmacies for prescription drugs. And then really just about anyone for over the counter drugs, because they can be sold anywhere. We've confirmed [00:56:00] that Naloxone is in this odd space in between. What tell us about what happens when harm reduction organizations then try to interact with wholesalers and actually kind of buy the product in addition to perhaps requiring numbers that shouldn't be required? What else happens?

Dr. Nabarun Dasgupta: That's a really good question. And this is like one of those things that is so in the weeds that you don't really think about it when you're thinking [00:56:30] about big policy, but it makes all the difference on the ground, right? So harm reduction programs have accounts with major pharmaceutical distributors and regularly buy OTC supplies like sterile water, syringes, antibiotic ointment, but the distributors don't have a customer account paradigm for a drug like Naloxone. You said it great. Differences cause friction. State standing orders are super variable and evolving, too. And so there's no single ordering system that's going to easily keep up with them. Therefore, when it comes to Naloxone, wholesale [00:57:00] pharmaceutical distributor's default position is to treat harm reduction programs like pharmacies because it's a prescription drug. So as many harm reduction programs don't have a pharmacy or medical license, they aren't eligible for the type of accounts that can purchase Naloxone or other prescription drugs directly.

They can only get OTC accounts. The distributors work around is to sell product between their OTC and prescription drug divisions. And then they [00:57:30] operate as separate financial entities. This process can take weeks or months. When you call the company, you might get a sales rep who hasn't heard of this arrangement. So what happens? Your order is denied. If you're a new program and this is your first encounter being told by the gatekeeper that they can't sell you the prescription drug. Right now, programs quietly share the names of sympathetic regional managers at different pharma distributors to order product. Are we rarely going to let Naloxone distribution [00:58:00] be predicated on these one-off relationships with pharma sales reps? I really, really hope that their job satisfaction is super high because if any one of them leaves, we will feel shock waves. These are some of the reluctant gatekeepers and we need for them to clearly understand how their federal government intends for Naloxone to be distributed.

I'll be candid. I was involved in writing some of the state standing orders years ago, and this is not something we anticipated. I mean, really, it's even hard to believe that lifesaving antidote is getting snagged on such a [00:58:30] mundane drag net. If we don't act now to find an alternative distribution system, then we are seating our public health duty to corporate compliance officers and uninformed bureaucrats. These reluctant gatekeepers place, overly cautious requirements on Naloxone. At my institution, at UNC and down the street at Duke, full of well-informed professional advocates and pharmacy and medicine, right? University compliance officers have killed project after project to place Naloxone vending machines in the community, and refuse [00:59:00] to let us hand out Naloxone in research studies where we're interviewing people who use drugs about their overdose risk, right? This is the level of... This is the cascade of consequences that happens.

There's always another reason to say no. In Alabama, there's a state law specifically prohibiting harm reduction groups from handing out Naloxone because they aren't licensed dispensers. A high level group of doctors and pharmacists convened last month and couldn't figure their way out of it. So just

one health department and the entire state offers Naloxone mostly by mail. [00:59:30] The deck is really stacked against harm reduction programs. In addition to manufacturers and distributors, government agencies also have excessive requirements. In places in Michigan, the regional entity distributing the SOR, State Opioid Response funds, insist that programs Naloxone are JCO accredited clinics. So like the hospital quality accreditation system. So who does this benefit? You'll hear from Pamela Lynch later, who runs one of the largest Naloxone distribution programs in the state. They [01:00:00] don't receive a single penny in federal support. In fact, half of the programs in the Naloxone buyers club don't receive any federal support from Naloxone, largely because the paperwork burden from state health departments is too high or because existing relationships include harm reduction programs.

When we think of wasteful administrative burden for Naloxone programs, as a reference, think about what Dr. Bratberg just said, too, right? What we've done to get methadone and buprenorphine to be easier. We've offered transportation vouchers to medical appointments. [01:00:30] We have a national physician training program, Telemedicine. None of this framework exists for Naloxone. The programs are left negotiating these paperwork requirements with powerful companies with essentially no legal backing. Reluctant gatekeepers lead to power imbalances. And when laws are murky, corporate compliance officers and government bureaucrats will make their own rules. They'll impose additional paperwork burden to cover their own legal exposure. So, again, who does the prescription requirement serve? [01:01:00] Honestly, it's a miracle their harm reduction program even operate at all in this environment.

Susan Winckler: Thankfully, they are operating. But as you note, we can do better, right? In saying, how do we help companies work through these friction points and get to a better system. You raise something that we wanted to turn to in our third vignette. I want to pull up that slide and let's pivot [01:01:30] to our last vignette here. And so we know that each one of you is conveying so powerfully the intent to save lives and get Naloxone into the hands of individuals who need it. And we have some novel distribution approaches that are emerging.

But I think it's fair to say that federal and state drug medical practice and pharmacy practice laws and regulations don't always deal [01:02:00] well with novel. I think we've illustrated that a couple of different ways here. So let's talk about some of those novel situations. What have we learned from those strategies? Where do we see promise for making Naloxone access easier? We have that common goal, but let's talk about some of those. So I'm going to turn first, Director Bolin, I'm going to turn to you, what does an expansive... I'll go ahead and say expansive, good, [01:02:30] Naloxone standing order look like from a state pharmacy practice act or state medical practice act perspective? What does good look like?

Josh Bolin: Sure. One of the examples we point to is actually something that Dr. Gupta, director for the Office of National Drug Control Policy referenced last year, there

was some work done by the legislative analysis and public policy association, their model on expanding access to [01:03:00] Naloxone. I shortened up the title of that just for purposes of time. But I think some of the things identified in that model, having a state designated physician to issue the issue, the order across the state. That way you don't have to do that within an individual community setting. It can be a statewide standing order, making sure that within that order that authorizes any prescriber or dispenser to prescribe or dispense Naloxone. And it also [01:03:30] allows for the possession, storage, distribution, and administration by any individual or entity within state.

Again, that's general that provides some of that flexibility. The other key point within that model is that it also speaks to that remaining in effect until the FDA classifies at least one version as being an over the counter product. I know that's all very broad, but I think it also speaks some of the constraints and concerns that we heard from Dr. [01:04:00] Dasgupta in terms of, you have these harm reduction organizations that are working so hard to save lives, and you have the boards of pharmacy and other regulatory entities that are also working hard to save lives.

They're, in many cases, being given a set of laws by a state legislature, and sometimes they don't have flexibility to, as you said, to do novel. I think that's where there's an opportunity, because if I were a state, and I used to be the director for a state board of pharmacy, [01:04:30] I wouldn't know where to put a harm reduction organization within the structure that exists. Short of the move toward OTC, then we need new structures to make sure that state at the state level they understand and have confidence in what harm reduction organizations are doing. But at the same time, give the flexibility so that it does remove those barriers and can get Naloxone in the hands of those that so desperately need it.

Susan Winckler: [01:05:00] I heard you share broad access in thinking outside the box in structuring the state practice act language. I also heard you speak to the intersection of harm reduction organizations with the more traditional healthcare system, which then I want to take that to a question to Dr. Mukkamala. How can prescribers think about working with harm reduction [01:05:30] organizations related to Naloxone dosing and just providing access? I think Dr. Dasgupta Would love to connect more with willing prescribers, but how should we think about that relationship?

Dr. Bobby Mukkamala: Yeah. Yep. Prescribers can leverage this expertise of harm reduction groups by not overthinking Naloxone dosing. We've already heard some the hesitancy across the board, but including the [01:06:00] prescribers, and not getting caught up in the marketing material of manufacturers about how big of a dose of Naloxone is needed for a given situation. As we've heard, and we'll hear from my fellow panelists, the key is getting Naloxone into people's hands. And so if you wouldn't mind just tossing up my first slide.

Manufacturers want to sell as much product as possible. While that's not surprising, we're in an unprecedented epidemic, and so new products of increased [01:06:30] dosages are good in the sense that there are more options available, but not if those options remain behind the counter and in particular cost prohibitive. I'm not sure if the slide's up or not, but it's basically somebody looking through their wallet at the pharmacy counter.

Yeah, there, exactly. So, it's essential that we all recognize the tens of thousands of lives that are saved because of the tireless work done by harm reduction organizations across the country. But Naloxone can't save a life if it's unaffordable [01:07:00] or not accessible for any reason. The nation's overdose epidemic is about unintentional overdose at this point. And that's why it's essential that we listen more closely to these harm reduction organizations about Naloxone dosing, Naloxone availability, removing stigma, and other initiatives that will increase access to Naloxone and other services, including sterile needles, syringes, drug supplies, drug checking supplies.

Whether it's two milligrams, [01:07:30] or four milligrams, or eight milligrams of Naloxone, if it's not in the community, it's not saving lives. When Naloxone is cost prohibitive at the pharmacy counter, like in this picture, it's definitely not saving lives. Furthermore, we should not view Naloxone in a vacuum as though it's the only harm reduction tool in the toolbox, but it is an essential tool, and that's why we're talking about it today. It has decades of proven efficacy and knowledge about dosing is important. Let's discuss it, but we need to make sure that [01:08:00] doesn't hinder the access. So in other words, given the multiple..

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PART 2 OF 4 ENDS [01:08:04]

Dr. Bobby Mukkamala: ... doesn't hinder the access. So, in other words, given the multiple formulations and delivery devices, let's keep the focus on getting the product into the hands of people where it can save lives. But that means making it widely available at affordable prices, right, and so in our pharmacies and our harm reduction facilities, somebody's got to buy this stuff. So making Naloxone available OTC will help remove stigma and pressure manufacturers, hopefully, to make their products more affordable. Removing Naloxone's [01:08:30] prescription status also makes it much easier and more affordable for organizations to bulk purchase, right, the backstop here that's saving people's lives. So, meanwhile, physicians must continue to do our part to prescribe Naloxone to someone at increased risk of overdose. But the current products on the market are effective. They're just not used as often as necessary. So, once again, I just want to emphasize that the question about dosing is an important one, but it is secondary and shouldn't detract from the need [01:09:00] to get more Naloxone into the hands of these harm reduction organizations.

Susan Winckler: So helpful in reminding us that part of the solution here is collaboration, right, and thinking through. An antidote is not at all helpful if it's not where it needs to be administered, if it's not available there. We've got to have the antidote present. [01:09:30] We did the physician's side. Let me turn on the pharmacist's side. Dr. Bratberg, how else can pharmacists contribute to increasing access to Naloxone? You spoke a bit about the component as it relates to collaborative practice and training and other pieces. Are there other things that we can think about? Are there model programs that expand pharmacy access?

Dr. Jeff Bratberg: Yeah. I always like to [01:10:00] take a step back and go, "How many of us got our COVID-19 vaccines in pharmacies?" Well, I can tell you what the national figure is. It's between 70 to 80%. You know why that is? Because we got paid to do it, because of partnerships with the federal government, because pharmacists are recognized as public health experts. While I will tell you everyone can point out a pharmacist, and they do, that some pharmacists don't sell syringes and they don't sell Naloxone and they don't stock buprenorphine, there's a lot that do and have done a lot of good. But you know [01:10:30] what? Almost every single one did vaccines despite how they're perceived in some fields.

We've learned that partnering with the federal government or partnering with insurance companies and, really, to contain the conversation, partnering with harm reduction groups... Rhode Island, where I'm lucky to work, is fantastic in terms of we have vending machines, they have Naloxone in them. We are going to have harm reduction centers, state-sanctioned, regulated harm reduction centers. They're going to have Naloxone in them. [01:11:00] We have Naloxone in all of our pharmacies, again, highest density. Where we don't have it is over the counter, right? My colleague, Anita Jacobson, Dr. Jacobson runs the Community First Responder Program with a great online program distributing Naloxone, and she actually goes to pharmacy parking lots. There are people who walk by this table giving away free anonymous Naloxone, right? People go into the pharmacy, and they come out, and they may say no, and they actually say yes when they come out. On our college campus, I have students asking for Naloxone [01:11:30] because they don't want their parents' insurance to know that they're purchasing it.

The anonymity aspect is really essential, and so partner with harm reduction organizations putting vending machines outside pharmacies, in one aspect, to reach known, identified folks at highest risk of overdose, or partnering with opioid treatment programs. These are called dyads, really, where the opioid treatment program only does buprenorphine, maybe naltrexone and methadone, but they don't have Naloxone, and so these programs partner with the pharmacy, runs it [01:12:00] through their insurance, most often, public insurance. Again, it's important we expand Medicaid in all states. That's proven to reduce overdose deaths. So payment's an essential part of this. So the pharmacy actually ships or delivers the Naloxone to the OTP, and we've found great success. We've pioneered that here.

That is a way to increase health equity, focusing on those people at highest risk. I'd encourage... We have fewer restrictions on mobile methadone programs. Let's distribute methadone because we [01:12:30] can't do it in pharmacies in the US. We can in Canada and many other places successfully, another aspect we need to change. Well, let's put mobile methadone in the pharmacy parking lots and have that dyad happen there. That is how we're going to do it, right? Again, sell syringes. Let's have pharmacists prescribe buprenorphine, it would be great, become waivered providers, but, really, bringing these people together because pharmacies are known, they're visible, the experts are there, and the more Naloxone that we dispense, the decreased societal and healthcare worker [01:13:00] stigma that we have.

Susan Winckler: So it's not only expanding access. I'm really intrigued by this idea of the opportunity to access Naloxone in the parking lot and broadening it there. But it's also about normalizing the availability of an antidote and that it is not only acceptable but perhaps our responsibility to have antidotes available when we can help someone. [01:13:30] Dr. Sokolowska, we've had the concept of vending machines come up. Does FDA have regulatory authority over vending machines for Naloxone?

Marta Sokolowska: Just to clarify, FDA typically defers to states on dispensing practices for prescription drugs, which would include dispensing through vending machines. As Dr. Cavazzoni has indicated in her opening remarks, FDA does not intend to interfere with the important work of harm [01:14:00] reduction groups in providing Naloxone to people in need and people in communities. FDA supports and encourages the work of local governments and community organization in finding innovative, accessible, de-stigmatizing, important ways to provide Naloxone to those who need them.

Susan Winckler: So if someone were to say, "FDA prohibits use of a vending machine," FDA defers to the states on [01:14:30] that distribution mechanism. So, Josh, that would come to your state, and then we'd look at that broad practice act and dispensing language. Is that right?

Josh Bolin: That's correct. I think, again, when it comes to the different methods or delivery mechanisms, different initiatives that harm reduction organizations are working on, that's why forums like this are so critical, because I think, even though I'm on this panel, I'm learning a lot about some of those [01:15:00] potential barriers. Because that puts NABP in a position to go back and work with our members on looking at model policy, our model act, and some other ways that we can remove some of those barriers but do so in a way that still gives the state regulators the assurance that they need that the supply chain is secure, which I think we would all of agree is critical. But, again, it's that square peg into a round hole. Let's find the right place for these types of approaches.

Susan Winckler: [01:15:30] Absolutely. So I'm keeping an eye on our time because we want to get to our public comments. So I've got a question for Dr. Dasgupta, and then

we're going to talk stigma and round it out with Doctors Mukkamala, Bratberg, and Dasgupta. So you're on notice, but that's what we want to get through in the next 15 minutes. First, Nab, we've heard about the vending machines and the parking lot. Are there other [01:16:00] novel approaches to increasing Naloxone access that we haven't touched on yet? What should we be thinking that Josh at NABP and Marta at FDA can think through the dynamics?

Dr. Nabarun Dasgupta: Great question. So it's 2022, right? We can't have a serious conversation about drugs in America without talking about race. In California, in 2018, black overdose mortality overtook that of white individuals. That was four years ago. Native Americans [01:16:30] have had the highest overdose death rate for many years longer, a fact that never gets mentioned. The greatest increases in overdose death rates are happening in communities of color, yet harm reduction programs serving those communities are less likely to have a physician who can order Naloxone for them. Many of the groups that approach Remedy Alliance Buyers Club are small organizations that attend to health disparities and civil rights more broadly, like diabetes, contaminated water, voting, incarceration. Oftentimes, [01:17:00] the groups are run by young community organizers.

Due to generational hostility and harassment encountered within the healthcare system, these groups are very understandably reluctant to waste their time begging doctors they don't know to purchase Naloxone for them. They usually get turned down. This is a structural problem. This is a generational problem. In fact, you likely won't even know that these groups exist. They aren't sought out for meetings like this or sought out by the public health establishment. They [01:17:30] come to the harm reduction community because we are a little bit more inclusive. Many of these groups don't even know they have any pathway to obtaining Naloxone. It's 2022. We can't wave away their non-participation as an unintended consequence like we expect them to do all the work. If we honestly want to dismantle structures of injustice, we have to make it easy for them to get Naloxone and pay their outreach workers and then we need to step out of the way.

Like many [01:18:00] of you, I feel frustrated that overdose deaths are increasing despite years of effort. Maybe that shows. Come June, it'll be 20 years since I gave out my first vial of Naloxone. I loved those days on street outreach in Portland, Maine, where I grew up, still wearing the bandana and baggy shorts of my youth, back when Oxycontin was still just a regional problem. So I say the following with humility. A big part of our failure to stop overdose deaths is that the medical and public health establishment cannot reach the populations [01:18:30] at greatest risk of overdose. We are outsiders to their community, and they have no reason to trust us. Yet there are thousands of small community groups that serve them already. This is a major reason, not the only reason, why overdose rates are increasing. We aren't reaching those we need to because pharmaceutical regulations stack the deck against the very caregivers who can get Naloxone where it's needed most.

Right now, the allies we need most are in communities of color, in rural Appalachia, in remote Native [01:19:00] American tribes, in homeless encampments, in insular island communities, in neighborhoods that you and I don't ever visit. That's where the overdoses are happening. We in our suits, flexing our privilege, cannot do this job. From heroin to prescription opioids to heroin again, the epidemic has evolved. It's time for new solutions. Again, we need to make it easy for small community groups to get Naloxone, pay their staff, and then we just need to get out of the way. This is what it takes. This is how the intervention was created in the first [01:19:30] place by Dan Bigg at Chicago Recovery Alliance. This is what the evidence base is based on, and when we provide the resources and step out of way, we realize that this is also how innovation flourishes. This is where creativity blossoms, and this is where the next round of public health interventions will rise up from.

Susan Winckler: You describe the powerful dynamic that when there's friction, [01:20:00] there are a bunch of groups who don't get over that friction. In this case, it's those who are also being profoundly and disproportionately impacted, and so we have to and we could do better. You also mentioned the dynamic of stigma, and we've touched on it a bit, but I want to come each to Dr. Mukkamala, to Dr. Bratberg, and Dr. Dasgupta to talk about what are [01:20:30] some effective strategies in addressing stigma around Naloxone distribution? We've had some initial insight, conversations, national associations raising policy and doing more. Dr. Mukkamala, I'll turn it to you first. What can we do?

Dr. Bobby Mukkamala: Sure. Yep. I'll use an analogy that I'll share with you if you wouldn't mind just loading up my second slide, please, that we need to think of Naloxone as a [01:21:00] lifesaving tool, just like we think of EpiPens as lifesaving tools. So we need to continue to work to remove the stigma about overdose. There's no stigma, for example, for using an EpiPen. People don't try to have an anaphylactic reaction. When we see a blue patient, the only thing that goes through a physician's or first responder's mind is how to make them pink again, right? The adrenaline of that moment just takes over, and we go into lifesaving mode. Whether the patient's blue from eating a peanut that they're allergic to or from an overdose [01:21:30] of an opioid, our compassion and care is the same. It should be the same. So that same compassion should be applied to the time before the emergency, right? We shouldn't look at a patient with a peanut allergy different than we look at a person with a substance use disorder when we stock a pharmacy with EpiPens or Naloxone.

So no one listening today has any negative feelings about using an EpiPen to save a life from an allergic reaction. You can take the slide down now. Thanks. So what's different about Naloxone, right? I mean, [01:22:00] I get that there are differences between allergic reactions and overdose events, but our focus should be, as said by Director Gupta, to support overdose first aid. So if someone gets stung by a bee and goes into anaphylaxis, we don't criticize or look down at that person. If someone begins to overdose, our reaction should be to save that individual's life, and our subsequent actions should be to support them so it doesn't happen again. That's the essence, I believe, of what

the AMA has learned from harm reduction organizations and [01:22:30] our physician colleagues in addiction medicine, and psychiatry, to meet people where they are.

This includes where we need our pharmacy colleagues to be as well and why we need manufacturers to submit these OTC applications. So it's hard for individuals to just ask their pharmacist about Naloxone. If they do, the conversation typically happens in an open setting where they're afraid somebody they know will see them getting Naloxone, or if they do get it from the pharmacist, there's a chance that the information will be used against them down the road, such as in life insurance [01:23:00] determinations. So the first step we can take is to continue the work to normalize Naloxone as a standard first aid tool. Naloxone, EpiPen, no difference. We need to work with employers, colleges, and others to make sure that Naloxone is available, as we've heard already today, as another well-known harm reduction tool like EpiPens or condoms, for that matter.

Second, we need states to enact laws and policies prohibiting the fact that someone uses a Naloxone script from being used against them in any way. [01:23:30] Finally, we need manufacturers to submit OTC applications, as we've heard before. One other comparison that I'll make is Naloxone compared to an an AICD, a defibrillator, right? So I've got one right here. We're having a conversation about trying to get a nasal spray over the counter while we have devices that shock the heart that are pretty much in schools from coast to coast. So when we do these things, we will save lives.

Susan Winckler: Direct [01:24:00] advice that is really important to that normalizing piece, the idea of the EpiPen, the defibrillator, back in the day, ipecac syrup, but we don't do that anymore. But do you have the antidote readily available? Dr. Bratberg, what would you add to that? What else can we do to address the stigma?

Dr. Jeff Bratberg: I mean, more Naloxone, [01:24:30] right? The more experience people have with it, the more that it becomes normalized, and that's the word that you used, and I really want to emphasize that. But more important than normalizing Naloxone is not having people experiencing overdose itself. The more people, the 80%, the millions of people diagnosed with OUD, increasing every year, despite massive deaths from opioid overdose, expanding the population that's accessing, really, [01:25:00] prevention as treatment of overdose, which is really being exposed to buprenorphine... People do not overdose on buprenorphine. People who get on buprenorphine and are retained are preventing overdose. They still need Naloxone. They can help other people. So that's important, and we have national gut guidance on that.

But, again, I push for pharmacist access in all care of people with OUD, and it's important that people expand treatment and we remove the barriers, the unnecessary barriers, to buprenorphine access [01:25:30] so that the more that pharmacists dispense syringes to those not ready to be on buprenorphine and

the more that pharmacists can recommend Naloxone but also give them treatment. I think there are pharmacists that are stigmatized because they say, "This person keeps overdosing." Well, that's a systemic problem. That's a structural racism problem. There's many, many problems there. That is an unstably-housed problem, right? We can't fix structural determinants of health on a whim. What we can do is treat people and form that base, right? So, [01:26:00] again, that person with anaphylaxis, with a bee sting, with epinephrine, there isn't a drug to prevent anaphylaxis, but we have it for opioid use disorder, so we need that.

The other thing is we need reform of our laws and we need to partner with law enforcement. My colleague, Dr. Jacobson, who distributes Naloxone, because it's prescription status, has her name on it, and I know people who have gotten arrested and their Naloxone confiscated because their name wasn't on their prescription. That is insane, [01:26:30] and we have to have over the counter Naloxone now. We have millions of people watching that, advocating for it, and I think it's essential where people can just grab Naloxone, have it, and we educate law enforcement and we educate policymakers to say, "We can't be taking away lifesaving anecdotes from people who are at risk. We need to give them the treatment when they want it."

Susan Winckler: And that pullback to remind us that there... We've focused our conversation very narrowly on Naloxone today [01:27:00] intentionally, but there is a lot of work to do generally in substance use disorder and our understanding and our treatment and our engagement with individuals to do more in this space. Dr. Dasgupta, I'm going to give you the last word on addressing stigma, and then at the top of the hour, we're going to shift to our public comment period. So shifting to you.

Dr. Nabarun Dasgupta: Okay. So a lot of the stigma against Naloxone comes from within [01:27:30] the medical and public health establishment, and we don't really talk about this. There's stigma against the injectable formulation, even though it's often preferred over the nasal spray because it has less withdrawal, it's what people are used to, a lot of reasons, and it's 30 times cheaper. The stigma comes from needlephobia and misinformation. Naloxone is injected intramuscularly, which actually means in the butt and the thigh or the shoulder. It can even go right through clothes. The needle for IM Naloxone is too big to fit in veins. [01:28:00] It's not the same size as what's used to inject dope. The needle used for IM Naloxone is the very same tool that we use to give vaccines to babies. More injectable Naloxone has been distributed than all nasal forms combined.

The stigma against community-based Naloxone distribution is also manifest in policy that only emphasizes pharmacy dispensing. In Utah, for example, in 2021, there were 73,000 doses of Naloxone distributed. 88% was injectable [01:28:30] and distributed hand to hand far from pharmacy aisles. Comparing that to the pharmacy prescribing in Utah, community groups distributed 20 times more at one sixth of the cost of the nasal spray, 20 times more, one sixth of the cost. You'll hear from Dr. Jennifer Plumb in the next hour. The most direct way to

motivate policymakers and news reporters and everybody else to fight this stigma is a simple field trip. You've all been working on Naloxone for a while now. What's prevented you from [01:29:00] going to the pharmacy and requesting Naloxone with your health insurance if you were being labeled as a drug seeker, having a recorded transaction, a lot of the things that Dr. Bratberg talked about? Here's what I think.

Many of us have internalized stigma against people who use drugs without realizing it, and sometimes it colors our professional judgment, and so it's just something that I've come to recognize and I've had to fight to overcome. Now, imagine going back and asking for a refill at a pharmacy. Super savers, so people [01:29:30] who have reversed six or more overdoses, make up a disproportionate number of reported community saves. It's a common phenomenon that has been documented from California to Norway to Vietnam. Overemphasis on pharmacy distribution goes against this evidence. How many doses of $150 medication do you think insurance will pay for in a year? Not a lot. The people who do the most good incur the greatest stigma and face the greatest barriers.

So, look, I'm a fan of pharmacy access. The program I founded in my state, Project [01:30:00] Lazarus, was the first program to do pharmacy-based Naloxone distribution in the country. I think pharmacists have a really important role to play, but right now, in this moment, what we need to do is ramp up community-based distribution with affordable Naloxone. We need to pay outreach workers, and we need to get out of the way. To our federal officials, if this is the moment, if this is the moment that help will come, please let it be quick because, frankly, our expectations are pretty low.

Susan Winckler: [01:30:30] Profound final comment. Thank you. Thank you all for joining us for this round table, and I hope we've captured and answered some questions and that we'll start to make some progress. I'm going to step away so that we can turn to the final part of our session today and do the public comment. So thank you so very much.

PUBLIC COMMENT

Lea Ann Browning-McNee: [01:31:00] Thank you, everyone. We apologize for the delay. Susan will be right back, but we are going to go ahead and get started with our public comment. So I'm going to call on our first public commenter, and that is William Amarquaye. William, are you ready to present comment?

William Amarquaye: [01:31:30] Hello. Yes, I am. Thank you guys so much for this opportunity to come and speak to you guys today regarding Naloxone access. My name is Dr. Amarquaye, and I'm a clinical pharmacist who works in the hospital setting, and here in Florida, I'm also involved with syringe exchange programs here locally in

my area. I want to discuss real quick the urgency of our public health crisis on our hands. Each day, over 100 people die of an overdose, which is entirely [01:32:00] preventable, as we've heard during this meeting. We have a life-saving medication called Narcan that is effective in literally reversing an overdose situation. One of the biggest barriers in getting this lifesaving medication distributed more widely is its RX status. As someone who works both in the pharmacy and in the harm reduction space, it's vital that we have different avenues of distribution in order to get this lifesaving medication more widely accessible.

Even though most, well, pretty much all states, I believe, have it where [01:32:30] you can go to the pharmacy and get Naloxone through a standing order, there are still barriers, even in the pharmacy, as we've discussed in this meeting. The harm reduction group that I work with actually does a much better job in getting Naloxone distributed to the people locally more than pharmacies in my same area. So freeing up Naloxone to the OTC status will allow this life-saving medication to be distributed more to harm reduction programs that actually work on the ground and provide critical services to the people who use drugs. [01:33:00] Every time a participant comes and we ask them about Naloxone, they get so excited and with emotion that they're able to use the Narcan that we give them to save their friend or to save someone else's life. So we need to make sure this medication goes to OTC status. We have many other medications now that are OTC status that result in thousands upon thousands of ER utilizations each year, like NSAIDs and Tylenol, so there's no reason why this life-saving medication, [01:33:30] Narcan, can't be OTC. Thank you.

Lea Ann Browning-McNee: Thank you for your comment. We do appreciate it. We're going to move next for our next two minute commenter to Minister Blyth Barnow, if you could go ahead, please.

Blyth Barnow: My name is Minister Blyth Barnow, Ohio Associate Director at Faith in Public Life. In Ohio, we build relationships between grassroots harm reduction programs [01:34:00] and faith communities in order to end the overdose crisis. Unfortunately, because of lack of access to cheap injectable Naloxone and bureaucratic barriers, it's taken us three years to get our congregational and community-based Naloxone program up and running. Our first barrier was the terminal distributor of a dangerous drug license, which was required in order to personally furnish Naloxone in Ohio. Naloxone is considered a dangerous drug in Ohio because of the FDA's prescription-only designation. [01:34:30] This license was required not just for each organization but each site where distributions were to take place. We partner with the Ohio Council of Churches, which serves over 4000 congregations in Ohio. It simply was not feasible on an administrative or financial level to obtain the license for all those who wanted to participate.

At the end of 2020, advocates, including those from Harm Reduction Ohio, pushed House Bill 341 through the legislature, which allowed [01:35:00] service entities to personally furnish Naloxone without a license if working under a

medical directive. Ohio does not have a standing order, so FPL sought out and obtained a medical directive. However, because we wanted to serve as a hub for Naloxone access, we were told that we had to apply for a warehouse license. We reached out to the Ohio Board of Pharmacy to ask for a waiver and advocate for removal of this provision, which they granted in May 2021. We were cleared to become members of the Remedy Alliance. Unfortunately, [01:35:30] our paperwork went through shortly after the national shortage. At that same time, a bottleneck in the flow of Narcan from ODH had left almost everyone in the state without the Naloxone and Narcan they needed. Because there was no simple to purchased other Naloxone products, we had to request mutual aid. Faith in Public Life received our first shipment of Naloxone January 2022, three years after advocacy and over 11,000-

Lea Ann Browning-McNee: Thank [01:36:00] you so much for your comment. We do appreciate it. We just want to remind all of our public commenters that we are strictly adhering to a two-minute limitation so that we can hear from as many people as possible who registered in advance. Susan, it looks like you're back on, so I will turn over to you.

Susan Winckler: Wonderful. Thanks so much, Lea Ann. So our next presenter is Alice Bell from Prevention Point Pittsburgh. Alice, I see you're unmuted. We will restart the clock, and go ahead.

Alice Bell: [01:36:30] Thank you. I'm Alice Bell. I've coordinated Naloxone distribution at Prevention Point Pittsburgh since 2005 at our syringe service and other community locations, reaching people who use drugs, who are most likely to witness an overdose. We also provide Naloxone by mail across Pennsylvania in collaboration with NEXT Distro. In 2021, we distributed about 24,000 doses of Naloxone and documented close to 900 overdose reversals. PPP has primarily distributed cheap, effective, injectable [01:37:00] Naloxone. In 2021, disruptions in supply forced us to rely heavily on nasal Naloxone provided by the state, struggling to maintain enough supply of injectable Naloxone for those who prefer that formulation. Then a gap in funding curtailed the state supply, shifting our reliance back to injectable. While there's no overall shortage in supply of Naloxone, bottlenecks occur due to the prescription status and resultant cumbersome protocols creating this supply insecurity.

I spend an inordinate amount of time monitoring [01:37:30] fluctuations in supply to anticipate stockpile, try to ensure there's no gaps in our ability to provide Naloxone to people who are saving lives every day. Prevention Point has our own standing order prescription that includes injectable Naloxone, but other organizations in Pennsylvania are dependent on state standing orders, which don't include the inexpensive injectable formulation. We employ a half-time staff person to help people across the state navigate the process of obtaining Naloxone through their county agencies and, if that proves impossible, through [01:38:00] the state portal. We have provided cheap, effective, injectable Naloxone to well over 11,000 lay individuals in the past 17 years and documented over 5000 reversals with not one reported death from

someone not understanding how to use the medication and not one friend or family member who failed to be able to inject the medication to save the life of a loved one, yet bureaucratic requirements for physicians, DEA licenses, and various other hoops create obstacles to getting this life-saving medication [01:38:30] in the hands who need it. It's time to get rid of Naloxone prescription status.

Susan Winckler: Thank you. Our next public commenter that we have on the list, although we did not hear... So I will call on Kimberly Buck-Glaze from Beyond the Pod. Kimberly, did you want to provide remarks? Go ahead and start the clock. If you unmute within the next 10 seconds, we will give you the floor.

[01:39:00] Okay. So we're at the 10 seconds. Robert Childs with JBS International is next. So if we stop that clock... [Busy 01:39:23], would you unmute... Yes, there we go. Robert Childs, you are unmuted. Let's start the clock, please.

Robert Childs: [01:39:30] Thank you so much. My name's Robert Childs, and I'm a technical expert lead with JBS International. In my personal time, I help run a volunteer-based harm reduction program that serves around 3000 people in Southeast Tennessee and Northwest Georgia. In our service area, people who use drugs, people in treatment, people in recovery, and their loved ones have an incredibly hard time gaining access to Naloxone due to long training time requirements by other programs, cost of pharmacy [01:40:00] products, preference for intermuscular Naloxone, stigma, service barriers, access deserts, transportation issues, especially in our rural areas, being denied access due to the amount of Naloxone they need, and COVID-related service disruptions. Our volunteer group provides services to people who actively use drugs and people who get services at MOUD clinics. To help these folks at risk of an overdose get access to Naloxone, we provide needs-based services.

Two key [01:40:30] points I would like the panel to hear from our program and our experiences from people who use drugs. One, our group cannot provide needs-based focused services without access to low cost and donated intermuscular Naloxone. We would not operate if we could only access higher priced formulations. They are out of our budget, which is almost no dollars. Two, in Southeast Tennessee and Northwest Georgia, people want low dose intermuscular Naloxone. In fact, 95. [01:41:00] 8% of our program's distribution is intermuscular Naloxone, and that is what people ask for and want. This is the formulation that people who use drugs in our service area and in treatment in our service area want and prefer getting, especially from harm reduction based teams over all the hoops and barriers of the larger entities within our service area. Also, folks want to gain access to the services from harm reduction folks over having to deal with high prices at pharmacies. I thank [01:41:30] you for your time.

Susan Winckler: Thank you. Our next speaker is Haley Coles from Sonoran Prevention Works. Haley, would you please unmute, and we will start the clock.

Haley Coles: Yeah. Hi, everybody. My name's Haley Coles. I'm the executive director of Sonoran Prevention Works in Arizona. We're a statewide harm reduction organization and the largest layperson Naloxone distributor in [01:42:00] the nation. Due to a miracle of circumstances, ample-

PART 3 OF 4 ENDS [01:42:04]

Haley Coles: ... in the nation. Due to a miracle of circumstances, ample government funding, a permissive state law, and persistent staff and volunteers within our organization, we've distributed nearly 650,000 doses of naloxone in the last five years, and have close to 20,000 overdose reversals reported to us. Last year during the shortage, we scrambled with the rest of the National Naloxone Buyers Club to secure alternative naloxone sources. What was unique about our situation though was that we had the money to pay for slightly more expensive [01:42:30] naloxone. We had a check ready, waiting to be mailed out for over a month, but because naloxone's status as a prescription drug creates a field day for lawyers and compliance officers to overregulate its sale and distribution, we were stuck rationing our dwindling supply of naloxone to communities across the state who depended on us, waiting for high-level officials [inaudible 01:42:52] distributor to finally agree to send us a medication we've been effectively ordering and distributing for five years.

As I mentioned, we distribute naloxone [01:43:00] to all types of individuals and organizations, many of whom can pay for it themselves if it weren't for its overregulation as a prescription medication. We're in the position we're in because we have essentially cracked the code to navigate state and federal regulations, pharmaceutical [inaudible 01:43:16] communities at the same time. Imagine if those resourced individuals and organizations could pop down to their local pharmacy or convenience store and grab the naloxone that they needed when they needed it. So much of the time and money we spend [01:43:30] could then be redirected to deeply supporting the most marginalize members of our communities, those without resources, those in the tribal and frontier areas without pharmacies and convenience stores. The decision to deregulate naloxone's prescription status is truly an ethical and lifesaving decision. On behalf of those of us trying to end this epidemic, I urge you all to make that-

Susan Winckler: Thank you. Next speaker signed up for public comment is Matt Curtis from the California Department of Public Health. Matt?

Matt Curtis: [01:44:00] Good morning. I'm speaking today on behalf of the harm reduction unit at the California Department of Public Health. You would think that California would be a state where naloxone access was a given. We have a statewide standing order backed by our department. Last year, the state spent

tends of millions of dollars on the medication alone. More than 60 harm reduction organizations operated in a majority of counties, and distributed hundreds of thousands of doses, and we increasingly saw naloxone offered through emergency departments, jails, and mutual aid groups. And yet, last [01:44:30] year we repeatedly saw stock-outs of naloxone in whole cities and counties. Access was radically unequal across the state, with naloxone deserts even in major population centers. Just yesterday, an emergency department in Modesto was threatened with a citation by an uninformed state licensing inspector for having naloxone outside of the pharmacy for distribution.

California has spent the last six months attempting to establish a means to purchase affordable injectable naloxone at a scale appropriate to the crisis, only to be stymied [01:45:00] by pharmacy compliance rules poorly suited to a public health emergency. As a result, groups unable to identify a physician to commit their license are forced to rely on a rationed supply of intranasal naloxone purchased by the state. It's unfathomable that this is happening in 2022, but it's the result of two factors, naloxone's prescription status and price gouging by manufacturers of intranasal naloxone. These failures lay at the feet of the FDA and other HHS agencies. Experts have appealed [01:45:30] to the FDA for more than a decade, but the agency continues to forfeit any sense of duty to act as hundreds of thousands of people die. The model OTC label clearly has not got the job done. FDA should stop passing the buck and bring nonprescription, low-cost naloxone products to market. Thank you.

Susan Winckler: Thank you. Our next public comment will be from Maya Doe-Simkins from Remedy Alliance. Maya?

Maya Doe-Simkins: [01:46:00] My name is Maya Doe-Simkins. I am co-director of The Remedy Alliance, which is a national naloxone buying club. We have been operating for over a decade, which is important, because only six states had laws that explicitly supported naloxone distribution at that time. It is important because 10 years ago was five years before there were any federal funds whatsoever to purchase and distribute naloxone. It's also important because at that time, there were zero expensive branded naloxone products. So, [01:46:30] we began before there were laws endorsing it, funds supporting it, or expensive products competing for market share. These are your vanguard overdose prevention programs that forced the way, developed the models, and established the evidence base for naloxone distribution to people who use drugs.

We currently help about 150 organizations in 40 states, to access affordable generic injectable naloxone. In 2020, they collectively distributed 1.3 million doses. Fewer than half received any federal funds to purchase naloxone, and a full third [01:47:00] received neither state nor federal funds. One quarter of programs had to ration their naloxone. To avoid rationing, 80% of programs either borrowed from or loaned naloxone to other programs. Depending on the location, this is either an explicitly prohibited activity or may be allowed in a very gray medical legal landscape.

It is time to relieve the very programs that gave this country the idea of naloxone distribution from the stressful and heavy burden of deciding if they will bend or break laws and regulations in favor [01:47:30] of an ethical imperative to ensure that there is enough naloxone to go around. Removing naloxone's prescription designation for harm reduction programs can do this. It is time to fully fund these programs so rationing is a distant memory. Ensuring that federal and state funds are directed to harm reduction programs that work directly with people who use drugs will ensure that the fullest effective naloxone distribution is realized. Thank you so much for your time and attention.

Susan Winckler: Thank you. Our next public comment will come from [01:48:00] Jeff Horwitz, S.A.F.E. Project administration. Jeff? And could we start the clock?

Jeff Horwitz: Good afternoon. Thank you very much for the opportunity to speak today. My name is Jeff Horwitz, and I am the chief operating officer for S.A.F.E. Project. S.A.F.E. Project is a national nonprofit dedicated to building collaboration to address the addiction crisis around the country. Collaboration must occur at all levels for us to overcome this crisis. None of us can do this alone, but working together, we can have the best chance to succeed, and that's why we applaud [01:48:30] the work of the foundation as well as the FDA data.

Every day, S.A.F.E. Project works with family members, direct service providers, policymakers, and others, and so we have a unique perspective to convey many of the concerns relating to naloxone access. Many of those concerns have been discussed today, and we support them wholeheartedly, and some of the solutions, such as the benefits of a federal standing order, the need to co-prescribe mandates, creation of consistent guidance and directions for pharmacies to provide naloxone, a national locator to locate naloxone, [01:49:00] requiring naloxone on college campuses, workplace first aid kits, concerts, and sporting arenas. Addressing the unintended consequences is also important, such as the risk of life insurance implications of naloxone, and providing education and access to naloxone for children under the age of 18 that are seeing this in tragic numbers.

But we must emphasize that none of these efforts will succeed until we find a way to normalize the fact that addiction is a disease, overdoses will occur, and naloxone is not harmful. Conversations [01:49:30] like today's are helpful, but we are talking to an interested audience. The greatest impact that we could have is to address those that believe that this is not their problem. Whether it's a construction worker that is two times more likely to struggle with substance use disorder, the student who believes that an extra pill might take the pain away, or a parent who's uncomfortable asking for naloxone at a pharmacy, we must act now. Until we can overcome this stigma and convince them all that this is a crisis affecting all of us, these great [01:50:00] naloxone access programs will be limited and have limited effect. I thank you for the opportunity to speak, and I wish us all the luck.

Susan Winckler: Thank you. Our next public commenter will be Michael Hufford from Harm Reduction Therapeutics. Michael?

Michael Hufford: Hi. Thank you. My name is Dr. Michael Hufford. I'm the co-founder and CEO of Harm Reduction Therapeutics, a 501(c)(3) nonprofit pharmaceutical company founded in 2017, whose mission is to make low-cost OTC [01:50:30] naloxone available to everyone. Our three milligram OTC intranasal naloxone product, tentatively trade named Revive, is currently on track for an NDA submission in the fourth quarter of this year, with a likely commercial launch in the first quarter of 2024. We appreciate the FDA has a difficult mission and are often understaffed to accomplish it, and work diligently with sponsors to advance their applications. At HRT, we have had and continue to have numerous meetings with the FDA as we prepare for our NDA filing.

I want to point [01:51:00] out what I believe, though, are some fundamental disconnects between the FDA's public pronouncements about their interest in OTC naloxone and the reality for pharmaceutical sponsors. It is these disconnects that continue to hamper and delay OTC naloxone product applications. The first of these example disconnects is best reflected in the FDA's recent denial of our fast track status request when they stated, and I quote, "Although opioid overdose is a serious condition, you have not defined the unmet medical need that your product [01:51:30] will address." They went on to say, "We note that multiple naloxone products intended for use in the community setting are available throughout the United States by prescription."

Likewise, the FDA's Division of Medication, Error Prevention, and Analysis has been three months late getting us feedback on our human factors work, with suggestions that are both overly complicated and make the study prone to artificial failure. In sum, it has often been said that hell is full of good meanings, but heaven is full of good works. It is my hope [01:52:00] that the FDA will embrace this critical distinction between good meanings and good action, and ensure that their reviewers and future ad com members focus on enabling good works, including those by Harm Reduction Therapeutics to make low-cost OTC naloxone a reality. Thank you.

Susan Winckler: Thank you. Our next public commenter is Larry Kenemore from Rotary. Larry? And let's start the clock.

Larry Kenemore: Thank you [01:52:30] much. Let me bring up my speech here. I'm the North American task force leader for Rotary Action Group Addiction Prevention Project SMART. Rotary is best known worldwide for eradicating polio, and keeping with the Rotary's success of eradication of polio worldwide, using the same playbook, we have begun implementation through the A of Project SMART, that is awareness for local communities of overdose signs and symptoms, and the use of Narcan to save lives. Project SMART began three years ago, and three years ago, we knew that Narcan [01:53:00] training, community by community, was a necessary component of addressing the opioid

crisis. Today, we know we were right. The recent February 2022 research report from Lancet provides the facts that no state, no city, no community has enough Narcan or Narcan training to save lives. Rotary Action Group Addiction Prevention has begun implementation in local communities. However, a number of issues have arisen to the success of Narcan training.

[01:53:30] First, nasal injectors having only one dose is not successful with the current fentanyl overdoses, which require more than one dose to be successful. Secondly, the cost of Narcan is another barrier. What Rotary Action Group knows is this epidemic was preventable, and the training and use of Narcan community by community will lower death rates and address one component of this crisis, and Dr. Dasgupta, I gave my first Narcan in 1976 as a paramedic. Narcan should be carried [01:54:00] by everyone. It's no different than a first aid kit, a fire extinguisher, an EpiPen, or a defibrillator. We encourage people willing to be good Samaritans to learn the use of and carry Narcan. Rotary is about changing lives and saving lives. Thank you.

Susan Winckler: Thank you, and I'll note that I skipped a name on my list and got out of alphabetical order, so Corey Davis, are you ready to pick up the microphone?

Corey Davis: [01:54:30] I'm here, thank you. My name is Corey Davis. I'm a public health attorney and an academic researcher. I've been involved in naloxone legislation and naloxone distribution for well over a decade, and I regularly work with individuals, organizations, and agencies working to expand naloxone access. Naloxone saves lives, but only when it's immediately available at the scene of an overdose. Community-based organizations are best [01:55:00] positioned to deliver naloxone to those most likely to use it, but as we've heard, its prescription-only status consistently stymies their efforts.

Federal law prevents FDA to move naloxone OTC on its own. There is no requirement that the process be initiated or requested by a manufacturer. FDA knows this. In 2003, the Washington Post reported that then Commissioner Mark McClellan said quote, "I've concluded [01:55:30] that we have the legal and regulatory authority to force a prescription to OTC switch." Commissioner McClellan was correct then, and nothing in law or regulation has changed. Indeed, federal regulations require that quote, "Any drug shall be exempted from prescription dispensing requirements when the commissioner finds such requirements are not necessary for the protection of the public health," end quote.

Decades of evidence show that the requirement is not [01:56:00] only unnecessary. It's actively harmful. Laypeople with little or no training can recognize overdose and administer naloxone, including the vial and syringe version. Nearly five years into the opioid public health emergency, it is long past time for FDA to remove this unnecessary and harmful barrier, a barrier that is literally killing people every day across the country.

Susan Winckler: [01:56:30] Thank you. Our next public comment comes from Dr. Steven Linder. Dr. Linder? And let's restart the microphone. [inaudible 01:56:42]

Steven Linder: Thank you. This is Dr. Steve Linder from Palo Alto, California. I have been working with OEND programs in Northern California as well as monitoring social media platforms and assessing concerns and attitudes of first responders and naloxone use. Our major concern now [01:57:00] is, as the Rotary spokesman said, is the illicit fentanyl problem, which is new from the prior problem of prescription opioid and heroin overdose. My concern question is how will over-the-counter naloxone enhance cross-communication between communities hit by fentanyl overdose spikes? How will communication between harm reduction and professional first responders, EMS, and law enforcement organizations be enhanced by this change in over-the-counter [01:57:30] naloxone use? Thank you.

Susan Winckler: Thank you very much. If we could... Great, we'll start the clock in just a moment for Pamela Lynch from Harm Reduction Michigan. Pamela, are you with us?

Pamela Lynch: Hello?

Susan Winckler: Yes.

Pamela Lynch: Okay, sorry.

Susan Winckler: Pamela, go ahead.

Pamela Lynch: All right. [01:58:00] Hi, everyone. My name is Pam Lynch, and I run a statewide organization in Michigan called Harm Reduction Michigan. I started naloxone work, I had the privilege of working with Dan Bigg in 1999, and learned a lot in that role. I'm excited, because I hear a lot of people talking today that we understand how important the option is for injectable naloxone to be continued and continually available to the populations in this country that find [01:58:30] that the most beneficial. We work closely with the target population. We have their trust. We are a recovery community organization, so that endears the trust pretty rapidly, and they prefer injectable naloxone over nasal naloxone, so I'm excited to hear in a number of the points made today that the FDA recognizes for that formulation to be continually available and also cheap.

[01:59:00] A second point that I'm here to express concern about, and I've identified it as a gap, and I'm not sure how well recognized this gap is in the availability of naloxone in rural areas, in Michigan in particular where we practice, but also I'm thinking probably in other areas of the country. In very small towns that have no chain pharmacy like CVS, Walgreen's, or Rite Aid, small independent pharmacies cannot [01:59:30] afford to stock naloxone. We were fortunate enough to barter for a vending machine as a part of a program with Wayne State University, and we put that vending machine, the only one that we were able to get because of the funding restrictions to our organization. We put

it in our office, or outside our office in Lake County, Michigan, so Baldwin is the city, Lake-

Susan Winckler: Thank you. [02:00:00] We'll next turn to Sarah Murray with Blue Mountain Heart to Heart. Sarah?

Sarah Murray: Hi. I'm Sarah Murray. I'm a registered, board-certified nurse. I work for Blue Mountain Heart to Heart, which is an organization serving 8,000 square miles in Eastern Washington, Rural Idaho, and rural Northeastern Oregon. [02:00:30] We could not distribute naloxone without access to the special low-cost prices that we are forbidden to talk about. These are not available to regular outside folks who are going to the pharmacy. If you go to a pharmacy here in the area, one syringe of naloxone costs $125 without insurance. A lot of times, it takes two or more sometimes, especially with fentanyl, doses of naloxone to reverse an overdose. As Dr. Dasgupta mentioned, we have these [02:01:00] phenomenon of savers who we have some of our clients who saved 19 lives last year, 20 lives. We're looking at saving over 300 more lives this year than we saved just last year in our small community of 30,000 people, just here in Walla Walla.

Naloxone access is a big deal here. There are no places to get it in rural areas unless you can pay the $125 at a pharmacy to get a syringe. We are also supporting organizations like law [02:01:30] enforcement and EMS, in giving them naloxone, and when it expires, we give them more naloxone, and they should be purchasing their own naloxone out of their own budgets, but they don't have a medical director, they don't have a way to purchase this, they don't have a way to get an account, and a lot of them aren't educated. Sometimes, it takes 20 minutes for a first responder to arrive here in a rural area, and that person can already be dead if there isn't naloxone with the first responder that arrives, so having easy, cheap access [02:02:00] is a really big deal out here, and we need more of it. Thank you so much for your time.

Susan Winckler: Thank you. Our next speaker for public comment is Jennifer Plumb. Jennifer? And we will start the clock.

Speaker 3: But he will be [inaudible 02:02:20]

Jennifer Plumb: Hello, there. Sorry about that. My name is Jennifer Plumb. I am a physician in Utah. I'm a pediatrician and [02:02:30] an emergency medicine physician. I'm also the medical director of Utah Naloxone. It is the main harm reduction organization in the state of Utah, and we've been able to get over 250,000 free doses of naloxone out. When I entered this space, I came in very much as a mainstream academic physician thinker, as many of us exist in these regulatory spaces are, and I was lucky to be connected with harm reduction [02:03:00] organizations who taught me the way to get naloxone in people's hands.

In our state, for example, in 2021, when you look at the ways naloxone went out, there were about 75,000 doses that went out. 65,000 of those went out

through Utah Naloxone and through its partners across the state, community-based organizations, non-mainstream. 4,000-ish doses went out through pharmacies, and 5,000 through our public health and health department structure. [02:03:30] The amount of money that it took to buy nasal doses in our health department structure, around $400,000, I can't even tell you what we could do in the harm reduction space with that, because we do use the generic injectable naloxone. I'm pleading for us to find ways to get out of the pharmacy and general public health speaking realms of getting naloxone to people. General, over-the-counter-based access is the way that we will save lives, and injectable [02:04:00] forms, I had a mom who told me that she saved her son's life. because she couldn't reach her nasal device behind the door to get him, the injectable kit saved his life. Thank you so much for this opportunity to speak. Appreciate it.

Susan Winckler: Thank you, Dr. Plumb. Our next public comment will be from the Reverend Erica Poellot. Reverend Poellot, I see you're unmuted. Your time will start.

Erica Poellet: Good afternoon. My name is Reverend Erica Poellet. I serve as minister of Harm Reduction and [02:04:30] Overdose Prevention Ministries for the United Church of Christ. I am also the founding director of Faith in Harm Reduction. Today, I am speaking in honor of Mr. Ralph Ortiz, who died on March 2, 2022, from an accidental drug overdose in our shared home city, The Bronx, New York, a community disproportionately impacted by the war on people who use drugs, on people of color. Two weeks ago, his family and I conducted a celebration of life for him, just eight months after the funeral for [02:05:00] his brother, Edwin Ortiz, who also lost his life to drug overdose. The Ortiz family's legacy of loss reflects the experience of hundreds of thousands of families across this country who have lost a loved one to overdose, who have lost a loved one to this entirely preventable cause of death.

This is on us. This is on you. We know overdose is but a symptom of the crisis of profits over people, stigma over evidence and access to lifesaving [02:05:30] healthcare, and bureaucracy before justice. The FDA must meet the urgency of this moment with expedient and just action. The FDA must remove the prescription-only status from all formulations of naloxone. HHS and the White House must ensure that naloxone, in whatever and every formulation the community prefers, be made accessible to the people most likely to be present at an overdose, people who use drugs and their loved ones. People who use [02:06:00] drugs reverse 90% of overdoses in the community. Thus, it is clear. People who use drugs will save us. It is our moral responsibility to give them the resources to do so. I want to conclude with my desire to faithfully refuse to do one more funeral resulting from federal inaction to stem the overdose crisis.

Susan Winckler: Thank you. Our next public comment will come from Antonia Sawyer with Ship Happens. [02:06:30] If we could start, thank you.

Antonia Sawyer: Hello. I am Antonia Sawyer, Founder of Ship Happens, Indiana's mail-based naloxone and safe use supplies harm reduction organization that primarily distributes injectable naloxone. Due to naloxone not being over the counter and there being a purchasing rule through the manufacturer Pfizer, that one prescriber can only help one organization in leveraging buying power, it continues to hinder the ability for grassroots harm reduction efforts like Ship Happens to have an adequate amount of naloxone to prevent overdose [02:07:00] death in our communities. One hindrance of not having an OTC status comes in the limited ability of the prescriber to support several organizations in obtaining buying power for naloxone, making it more difficult for organizations to locate a prescriber to support and join their efforts to sustain naloxone access to people who use drugs.

Another comes in the fact that having to locate a prescriber can place an organization who is successful in doing so with unequal naloxone distribution power, where they are able to purchase [02:07:30] the majority of naloxone within a state and construct organizational distribution policies that can monopolize or impede smaller grassroots efforts from autonomous distribution based on their participant needs, which Ship Happens experienced prior to leveraging our own prescriber. Another example may be that organizations require data collection on participants who received the naloxone in order to access this lifesaving medication.

It is important to understand that making naloxone OTC will positively impact harm reduction [02:08:00] entities that are grassroots, have limited resources, and may be working in highly stigmatized areas where prescribers choose not to participate, limiting the ability for harm reduction efforts to begin, maintain, and sustain equitable access to overdose prevention for people who use drugs in their communities. I would like to close with words shared from people with lived experience in Indiana who are alive because of naloxone. "Every person deserves a chance. If this can save just one, it is well worth it. Naloxone should have been available like this [02:08:30] years ago. A lot more lives could have been saved."

Susan Winckler: Thank you. Our next public comment will be from Dr. Kimberly Sue. Dr. Sue, with the National Harm Reduction Coalition.

Kimberly Sue: Hi, my name is Kim Sue. I'm an assistant professor at Yale and the medical director of the National Harm Reduction Coalition. In this capacity, I oversee naloxone distribution programs in New York City and State, and I have seen how broken the current naloxone distribution system is and how truly byzantine it is, [02:09:00] not serving people who use drugs. Co-prescribing naloxone will not get us out of this problem. I co-prescribe naloxone daily as a physician. However, many of my colleagues do not, and my patients encounter numerous barriers to pharmacy access. I also have taken care of patients accessing harm reduction programs where they received naloxone directly handed to them. DEA registrants like myself do not have to be involved in the distribution of naloxone and in these programs. Many people who use drugs do not come to

[02:09:30] see us, because of structural violence, structural racism, and stigma, so the idea of writing it as a prescription through healthcare channels really doesn't make a lot of sense.

Even looking at standing orders from New York State pharmacies, only a handful of people can access them. It's cumbersome for patients and for prescribers. One of the Yale addiction medicine fellows tried to access it here at the Yale Pharmacy and was looked at with misunderstanding and ignorance. So we know that people are not getting the naloxone [02:10:00] they need because of this scarcity. Harm reduction groups like NEXT Distro are being forced to redistribute expired naloxone, which contributes to thousands of reversals. There's simply not enough access. In many cases, it's locked up in health departments, fire, or police. I was just in Texas, and basically, they were worried that in rural states, they couldn't have access to naloxone, so we have to get them in the hands of family, people who use drugs, and harm reduction programs are the best equipped to do that, so take us [02:10:30] out of the process and get it into the hands of harm reduction programs that know how to do this thank you.

Susan Winckler: Thank you. Our next public comment is from Eliza Wheeler with Remedy Alliance For The People. Eliza?

Eliza Wheeler: Yes, hi. Hello, my name is Eliza Wheeler. I'm the other co-director of Remedy Alliance. I want to discuss our new no-barrier procurement mechanism for harm reduction programs to access affordable naloxone, but first some historical context for how we [02:11:00] got here. In 1996, the Chicago Recovery Alliance began distributing naloxone directly to people who use drugs. This was the first naloxone distribution program in the world. For many years, harm reduction programs followed CRA's lead under the radar without the funding or legal authorization to do so. Harm reduction activists and people who use drugs have been imagining, innovation, and demanding solutions to the rising death toll in their communities for more than four decades.

However, despite being [02:11:30] the originators of this lifesaving intervention, harm reduction programs still struggle to get adequate access to the naloxone that they need. They are systematically excluded from adequate funding, restricted by state legislation, avoided by risk-averse medical providers, and stymied by pharmacy regulation and bureaucratic gatekeeping. They often receive inadequate quantities of naloxone from their state or local public health departments, and still need to ration, borrow supplies, or raise their own funds to purchase what they need. [02:12:00] They are forced to collect expired naloxone that has gone unused for redistribution to people who use drugs, where it should have gone in the first place.

Following in the footsteps of CRA and other groundbreaking colleagues throughout the years, Remedy Alliance has created a solution to address these issues. We will provide no-barrier access to naloxone directly to harm reduction programs at low or no cost. We have listened to harm reduction programs,

heard what the barriers are, and we will finally remove them. We are asking now that your [02:12:30] regulatory structures adapt to us instead of us continuing to contort ourselves into compliance with rules that limit access to lifesaving medicine. In honor of our mentor, Dan Bigg, and over one million lives lost to overdose in just the [inaudible 02:12:46] three years, we invite you to join us in implementing solutions.

Susan Winckler: Thank you. And our final registered public comment will be from Doug White with Emergent BioSolutions. Doug?

Doug White: [02:13:00] Yes, good afternoon. My name's Doug White, and I'm the senior vice president of Emergent BioSolutions. Emergent is a global life sciences company whose mission is to protect and enhance life through our pharmaceutical products, including Narcan nasal spray. We're dedicated to providing solutions that address public health threats. Naloxone is a critical component of a larger, more comprehensive strategy to combat the opioid epidemic, and we understand the importance of being able to access naloxone through a variety of channels. In the pharmacy, standing orders make [02:13:30] naloxone available without a prescription in all 50 states, DC, and Puerto Rico, though those policies vary by state. Currently, 100% of insured lives in the United States, including those insured by Medicare and Medicaid, have coverage for naloxone. Medicaid plays a critical role in enabling affordable access to naloxone to low-income adults. More than half of the people with opioid use disorder have incomes below 200% of the federal poverty line. The discussion [02:14:00] around OTC naloxone should consider how to safeguard affordable access to naloxone for patients, particularly vulnerable populations.

Second, outside the pharmacy, vulnerable populations receive naloxone through hospitals, emergency room discharge, criminal justice systems, local law enforcement, and other state-funded initiatives or community-based organizations. Community distribution is critical, and we have established discount pricing through harm reduction, public health clinics, fire [02:14:30] departments, police departments, and other nonprofit organizations. In summary, our work at Emergent is focused on widespread education and equitable access to naloxone. Thank you for the opportunity to provide comments.

Susan Winckler: Thank you. And with that, we complete the list of those registered commenters who both signed up to comment and then confirmed with us on site. Thank you, everyone who signed up for the public comment, [02:15:00] and for all of you for joining us today. As a reminder, we will be posting the recording, and the slides, and a transcript from this meeting, later this week at the reaganudall.org website, and we thank you for joining us, appreciate your participation. Take care, and we'll see you soon.

PART 4 OF 4 ENDS [02:15:31]