Center for Strategic and International Studies

TRANSCRIPT

Event

# "One Year of Over-the-Counter Naloxone"

DATE

**Thursday, August 1, 2024 at 9:00 a.m. ET**

FEATURING

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**Paul Williams**

*Senior Vice President, Products Business, Emergent BioSolutions*

**Heather Saunders**

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J. Stephen Morrison: Good morning, good afternoon, good evening. I'm J. Stephen Morrison, senior vice president here at the Center for Strategic and International Studies – CSIS – in Washington, D.C., where I direct our global health work.

Today's session, this conversation, is focused on naloxone, the medication used to reverse opioid overdoses of those who overdose from heroin, from fentanyl, from prescription pain medication such as oxycontin.

This production's part of the work of the CSIS Bipartisan Alliance for Global Health Security. A special thanks to my colleagues Sophia Hirshfield and Michaela Simoneau; and our production team, Eric Ruditskiy and Alex Brunner.

On March 29th of 2023, FDA approved over-the-counter sales of nasal spray versions of naloxone. Prior to that, almost all states had issued standing orders that permitted access to naloxone in pharmacies upon request without a prescription. That decision was hailed – that decision by FDA was hailed as a major step forward in the fight against what we've seen as soaring numbers of deaths from overdoses, up to 112,000 in 2023. We'll hear from Dr. Gupta momentarily. Some projections of the trend lines are fairly harrowing. These are harrowing numbers to begin with, but the notion that this could go much higher – 70 percent of those deaths caused by fentanyl.

The rollout of this new policy began in earnest in September of last year. So as we meet today, we're at the – we're approaching the one-year mark of the advent, the true execution and implementation of the over-the-counter sales and what that means. And during that year, there was a lot learned. There was a lot of discussion around the complexity of bringing forward what is a national transition, in a way. And we shouldn't be surprised that, indeed, this turned out to be fairly complicated, that there were a certain amount of confusion and uncertainty, gaps in understandings, gaps in awareness, things that needed to be thought through much more carefully.

Data has come through slowly. That also is not a big surprise. We're going to have lags in understanding the health impacts and understanding the sales and uptake patterns across this complicated country. Access was problematic in many different ways across different geographies and populations. Equity is always a concern. Affordability, price, cost has been a matter of great debate. The packets that are on

sale are running at about $44 for a two-pack. The market has begun to change – and we'll hear more about that – as Walgreens announced it's entering, as California has begun plans to produce its own generics, and other actors that are entering. Insurance is an important issue. We'll hear from some of our experts today about both public and private channels of coverage. Supply chains themselves are problematic when we move. We saw that during COVID. It shouldn't be surprising that there's complexities there.

I think people have been very encouraged to see the calls for expansion of widening access, to co-locate with defibrillator cabinets. to introduce into schools, workplace places, sports venues, entertainment venues. The White House has played a significant and remarkable leadership role in elevating the significance of affordable and accessible naloxone as a priority within its national strategy. We'll hear more about that. In the spring, the launch of the White House Challenge to Save Lives From Overdose brought forward this argument. And we'll hear from Dr. Gupta momentarily.

We've also seen a recognition, an active push, for the centrality of bipartisanship, particularly in Congress in 2018, with the SUPPORT Act, the five-year authorization. The reauthorization remains a very important consideration here today. The centrality of corporate partnerships in this, the centrality of communities' engagement, and across a broad span. And the need for good data and good analysis that's informed. And we'll hear from people who are working in that domain.

Today, we're going to try and unpack what we have learned and experienced in this first year. We will be taking, the first half of this conversation, a quick retrospective look. We're also going to take a prospective look ahead in the second part of our conversation to think about what is the agenda looking forward for sustaining progress and deepening that – and deepening that progress. Obviously, what happens in naloxone is part of a bigger strategy, and we can't avoid talking about those larger elements, and these – the congressional and legislative piece that I mentioned.

Our lead off keynote speaker this morning is Dr. Rahul Gupta, director of the White House Office of National Drug Control Policy. His mandate is to reduce substance use disorder and its consequences by coordinating the nation's drug control policy. He's the first physician to serve in this role. Prior to his appointment by the president in 2021, he served as a director of the White House – of the West Virginia Bureau for Public Health, where the reduction of overdose deaths from the opioid epidemic was his top priority and the top priority of the leadership of

that state. He also served, prior to coming to the White House, as the medical director for the March of Dimes.

Saw you just briefly in Beijing in June. Congratulations on the success of the negotiations with the Chinese on bringing greater controls over the manufacture and export of the – of the precursor elements used in fentanyl production. Progress in that area is just so important to our country.

We're also joined by Heather Saunders from KFF, previously known as Kaiser Family Foundation. But we're now calling it KFF. And thank you for journeying here this morning from Richmond. Heather's a senior research manager at KFF, a nonprofit health policy research, polling, and news organization. She focuses on mental health and substance use policy within and outside of Medicaid policy. She has experience as a social worker – training as a professional social worker, and as an evaluator of state Medicaid waivers and programs. Kaiser, KFF, has been a very close partner with us at CSIS – among our closest partners over a 25-year period. And we're very grateful that you could be with us today, Heather.

Paul Williams, our third speaker today, is senior vice president at Emergent BioSolutions. As the head of the portfolio – the product portfolio for Emergent, he's responsible for medical countermeasures for military and civilian populations, and commercialized products that address endemic public health threats such as the opioid epidemic. Emergent BioSolutions is the producer of the familiar nasal naloxone product Narcan. Emergent BioSolutions is also a very active member of the CSIS Bipartisan Alliance and we're very grateful to them for being part of that.

We're going to have a spirited and lively exchange here today. We'll be hearing from our audience. Those who go – are coming online, welcome, and please turn to the event page and you can see there's a button there for viewers to add live questions. I'll do my best to integrate some of those questions into our conversation.

So let's get started. Dr. Gupta, I want to start with you. We've asked all three of our speakers to come with some prepared remarks to sort of get out on the table your top line reflections on this period. It's great to have you with us. I know you've been to CSIS a few times and we're very honored to have you back again today.

Over to you.

Rahul Gupta: Well, thank you, Steve, for having me back and thank you to CSIS for continuing to having me – having me have back, and I appreciate my colleagues here as well.

It's an important topic, as you highlighted. Some of these numbers are important, but the issue is very important to the everyday Americans. You know, as a practicing physician this is something that gives me pause that what can we do to save lives, first and foremost.

In fact, when this administration came in in 2021, we were seeing 30 percent rise in overdose deaths per year. That's 30 percent. First, you have to think why, because you can't solve big problems without understanding the why.

There's pretty much three reasons. One, the drug supply, predominantly opioids like fentanyl, had gotten much more lethal and complex. Second, there was not enough treatment available. But the third, there also was not enough antagonist overdose reversal medications like naloxone available so we were not able to save so many of these lives.

We know when a disaster strikes you don't have to be a physician in an emergency room. You don't have to be on a battlefield. The first and foremost thing is you've got to save lives. You've got to stop the bleeding. Then you go back and look for what the cause of the bleeding and solve it because you can't treat dead people.

So at that point it became important for us to put an emphasis on saving lives first and how do you do that when people are dying of fentanyl, predominantly overdose, as you mentioned? It's by getting the overdose reversal medications out there, the antidote available far and wide.

So our goal was to make sure that we have the three As – have it affordable, have it accessible, and have it administered – because these medications sitting on a shelf do no good for anybody.

So we took that journey, as you mentioned – the first administration – to have these medications, now a set of them – naloxone included and others as well – available over the counter, continuing to bring the price down to the extent possible, and making sure that people are getting the drug – the medication – when they need it. Really important.

But also understand that the issue of people suffering many – so many overdoses and disease is the issue of supply and demand. It's both sides of the same coin.

So let me talk about the demand side of the coin first. For the last three

and a half years one of the things we've done is expanded treatment. We have worked to make sure that there's a treatment provider in every county across the United States. This wasn't the case before.
We've put a historic amount of resources into communities, a hundred and sixty-seven billion dollars already, which is 40 percent more than the last administration. We've now also focused on getting investments into young people to make sure that young people know the threat of counterfeit pills when they're ordering something like they think it's Xanax or Adderall. It's not. It has very high likelihood of having fentanyl in it.

So we put together a realdealonfentanyl.com to approach laypeople, tell them this is dangerous, and carry drugs like naloxone with you. And then we made it easier for ever for people not only to access treatment, but also recovery and support services including engaging businesses.

Now, on the supply side, if you think about it, we are disrupting drug traffickers where they may be. We're seizing record amounts. We're adding more scanners at the Southwest border. But we're also going after the enablers through sanctions and disrupting the commerce of this business, because it is a business. Just last week you saw the arrest of two high-profile cartel members, El Mayo and the son of El Chapo. These things don't happen in a vacuum. They're happening because there's a concerted effort to both bring these bad actors down, but also disrupt the commerce.

You know, today the fact is, the whole – this is a global threat. We have three types of countries you can divide the world into – those that have a synthetic drug problem, like fentanyl, and know about it, like the United States; those that have a synthetic drug problem but don't yet know about it, and we're working to make sure they understand that; and the third category is those that are going to have a synthetic drug problem in the future.

So we're working with all countries. Over 150 international nations have joined the global coalition to go at it as a global threat. And this is why this is so important and the work is important. My meetings with the Chinese officials has been critical to ensuring that we are going after the bad actors, the criminal elements, no matter where they are in the world.

Let's talk about results a little bit. Because of these efforts – I mentioned the 30 percent-per-year rise. Now we're seeing last year's data that overdose deaths are down by 5 percent. Now, that's not enough. We have to do more. But what we have learned through this process is we know what works.

One of the things that works is getting more opioid overdose reversal medications to people. This is the reason why we've brought together all or many of those naloxone manufacturers and non-naloxone manufacturers to the table at the White House; not one but two meetings already. We've gotten great commitments from folks, and I'm sure we'll hear about some of those commitments today here.

But the point is that this is the reason we put the White House Challenge across the country today. Our challenge is the following. If you're a public or private entity, small or large, join us. Join us in making naloxone or drugs like that a priority in having engagement and training.

At our office, Health and Human Services office, we've put that as a kit right next to the AED device or the fire extinguisher, as you mentioned. And I'll tell you, this works. Today we have over 200 entities that have joined the challenge. We have the likes of airlines like Delta and Southwest that are putting this medication into their safety kits. We have school districts all around the country. We have transit subway systems, music festivals, businesses large and small, that have stepped forward. I was just in West Virginia. We had over a dozen entities join us just during that trip, academic institutions included.

But what does that mean? I'll give you an example. The L.A. school district has utilized naloxone 50 times already since they joined the challenge. These are 50 lives saved just because they have this life-saving drug available in the school system. We do not have to wait for a child or a worker or someone else in a restaurant or a mall to overdose and die before we decide to do the right thing. We can do it right now. And that's the intent of having this naloxone challenge.

We've got to stop the bleeding. We have to change the trajectory. That takes time. We have more treatment available. And what we have to right now do is make sure that everyone who can and is able to have these medications, have it available, because at the end of the day this is about saving lives. And everyone out there has a role to play.

Dr. Morrison: Was there any surprise this year for you personally in the rollout of the naloxone across the country? Was there things that really caught your attention?

Dr. Gupta: I think one of the surprises was that the interest – we have, for instance, right now Major League Baseball that's a part of this challenge. We have so many other professional sports that are also interested, as well as college sports, in this.

So one of the surprises oftentimes is while we're making sure that everybody's part of it, there are those who have the ability to influence larger than you think. And that gets more people interested and engaged.

And another piece is that this is a bipartisan issue. So one of the things that's happened is we've gotten support and sort of push from all sides across the country. We knew, because this is part of President Biden's unity agenda, one of the four pillars of the unity agenda. But we've been able to see that across the country.

Ten years ago I would have – probably I was seeing much more resistance in the field. Today there is no resistance, because people realize everybody, just about, their families being impacted or someone they know. So we have a dynamism where people are now more acceptable of the right thing to do, which is try to save a life and not be judgmental about this.

Dr. Morrison: Thank you. Thank you very much.

Heather. Heather Saunders, KFF.

Heather Saunders: All right. Hi, Steve.

Dr. Morrison: Hi.

Heather Saunders: Great to be here, and thank you for your comments. I'm excited to be a part of this conversation today.

At KFF, we specialize in policy, polling, and journalism. My role is to inform the policy conversation as it relates to substance use disorder and mental health. And I do that through data analysis and policy analysis.

Last summer, KFF polling found that about one in three people report that they or someone they know has an opioid use disorder, which speaks to Dr. Gupta's point about how widespread this epidemic is and how many lives it touches. Over-the-counter naloxone was just one of an array of federal policies and state – and there are also state policies that aimed to address the opioid epidemic and reduce the rise in deaths that we've been seeing over past years. The idea of over-the-counter naloxone was to make it easier for people to get. When we lower barriers, the hope is that people will gain access to this live-saving medication.

But when that was released last year, we had some questions. We weren't sure if the reach was going to make it to the population it was intended to. For example, we wondered if pharmacies would carry naloxone. A 2022 research study found that 30 percent of pharmacies didn't cover – didn't carry prescription Narcan. And if they don't carry that, then is it fair to assume that they're going to carry over-the-counter?

Another area, of course, is affordability; $44-45 a box is a lot of money for most people. Most people simply can't afford that, and so that could be a barrier to access as well.

Related to that point, what are insurers going to do? What's the role of insurance? Will they add it to their over-the-counter formularies? If they do, will people have any idea that they can access it and how to access it, as these procedures and polices can be confusing to navigate?

And a final major consideration that we thought about is related to awareness and stigma. So most people have probably heard of Narcan, but do they know when to use it, and do they know how to use it, and do they know where to get it? Related to stigma, if stores – if pharmacies place naloxone behind the counter, will people know, hey, naloxone is behind the counter even though it's – you know, I can – I can buy it without a prescription? Will they know that they can reach out to the pharmacist and say I would like over-the-counter naloxone? Maybe, maybe not, especially not if that's not advertised in the pharmacy.

So we know that what happens at the federal level matters. Policy, like making over-the-counter naloxone available, but so does what happens at the state level. And these two often intersect. Medicaid covers four in 10 people that have opioid use disorder. And states have a lot of discretion in how they run their Medicaid programs. Prior to the approval, one in three states reported that they intended to add over-the-counter naloxone to their formularies, which is one of the many ways that Medicaid has helped to address the opioid epidemic.

Other examples include reducing prior authorization, which can be a barrier to access – just another step that people have to go through to gain access to life-saving medication. Another example is expanding benefits to people who are incarcerated. So sometimes that means extending benefits up to 90 days to people who are about to be released from prison, which provides them access to substance use disorder treatment services and transition services at a time that we know they're at very high risk of overdose – in the two weeks especially after release.

So where we are now. Now we're one year past when naloxone became available over the counter. And a lot of questions remain, including how effectively and easily it's gotten out to the people it intended to get out to. And a larger question, which Dr. Gupta already touched on, which is: How is the community safety net of this life-saving medication forming? Is it there? Are schools carrying it? Are libraries carrying it? And then, to circle back to the original question, even if it is in those locations, do people know when they should use it and how to use it?

So, as Dr. Gupta stated, we do know that opioid deaths dropped in 2023, according to provisional data. And we also see that that decline coincided with the release of over-the-counter Narcan. So when we look at monthly death data, month by month in 2023, we see that overdose – opioid overdose deaths started to drop in August of 2023, a slight decline in August, and then that drop accelerated until the end of the year. So by December 2023, opioid overdose deaths had decreased 19 percent compared to July of that same year. There were a lot of factors, a lot of policy, a lot of initiatives and movement and energy moving towards the opioid crisis and trying to reduce the number of deaths.

So we can't say, you know, for sure, that the release of over-the-counter Narcan led to the reduction in deaths. But it's possible that it played a role. So moving forward, there are – Narcan is the emergency, lifesaving piece of the puzzle. It stops the bleed. But there are a lot of other components that need to – that are yet to be – that that are also included in that movement. So including treatment access, insurance churn, a number of other factors which I'm excited to talk about today.

Dr. Morrison: Thank you. Thank you very much. It does sound like KFF has a pretty full agenda looking ahead. We'll come back to that in a moment, in terms of just the opinion – tracking the opinion climate. I mean, you – Dr. Gupta, you and Heather have both put a heavy emphasis on the attitudes and perceptions of our population, and how the – how opinion is evolving in this – in this period.

Paul Williams, Emergent BioSolutions. Thank you so much for joining us.

Paul Williams: Steve, thanks for having me. Yeah, great to be here. Great to be here with Dr. Gupta and Dr. Saunders. Certainly, at Emergent we think this is a national issue, and certainly one that deserves national action and, I think, even greater conversation. You know, for us at Emergent, you know, since we acquired Narcan in 2018 we have really played a leadership role in trying to play our part in combating the opioid crisis, and really built that around awareness, access, and affordability for our patients and our customers.

This obviously is in service to our mission as a company to help protect, enhance, and save lives. But there's still a lot of work to be done by all stakeholders across the boat, especially with the rise in fentanyl poisonings, as we continue to see opioid overdose deaths continue. And, you know, even though the numbers are coming down, 100,000 is still a shock number that is something we need to continue to work, to get to zero I think would be great.

Regarding, like, access, you know, for Emergent, we have really worked to broaden access. And certainly getting Narcan available as an over-the-counter treatment has been key to that, and really it has enabled us to be able to put it on shelves where individuals can purchase it at leading grocery stores, retailers, and online e-commerce sites, such as Amazon.com. We're also expanding this into workplaces and businesses, because an opioid overdose can happen to anyone, anywhere, at any time. And certainly, most importantly, continuing to broaden our work through the ever-critical public interest channel, where Narcan's deployed to at-risk communities and patients.

On the awareness front, we have invested resources and done numerous educational campaigns, starting in 2021 with Reverse the Silence and evolving that campaign to an even larger platform as we launched over-the-counter with what we call Ready to Rescue, which is really designed to raise awareness of accidental overdose and provide education and ways to be prepared to save a life if needed, going to some of what Heather was talking about earlier. We've been a consistent vocal supporter of efforts to expand access for all forms of opioid overdose reversal treatments. We've always advocated for co-prescribing as well as standing orders across the – across the United States.

On the affordability front, I think one example is the critical role that Medicaid plays in enabling access to naloxone for low-income adults. More than half the people with opioid use disorder have incomes below 200 percent of the federal poverty line. We know that increasing access to naloxone for Medicaid beneficiaries was a subject of a HHS OIG report, which highlighted the need to raise awareness and availability of naloxone under Medicaid and encouraged – and encouraged efforts to allow family members and friends to purchase naloxone through the Medicaid program. Happy report that Narcan is available on 90 percent of the Medicaid preferred drug list at this point. So, trying to do our part to solve that piece.

As I mentioned, we introduced Narcan nasal spray as an over-the-counter treatment for opioid overdoses one year ago. This has given us

great insight into consumer behavior as it relates to naloxone, and the stigma associated with it. And here are a few things maybe to share. Online purchases of Narcan nasal spray have exceeded our expectation, but perhaps this is a result of physical pharmacies making it harder to find in stores and/or just due to the stigma of folks actually asking for Narcan in person.

And while online sales allow people to order it and have it delivered straight to their door we believe we have an opportunity to increase access through brick and mortar retail pharmacies. We're certainly working closely with our partners, both national retailers as well as smaller regional pharmacies, to ensure that it's ready, available, and identifiable in stores and consumers are aware of its availability, especially in underserved communities.

We're also having conversations with nontraditional retail outlets like convenience stores and more rural community chain stores as we continue to expand the availability of this treatment through other online retailers.

As far as next steps, you know, I think moving to OTC has certainly made it easier for individuals and business businesses to purchase Narcan nasal spray. In 2023 we distributed more than 11 million two-dose cartons and we expect to supply even more in 2024 based on demand, especially demand coming from the public interest channel, which services state and local governments, law enforcement, harm reduction, and community organizations.

Given our extensive network of public interest groups and years of experience working to increase awareness and access to naloxone we see three areas of opportunity to get this product into more hands.

I think, first, we need to do more to ensure the resources designated to combat the crisis are getting into the hands of the organizations who can help. Federal grants are one example but so too are the state opioid settlement funds. When these are used for their intended purposes these resources provide states and local organizations with the ability to make naloxone widely available.

I think, second, we must explore all ways to expand access, leaving no stone unturned. With naloxone available without a prescription we must strive to make it as prevalent as defibrillators and fire extinguishers on construction sites, hotels, restaurants, shopping centers. I think the list goes on.

We at Emergent have – we are also working directly with businesses.

We've created narcan.com/workplace to allow businesses to order and have Narcan delivered directly to their door. We've engaged with partners like the National Safety Council to educate businesses on the risk of overdose deaths in the workplace. Important to note, I think that the crisis reaches employees in all industries and occupations with workplace overdoses now causing nearly 9.6 percent of all worker deaths on the job.

And then, third, we need greater industry commitment and investment in education and awareness initiatives. In June we were honored to join Dr. Gupta in the White House ONDCP with some of our industry colleagues, as he shared earlier, and what can be done collectively to help reduce the stigma and get opioid overdose treatments into more hands.

We have long invested in public education efforts to raise awareness around overdoses from fentanyl and teach people where to get and how to use nasal naloxone. Our recent campaign Ready to Rescue features pro football legend Emmitt Smith. We are proud to be supporting the Ad Council and the Real Deal on Fentanyl campaign.

Just to close, I think, look, governments, organizations, companies, individuals, we all have a responsibility to do more, especially as it relates to getting naloxone into the hands of those that need it the most and we're certainly committed to doing our part, and look forward to the conversation.

Dr. Morrison: Thank you. Thank you.

Mr. Williams: Mmm hmm. Appreciate it.

Dr. Morrison: Those are all wonderful opening remarks, and thank you.

I want to come back to stigma because it is an enduring problem for us, and I was struck by the fact that none of you said that we face a problem of public trust, which in the post-COVID era that is a very dominant theme in all public health discussions.

But in this domain we're not hearing that. We're also not hearing in your prepared remarks that disinformation and misinformation, that you're facing that as a major obstacle. So why is that? Why – what is it? Are we in a different domain here with the opioid epidemic where we're facing less of that trust – trust collapse and misinformation and disinformation And what does that mean when we're talking about trying to reduce stigma and how do we gauge whether we're making progress on that?

Dr. Gupta, your thoughts?

Dr. Gupta: Yeah. Thank you for that. I think it's where less of it is true, accurate, is still out there, but the fact today is – and I look at this, where we were 10 years ago, five years ago, because having been in the field, we're in a place where there's a broad understanding of the dangers of the, you know, fentanyl-related drugs and the – whether it's overdoses or it's poisonings, the danger to life, especially for our young people as well as for those who don't know what they're taking and they may end up. So that's allowed us to not have to focus so much on the politics of it, but more broadly that this is an American problem. It's not a red or a blue state issue. This is a problem that we can all come together to solve, and that's been one of the president's sort of words on this issue. And this is important. It's important to people because we can no longer afford to not follow data and science on this issue. We know it's not enabling. We know that through research. We also know the fact that when people need it – for instance, when we saw the doubling of overdose deaths in adolescents from 2019-21, in two out of three of those cases bystanders were nearby but overdose reversal medication like naloxone was not.

And that's a tragedy. And that's what people now understand that we must reverse. That's why we see some. And it's important to educate, and continue to educate, and continue to share as much information as possible. But also understand that this is a problem we must all come together to solve. And I think that's what we're, as a nation, attempting to do right now.

Dr. Morrison: Heather, your thoughts.

Dr. Saunders: I think that's a – I think that's an interesting point that you bring up, about stigma. And it still plays a role in some way, I'm sure. We know that when we ask people, through KFF polling, what they think about naloxone being widely available at schools and, you know, bars, and firehouses, 80 percent of people support it. And that's across both parties. The support is high across both parties. So given that, and given that so many lives have been touched by someone, you know, having a family member or friend themselves struggling with an addiction, or knowing somebody who died from an opioid overdose – it's touched so many lives.

Dr. Morrison: You know, in 2017-18, and up to the pre-COVID period, we were doing some convenings here at CSIS with members of Congress, with the business sector, and with the administration. And that cut across – it was the late Obama administration and the early – the early era of the Trump administration. And we were also out traveling to eastern

Kentucky, to central Wisconsin, to New Hampshire, talking to people. There were a couple things that jumped out in that period. One was that the first responders – whether they were firemen, or police, or emergency medical – were carrying Narcan at that time. And they were very proud of this. But they were uneasy. They were a bit uneasy in that early phase, right? It was 2018 that you purchased, and it began to be – and it was starting to be introduced.

Another big impression was the discomfort that the corporate sector had, outside of production – those producing products, to be identified too closely with something that was an addiction, a substance disorder.

In other words, we would convene, and we would have the Walgreens, and the Walmarts, and, you know, large employers coming with us – FedEx, others were coming to – they would come to the convenings readily and eagerly. But in terms of overtly identifying with a working group focused on this particular problem, there was a discomfort level. They didn't want to have their name associated in some formal fashion.

My question is to you – and I'll start with Paul – have we crossed a threshold here, where, you know, we now have Walmart agreeing to introduce its own medications, right? I mean, the – we have embrace coming in various forms. And you've done this convening in June – in early June, and the turnout there. So have we – has the political climate and the sensitivities changed, Paul? What's your sense?

Mr. Williams: Yeah. I think the reality of – like I said, the crisis didn't sort of turn on a dime and start from zero. It's been building since, you know, as you said, 2017. And certainly in the last three years you've seen the spike and the number of deaths and fentanyl-related deaths. And so I think what's staring all of us in the face is this significant challenge that we have in front of us, with over 100,000 people dying a year. And so I think when you talk about stigma and you talk about companies, like the – I think the will is there, right? Wow, we need to do something.

The implementation piece creates some really interesting things for them to think about. What does this mean for us as a company, if we're going to tell our workforce we're going to have Narcan, or naloxone, or an opioid overdose reversal agent in every one of our facilities? OK, how am I going to implement that? What's that mean for my EH&S team? What's my legal liability? What happens – you know, so you've got all these things that you should be practical and be, like, this is a no-brainer for anyone to actually implement.

There are still some things there that folks have to think through. And the – if you want to call it the stigma associated with addiction and

overdose, we have to move past that in a way so that folks really are able to think of this as an automatic and something I have to do, as simple as anything else that they're actually doing.

Dr. Gupta: I think, look, when someone suffers from a heart attack, we don't judge that individual. We are really proud to provide CPR. We train CPR in high school and even less than that. We do AED device. Same way, if a house catches fire, we don't judge about that before we call the fire department.

I think we're slowly getting there where we understand this is about life. This is about saving those lives. We're working, again, with states to do the same, local communities to do the same, because it goes back to some of the points that what does the over-the-counter designation get you? It gets the ability to mainstream this into – look, if you are a restaurant or a mall or others, does it make sense for you to have a product that will last a couple of years that costs about $24 to $44 apiece there that you might be able to save someone's life? We believe it does. It does make sense. And for a lot of people who are high-risk and in those communities, vulnerable populations, we have to then work harder to get these products to them, as opposed to expecting them to walk into a CVS or Walgreen.

So there's – it's a double-edged part of the work and where we're working with states and local communities to use those unprecedented federal dollars to get out there to be able to create – so the money, the cost, is not a barrier, the ideology is not a barrier, and people know how to be – and be trained in how to use it.

So when we get all these things lined up – and interestingly, that's just the beginning, as Heather mentioned. That is the beginning of helping people get – stay alive and heal themselves. The job doesn't end there. Arguably you can say that's where the job starts.

Dr. Morrison: Thank you.

COVID had profound impacts, it seems to me, with respect to the opioid epidemic. And I'd like each of you to sort of share what that meant. I mean, on the one hand, it overwhelmed and distracted and diverted attention in a critical period. And then when it became possible to come back, it was at a worse point, and people understood. So there was a re-mobilization with each emergency that happened.

On the other hand, we learned a lot in COVID in dealing with this kind of threatening emergency.

So I'd like you to just say a few words – Heather, I'll start with you – say a few words on, like, what was the impact, good and bad, of COVID on this struggle to reverse this epidemic?

Dr. Saunders: Sure. I can start by putting a number out there, which is that during the pandemic, from 2019 to 2022, overdose deaths, opioid overdose deaths, rose by 64 percent – a lot. So

Dr. Morrison: So they spiraled.

Dr. Saunders: Yeah, absolutely, absolutely, due to a number of factors. But one thing that people often talk about is the silver lining of the pandemic is that we began to have conversations about mental health and about substance-use disorder in a way that we weren't open to having them before. And so I think that we worked towards establishing a new comfort of these conversations. And the progression of the opioid epidemic and the number of deaths only moved that forward.

Dr. Morrison: Thank you.

Dr. Gupta, your thoughts?

Dr. Gupta: As Heather mentioned, you know, there was a lot of disruptions, both in the demand as well as the supply. But what good came out of it was that, you know, you have to have the provided two licenses, not just to prescribe opioids, but then another license to treat people with opioid addiction. And, you know, the president called for it and we were able to get rid of that extra license need that expanded treatment ability from 129,000 providers in this country, like myself, to almost 1.8 million providers.

Dr. Morrison: So this was a very pragmatic step with profound impact.

Dr. Gupta: Absolutely. An artificial barrier in the system, in the bureaucracy, that didn't need to have in the first place, but really impactful.

Second, telehealth. We were able to get more people now treated where they are, especially for marginalized and vulnerable population and rural population. It was a big step. And we are working now to make some of those permanent rules. So that the silver lining – one of the biggest silver linings that Heather's talked about is actually moving out telehealth – phone and video consultations – by about a decade because of the impact of the pandemic, and then mobile vans. We now have in rural communities vans that can travel, that can provide treatment. We are continuing to push to say, well, our mobile vans can EMS, not induce treatments in the field, can we not do more. But it's given us the

stimulus to jumpstart a system of treatment and access to care and affordability in a way that was not possible pre-pandemic.

Dr. Morrison: Thank you.

There's a question that's come in from our audience around cost of over-the-counter naloxone. And the way I'd like to approach that is: Are we seeing reductions happen already? Are we anticipating that changes in the market in terms of new entrants and the like, or policy interventions themselves, are going to bring the cost down inexorably? Is that part of our thinking, that the cost equation – I mean, we've seen this in many other health interventions, right, where there's a – there's a great product developed, the cost is at a high point, but as the – as the distribution and access deepens and widens the cost formula changes. Is that what we're likely to see here looking ahead, Paul?

Mr. Williams: I absolutely think so, right? I don't see how you can't. Especially if affordability is a third of your platform, I think that's something to be expected.

Dr. Morrison: Yeah.

Mr. Williams: You know, it's fascinating. When we, you know, talk to our retail partners, you know, what's driving the uptake or maybe – let's say maybe the slower uptake that we have expected in that necessarily segment of potential folks that would acquire Narcan. You know, it's not cost, right; it's the awareness, it's do I need it, what's my proximity to an overdose. At the same time, I think the importance of making sure that we are providing for us Narcan or any opioid reversal treatment through the public interest channel at the lowest cost possible is most important, because that's really where the product gets distributed and into the hands of folks for free. But I think we're going to have to continue to look and understand, like, what is the – what is that – what is that balance, right, also making sure that we have enough investment to continue to expand and grow demand and support supply and everything. There's two sides to that.

But I think when, outside of the public interest channel – and this is where you say it's one year past, that's a long time or that's really not a lot of time – and I'd probably put it in it's not a lot of time; it's fairly nascent – for folks to really understand, well, if the price was $10 higher or $10 lower, would we be in any different place, or is that going to make the difference for someone deciding to actually, you know, walk into a Walgreens to purchase Narcan? That hasn't been the case, so I don't think we know the answer to that yet. But we'll continue to test different things to understand that.

Dr. Morrison: But I assume – Dr. Gupta, I assume the White House strategy has in its mind that there's going to be a budget power. You've got ample resources. You may not have exactly what you need. But you've had – you've been equipped with pretty strong budget support. The SUPPORT Act was fundamental to that, bipartisanship, action in the appropriations and authorization process in both chambers. That gives you a power over the long term to shape markets and to use the convening power of the White House, as you have done just recently in June. How does that – what is your vision and strategy looking for? What can we anticipate on the price and affordability front?

Dr. Gupta: Well, first of all, think about what's the cost – what's the cost to save a life, right? That's the first piece, that no one should be denied a life-saving drug. That's the first piece of this, that we – with the north star being save lives.

At the same time, I have been where these drugs cost thousands of dollars in the past, and today just within this administration they've come down to, as I said – if you look at the California data it's about 24, over the counter is about 44.99, about $45, the price. That's significant reductions.

We also know that the larger the need is, which we are clear that there's a lot bigger need. And that's where stigma and information and awareness comes in, that if we have – we surge more of these medications out there we are going to save more lives.

To surge more medication we're going to need more volume and one of the things we've done in the June meeting by convening is have a commitment from a number of manufacturers and really want to acknowledge that, including Emergent, about how to go up in volume production so that we can support the surge so we don't hit a bottleneck when it comes to this.

We want to continue to match the need increase with a surge in production and then hope that the price goes down as a result of the market forces. That's the ultimate idea. But there are resources available from the federal government. We are convening states. We're bringing together naloxone policy academy. We've brought together dozens of states to learn from each other and figure out how to even do a better job as they are doing already pretty good of further – having a better acquisition strategy, better distribution strategy, going to more vulnerable population(s), high-risk need population(s), and having a distribution challenge.

Because this drug, even if you were to acquire in bulk, can't just be sitting on the shelves. It's got to be used.

So these are all the things from the White House perspective we're doing with the ultimate goal of getting more product out there to save lives, and making it more affordable, and then getting it into people that need it and when they need it.

Dr. Morrison: You know, I was struck by – please, Heather.

Dr. Saunders: I just wanted to remark quickly on the insurance perspective from this.

Insurers can add over-the-counter naloxone to their formularies and if they do that then the cost is whatever the co-pay is, or for people who have Medicaid the cost will be, you know, minimal or nothing.

So that is potentially a way to reduce the out-of-pocket direct cost to people. However, people understanding how to navigate that process and, you know, move to that place may be part of where the challenge lies.

Another thing that I'd like to mention related to Medicaid and insurance is what's been happening over the course of the past year or so, which is Medicaid unwinding, where a number of people have lost coverage and with a loss of coverage – you know, sometimes they have other insurance, sometimes they don't.

Sometimes they get back on Medicaid. But it's a disruption of access to care and with a loss of coverage comes a disruption in access to treatment which may have impacted people who have opioid use disorder and their access to treatment.

Dr. Morrison: Thank you.

I was struck by – in reading in preparation for this and listening to you all speak I was struck by the emphasis on bringing in new voices of advocacy and champions and validators, and turning to sports celebrities and leaders and iconic cultural figures – hopefully, we'll see Simone Biles out there soon or Taylor Swift – but using different media as we've seen of a – that reaches a different generation.

In our own work governors and mayors and county officials are terribly important at changing attitudes and they have enormous power and influence as does the faith sector. Say a bit about how you bring in more engagement and more commitment from those levels.

Dr. Gupta: Well, I'll start, and let me just say that from day one it was very important for me, having worked not only in private practice but also at local state government before coming here, the important role that local and state leaders play in addressing a problem.

So, it's been an important piece of my journey across the country to make sure that I'm meeting with those leaders and empowering them to challenge us, the federal government, to do more, empowering them to look at what is available in terms of funding and bringing down that funding and utilizing that for their constituents.

Similar thing goes with Real Deal on Fentanyl. This is a(n) online campaign through social media for young people but it's by young people. It's by young people, influencers, that are telling young people what the dangers are.

So it's been important to reach out, and then, you know, in this administration we held the first faith summit in the White House in the Roosevelt Room where we brought together all of the leaders of various faiths to come together to help address this. Because, look, I'll tell you, if you are alive during a disease of addiction – which is a brain disease – or overdose, you end up more or less in three places – either in jail, today, in a hospital, or at your place of worship across America. So it's really important for us to empower all of the actors in all of these areas to make sure they have the most current, most knowledge and information, they're connected to appropriate treatment and other aspects. And that's the work also we're doing with – you know, including faith leaders. From health professionals, to carceral setting professionals, to faith leaders, all across the spectrum because, again, everybody has a role to play of this problem to solve.

Mr. Williams: Yeah, I think where we come in is – and perfect segue – is we're sitting down with state leaders trying to understand, as that funding comes in, what are your goals? What are your goals with naloxone distribution? What are you trying to achieve in terms of reducing your overall opioid death rate? And then, how can we help you design a program within your state to enable the results that you want to get, which is really – which is really important.

And I think the one thing – not every state is created equally. Some have very sophisticated and well-thought-out plans. Others are still building and growing those. Some are still playing catch up. And so not one size fits all. And I think the ability to get in and really help these states think through how to get Narcan into the hands of the folks that need it and

not sit on a loading dock somewhere, as would be a contrast, is critically important.

The other – the other piece, you asked about, like, sort of, what's changed since COVID. And you talk about Simone Biles. I think the one thing is the rise of the influencer, pre- and post-COVID, is huge. And the rise of influencers in this space is significantly higher. And the voice is louder. And I think we need to continue to help and support those folks that do that, because in some cases while it's great to hear from an Emmitt Smith, and that resonates with folks, or a Simone Biles, sometimes having someone who's walked and lived in their shoes is sometimes even more important to do.

Dr. Morrison: Heather, your thoughts.

Dr. Saunders: I guess I would like to address this from a prevention point of view, which is on Dr. Gupta's strategy. We can talk with people who might be affected by and knowledgeable about the opioid epidemic now, but another direction is through school-based services. Medicaid's doing a lot in that direction. And some states are also expanding school-based services, where there may be opportunities for education around these topics, and also treatment for and screening for substance use disorders mental health needs, which can be a precursor to development of other addictions or other needs. So through the bottom-up may be another channel.

Dr. Morrison: Thank you.

Mr. Williams: Love it.

Dr. Morrison: We're getting towards the end of the hour here. And what I'd like to do is ask each of you – and I'll start with Paul, and Heather, and then Dr. Gupta. Have you tell us in your closing thoughts, what should be the one or two top-line priorities looking ahead in this next phase? What should we really be seized with in this period? And what gives us the greatest hope and optimism looking forward? Those are two questions combined into one. So, Paul, over to you.

Mr. Williams: Yeah. You know, I think, as we're – the premise of this is one year post, you know, over-the-counter availability of naloxone. And I think, you know – well, I think there's a thought this is going to solve all the world's problems, and everything's going to be easy, and we're getting Narcan or naloxone into the hands of folks. I think we realize that that's – we have a long road to go down. But I think there's an opportunity to raise the conversation at a national level to a point where this is something that is easy to talk about as any other topic.

And help folks understand, whether it's around fentanyl poisoning, whether it's around mental health, whether it's around your proximity to somebody that's using opioids and what to do about it, I think is going to be critical. I'm hopeful because, you know, we've had two meetings at the White House. And the – I think the critical mass that's coming together around all the attributes of this, I think, is really pointing in the right direction. And, you know, it's great to see that we have had a reduction. Albeit, as I said, 100,000 is way too many, but it's nice to see the arrow going down a little bit. So, you know, excited about what's to come, and to be a part of it.

Dr. Morrison: Heather, what should be the top-line priorities, and what gives you hope?

Dr. Saunders: Well, I can tell you what the data says about where some of the gaps are. We know that there are substantial gaps in behavioral health workforce. We know that about half of the U.S. lives in a mental health workforce shortage area. And having workforce to provide services is a core component of being able to get people into treatment. Another thing that we've seen is that even though treatment – evidence-based treatment is available, a lot of people, 17 – over 80 percent to 50 percent, depending on what estimates you look at, don't access treatment, or medication-based treatment specifically.

And so the other piece that I'd emphasize is what are the barriers there, and also what are the barriers that keep people from staying in treatment? And are any of those barriers related to insurance – are they insurance-based barriers? For example, prior authorizations are churned from one insurance to another, or providers moving from one plan to another plan. And logistic – what insurance-based and structural barriers are there that haven't been looked at or addressed that may play a role in people accessing and staying in treatment?

Dr. Morrison: What gives you the greatest hope?

Dr. Saunders: That we're having conversations like this, that we have leadership that's laid out a strong plan about moving forward and that, you know, it seems like we have movement in terms of emergent, you know, medicine, life-saving medicine, getting potentially starting to get to people who may need it; so, steps.

Dr. Morrison: Yes.

Dr. Gupta, you get the last – the benedictory remarks here on your topline priorities and what gives you the greatest hope.

Dr. Gupta: Well, thank you.

Look, think about a large ship moving at a fast speed. You've got to slow this down and then you've got to turn it around and go in the reverse direction. That's kind of what's been happening with the big picture. We have 46 million Americans today that suffer from the disease of substance-use disorder. So you have to look at not only the tip of the iceberg, which is the overdose deaths, but also the non-fatal overdoses and the bottom which people who are suffering, because it's the suffering of everyday Americans.

So where we go with this is to look at the entirety of a complex problem. This is a complex issue that requires our work from prevention to life intervention with life-saving medications to treatment to building recovery-ready nation through recovery-ready businesses and others, while making sure we're addressing the supply side and working with our global partners at the same time.

So there's a lot of tentacles to this. But our north star has to be saving lives first. It also has to be going through evidence, making sure that we're data-driven and doing the right thing for the right reasons at the right time. All of those things are part of the president's strategy, which we released the 2024 version earlier this year. And the strategy aims to work in a way – and we have predictive analytics, which is if we do this, here's what will happen, which is we will literally change the trajectory of where we are, and if we don't do the opposite.

So the groundwork has been done. The program has been laid out. The investments are historic. And it goes back to the hope piece, which is now we're beginning to see the ship turn. We are beginning to see the impacts, whether it's the expansion of opioid overdose reversal medication, expansion of treatment.

But this is the time to double and triple down on the efforts thar are working. That means that we have to put a lot of energy on those elements of the plan, of the work, of the investments, that are actually creating the savings of lives. And again, we say 5 percent. That's more than 5,000 people who are alive today, at those tables, dinner tables, are there, and they're in the chairs because of this work.

So I do think that we have an opportunity here to have a much greater impact. It is a bipartisan issue. It is one that most Americans align with the way the direction is. And that's what gives me hope.

Dr. Morrison: Thank you.

We're at the end of our hour. I just want to thank Dr. Gupta, Heather Saunders and Paul Williams for taking the time to be with us and to offer such thoughtful insights for this conversation, and your openness and candor about the complexity of this issue, but, most importantly, your leadership and your commitment to this problem in your respective roles, which are terribly important.

I also want to thank the staff at the White House, at KFF and at Emergent BioSolutions, who came readily to the table to help us make this all possible today, as well as my CSIS colleagues.

As I mentioned, this – you will be able to find this video and a transcript on the CSIS homepage, CSIS.org. So thank you so much. This has been a wonderful conversation. We'll be back again in the future. Thank you.

Dr. Gupta: Thank you.

(END.)