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UNITED STATES SENATE

The Federal Response to the Drug Overdose Epidemic

Tuesday, July 20, 2021

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U.S. Senate

Caucus on International Narcotics Control

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The caucus met, pursuant to notice, at 2:29 p.m., in Room SD-608, Dirksen Senate Office Building, Hon. Sheldon Whitehouse, chairman of the caucus, presiding.

Present: Senators Whitehouse [presiding], Blumenthal, Hassan, Grassley, and Cornyn.

OPENING STATEMENT OF SENATOR WHITEHOUSE

The Chairman. The hearing will come to order.

Let me first thank my distinguished ranking member, Chuck Grassley, for being here. We have worked together -- we had a brief sidebar before I turned on the microphone, and he pointed out that this has always been a very bipartisan committee, and I pointed out that he and I had always worked well together on top of it. So there is a good personal overlay here. So I hope to be able to continue that, and I thank him for being here.

I will give a brief opening statement, and then I will turn to Senator Grassley for his opening statement. And then we will turn to our first panel, and I will yield my questioning time, since I am going to be here through the whole hearing, first to the ranking member, Senator Grassley, for whatever questions he may have and then on to the senior person on our side. And we are doing it by gavel. So that would be Senator Hassan. So she will be our lead-off questioner when we are done, and then we will proceed forward from there to the panel.

I will announce to all of you that by virtue of the way the Senate operates, your testimony is taken as sworn, and I will spare you the photoshop moment of putting your hands up. But it doesn't change the requirement that your testimony be under oath.

So welcome, everyone, to our first Drug Caucus hearing. Drug traffickers prey on American demand for illegal drugs, and the consequences for our people and for our communities and even our democracy are deadly. My goal in my time as chairman of this Drug Caucus is to shine a light on the dark economies drug traffickers harness to hide their ill-gotten gains.

In coming hearings, we will examine how drug trafficking networks exploit our rule of law and financial systems to sustain their criminal enterprises. We will lay out the foundation for this work with today's hearing, which focuses on the Federal response to the drug overdose epidemic and the drug threats that have emerged or changed as a result of the COVID pandemic.

After a modest drop in 2018, overdose deaths surged to over 93,000 last year, a new record. Four hundred of them were my fellow Rhode Islanders.

While synthetic opioids, like illegally manufactured fentanyl, are the primary driver, these deaths often involved multiple substances used together. This dramatic increase, accelerated by COVID, underscores the need to revise and improve our drug policies. An effective strategy should reduce U.S. demand for illicit drugs by expanding prevention, treatment, and recovery infrastructure; and build and strengthen our domestic and

international partnerships to reduce supply; and attack the financial networks that drug traffickers utilize for their ill-gotten gains.

We know prevention and treatment save lives and money. The National Institute on Drug Abuse estimates that illicit drug use costs the United States over $600 billion per year. Every dollar invested in evidence-based prevention can save up to $20, and every dollar invested in treatment can save up to $7. So we have to continue to invest in effective prevention, treatment, and recovery programs.

In recent years, we have enacted bipartisan legislation to do this, including my bill CARA and provisions of CARA 2.0. These laws have infused billions of dollars into our substance abuse prevention, treatment, recovery, and enforcement infrastructures. But more remains to be done, which is why I introduced CARA 3.0, a bipartisan bill to invest $785 million into expanding access to treatment and building the addiction medicine workforce. It also includes measures to ensure equitable and culturally competent care.

The COVID pandemic forced us to expand access to treatment through new strategies and technology, and I have introduced legislation to permanently allow prescribers to use an audio-video telehealth evaluation to prescribe Schedule III and IV medications to treat substance use

disorders and to allow for Medicare reimbursement for those services. The pandemic forced this innovation, and now we know it can work. We should seize the moment, which is why I am pleased to see that ONDCP's Statement of Policy Priorities largely aligns with the provisions in these bills.

As the success of the CARA legislation shows, efforts to reduce demand for drugs need to emphasize public health. Still, we must think clearly about the vast supply of drugs flooding our communities from abroad and what it will take to stem that flow. With a skilled chemist and the right precursor chemicals, drug traffickers can produce an infinite array of new synthetic drugs to wreak havoc in our communities. Traffickers in Central and South America can easily obtain those precursor chemicals. So an effective Federal strategy must strengthen international partnerships to attack the supply chain.

Finally, given that drug traffickers are motivated by money, an effective Federal strategy should explicitly prioritize efforts to understand and aggressively attack the financial networks the traffickers exploit. As part of this effort, ONDCP should convene an interagency working group to determine whether the disruptions in trade-based money-laundering schemes, dark web activity, and bulk cash smuggling that occurred during the COVID-19 pandemic can be

maintained.

The rapid escalation of drug overdose deaths during the pandemic means we must reexamine and strengthen our existing drug policies. At the State level, I am particularly proud work that Rhode Island has done so much to refine its policies under the leadership of Womazetta Jones. We must mirror that success on the Federal level.

I look forward to hearing what witnesses think of the Federal response to the drug overdose epidemic, how the pandemic has deepened the crisis, and what we can do to save lives.

I recognize Ranking Member Grassley for his opening statement.

STATEMENT OF SENATOR GRASSLEY

Senator Grassley. Thank you, Mr. Chairman.

You correctly stated our working relationship, and particularly on this caucus over a long period of time that I have served on it, whether Republicans have been in the majority or Democrats in the majority, there has been a strong bipartisanship, and there ought to be, and it is easy here. So I look forward to continuing our relationship now that you have become chairman.

Also, I welcome all of our witnesses today, as I had a chance to say hello to you in the ante room.

Ninety-three thousand. That is the number of how many people died from drug overdoses last year. This is the sharpest annual increase in 30 years. The New York Times wrote that 2020's overdose death numbers eclipsed the peak yearly deaths from car crashes, gun violence, and the AIDS epidemic altogether. That ought to be an astonishing figure for all of us to consider.

No region was spared last year. Every corner of the United States suffered an increased death toll. The main culprits, COVID-19 and deadly fentanyl analogues. So today's hearing is timely because it is urgent that we evaluate our Federal approach on the drug crisis.

COVID-19 played a significant role in the increased drug overdose rates. The pandemic brought about social

isolation, trauma, job losses, made necessary tools like access to treatment even more difficult. Data shows us that overdoses took off in March 2020, when the pandemic-driven shutdowns and physical-distancing measures all began.

We must learn how to navigate drug policy in a post-COVID world. What lessons did we learn? How can we improve? These are questions that I want answered.

Also, fentanyl analogues are driving up the death toll. According to Customs and Border Patrol, the amount of fentanyl and analogues seized so far this fiscal year nearly doubles what was seized in all of 2020. This statistic alone should be enough to compel serious long-term actions on controlling deadly fentanyl-related substances.

Drug dealers often mix fentanyl with other drugs like meth, cocaine, and marijuana. Traffickers prey on those suffering with addiction by adding deadly analogues to other drugs. Sometimes users know what they are consuming, that they are consuming a fentanyl substance, but sometimes they don't know that. In any event, the data speaks for itself. Polydrug abuse, mainly due to fentanyl substances, is a driver of overdose deaths.

So at a time of record drug abuse and deaths, where should our priorities be? I recently outlined in a letter

to the Office of National Drug Control Policy what I think must be prioritized in a Federal approach to drug policy. Among others, I highlighted the need to build a plan to deal with historic levels of methamphetamine supply and use, that we need to address polysubstance trafficking, and we must proactively address fentanyl analogues.

The authority to schedule fentanyl substances expires in October. The administration must support efforts to proactively and permanently schedule fentanyl analogues. To do anything less will surely enable the spread of these deadly drugs.

I am grateful that Acting Director LaBelle invited me to weigh in on the National Drug Control Strategy, and I am pleased to have her testimony today. We must work together in a whole-of-government approach to assess gaps in policy so we can tackle the crisis. Simply put, it is a matter of life and death. Ninety-three thousand Americans lost their lives last year because of the rampant scourge of drugs in our country. I hope we all agree that this must end.

Thank you again for today's witnesses for being here. I look forward to hearing about how we can work together to strengthen our approach and combat this problem.

Thank you.

[Discussion off the record.]

The Chairman. My apologies, I was going straight to

questions. I see all these witnesses here I want to ask questions of. So let me just do quick intros, and they can each make their statements.

Ms. LaBelle is Deputy Director and Acting Director for the Office of National Drug Control Policy. She was a distinguished scholar and program director of the Addiction and Public Policy Initiative at Georgetown University Law Center's O'Neill Institute for National and Global Health Law and founded and directed the Master of Science and Addiction Policy and Practice Program at Georgetown University.

She has also served as the ONDCP chief of staff. So she certainly knows her way around the organization, and I welcome you today, Ms. LaBelle.

Tom Coderre is the Acting Deputy Assistant Secretary for Mental Health and Substance Abuse at SAMHSA and is the first person in recovery to lead that agency. In his role as SAMHSA's Region 1 administrator, Mr. Coderre led the prioritization of prevention, treatment, and recovery services through COVID-19. While chief of staff to the Assistant Secretary for Mental Health and Substance Abuse and Senior Adviser to the Administrator -- you guys go for really long titles in this line of work -- Mr. Coderre led the team that produced "Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health."

As a senior political appointee, he has represented SAMHSA at the White House and other HHS offices and operating divisions and has been involved in leadership positions in the State of Rhode Island, as well as the national field director of Faces and Voices of Recovery.

Dr. Volkow is Director of the National Institute on Drug Abuse at the National Institutes of Health. Her work has been instrumental in demonstrating that drug addiction is a disease of the human brain. As a research psychiatrist and scientist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic and addictive properties of abusable drugs.

Most of her professional career was spent at the Department of Energy's Brookhaven National Lab in Upton, New York, where she served as Director of Nuclear Medicine, Chairman of the Medical Department, and Associate Director for Life Sciences. She was also a professor in the Department of Psychiatry and associate dean of the medical school at SUNY Stonybrook in New York, and she has also co-edited the "Neuroscience in the 21st Century Encyclopedia."

So this is a stunning array of witnesses, and let me ask Ms. LaBelle to proceed with her testimony.

STATEMENT OF REGINA LABELLE, ACTING DIRECTOR,
OFFICE OF NATIONAL DRUG CONTROL POLICY

Ms. LaBelle. Chairman Whitehouse, Co-Chairman Grassley, and members of the caucus, thank you for inviting me to join you today to discuss the Office of National Drug Control Policy's role in the Federal response to the drug overdose epidemic. I am honored to testify as the Acting Director of the agency where I served for 8 years in the Obama administration.

ONDCP coordinates drug policy through the development and oversight of the National Drug Control Strategy and the National Drug Control Budget. As Acting Director, I act on critical current and emerging drug issues affecting our Nation by facilitating close coordination of Federal agency partners on supply reduction and public health efforts and by overseeing our budget authorities to ensure that adequate resources support the Nation's drug policy priorities.

ONDCP's central coordinating role in drug policy has never been more important. As you said, the CDC estimates more than 93,000 people died of an overdose in 2020. These overdoses involved illicitly manufactured fentanyl, fentanyl-related substances, psychostimulants, such as methamphetamine and cocaine, all increased by double digits.

The COVID-19 pandemic exacerbated the overdose epidemic, and overdose rates were beginning to rise even before the pandemic began. The drug environment we face today differs significantly from even 5 years ago and requires an urgent response.

Since President Biden took office, he has made it clear addressing addiction and the overdose epidemic is a significant priority. On the public safety side, he is focused on reducing the supply of drugs entering our country by strengthening interdiction, domestic law enforcement, and international partnerships.

For example, we are working across the interagency to develop a solution on scheduling fentanyl-related substances. We are grateful that Congress extended the temporary scheduling earlier this year as it has given us an opportunity to develop a consensus approach to the issue.

On the public health side, the President is focused on expanding access to the continuum of care for people with substance use disorder. We have already taken several actions. The administration removed the X-waiver for prescribing buprenorphine to 30 or fewer patients, making it easier for physicians and other medical practitioners to treat patients with opioid use disorder with the standard of care. We have allowed Federal funds to be used for

fentanyl test strips, and we have ended a decade-long moratorium on methadone bans so treatment can be brought to underserved communities.

In addition to the actions outlined above, the Biden-Harris administration has dedicated historic funding to address addiction and overdoses. The American Rescue Plan, which Congress passed in March, invested nearly $4 billion in vital mental health and substance use disorder services. This funding also included $30 million for harm reduction services, an historic amount.

In May, President Biden released his first budget request, which calls for $41 billion to fund drug policy programs. This includes both public health and public safety efforts, including an unprecedented focus on prevention, treatment, harm reduction, and recovery support services while also supporting key drug supply efforts.

Last week, ONDCP announced new High Intensity Drug Trafficking Areas discretionary funding, which includes funding to bolster public health and public safety collaborations. Earlier in the year, we also announced that the HIDTA Overdose Response Strategy, which brings together local public health and public safety leaders to address overdoses, will be extended to all 50 States.

And in June, our office announced new grant funding provided by Congress under Chairman Whitehouse's leadership

through the Comprehensive Addiction and Recovery Act. This enhances the work of community coalitions to prevent youth drug use, and more grants will be released through our Drug-Free Communities program throughout the summer and fall.

All of these actions fall under the Biden-Harris administration's drug policy priorities for the first year, the guiding principles as we formulate the National Drug Control Strategy, which is due to Congress next February. The priorities also represent a focused approach to reducing overdoses, creating more opportunities to engage people with substance use disorder, targeting and disrupting drug trafficking networks at home and abroad, including through anti-money laundering efforts, and ultimately saving lives.

The priorities provide guideposts to ensure that the Federal Government promotes evidence-based public health and public safety interventions, which include advancing racial equity in drug policy and embracing a full continuum of interventions. These actions and this funding are just the start of the administration's historic commitment to ensuring the Federal Government promotes evidence-based public health and public safety actions.

I thank the members of this caucus for their work to advance effective drug policy, and I look forward to

today's discussion and continuing our important work together.

[The prepared statement of Ms. LaBelle follows:]

The Chairman. Thank you very much, Director LaBelle.

Mr. Coderre?

STATEMENT OF TOM CODERRE, ACTING DEPUTY ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Mr. Coderre. Good afternoon, and thank you, Chairman Whitehouse and Co-Chair Grassley, for inviting me to testify today, as well as to the other members of the committee joining us this afternoon.

My name is Tom Coderre, and I am currently serving as the Acting Assistant Secretary for Mental Health and Substance Use at SAMHSA. I would like to start today by sharing a short story with you.

This story is about a man who came from a loving family and had many friends. He was involved in his community, enjoyed politics and policy, and was elected to the State Senate at 25 years old. By 30, he had risen in his career to become the executive director of a large nonprofit agency.

On the outside, everything about this man's life looked normal. Some would even say perfect. However, on the inside, he was tortured. So he turned first to alcohol and then to other drugs to cope with the stresses he was experiencing.

Underestimating the power of these substances and not understanding the neurological consequences of taking them, he quickly became addicted. And his life? Well, his life

began to unravel. He started to lose the things that were most important to him. When his family and friends tried to help, he resisted their help and pushed them away. This caused him to lose them.

He lost his job, and he lost his position in the Senate. His health deteriorated. He lost his apartment and became homeless. He lost his spirit. In the end, he lost everything, even his desire to live.

This man's life, which at one time was so full of hope, became hopeless. I know this story well because it is my story.

But I was able to get the help that I needed, and today, I am a person in long-term recovery, which, for me, means I haven't used alcohol or drugs since May 15th of 2003. During these 18 years in recovery, my life has vastly improved. Being in recovery has enabled me not just to create a better life for myself, but also to create a better life for my family and, ultimately, my entire community.

With help, people can and do recover from substance use disorders. I am here today not only representing SAMHSA, but also the 22 million Americans who have resolved their issues with substances. Unfortunately, too many people do not have stories as hopeful as mine, and the COVID-19 pandemic has exacerbated the already crisis-level

drug overdose epidemic, presenting new challenges for SAMHSA.

Last week, the CDC, as you have already mentioned, released devastating data, revealing more than 93,000 people died from drug overdoses in 2020, a nearly 30 percent increase from the previous year. Even one life lost is too many, and SAMHSA is committed to doing all we can to turn that data around. To do so, SAMHSA is focused on each aspect of the care continuum -- prevention, intervention, treatment, of course, and recovery support.

For example, this past April, SAMHSA expanded treatment services nationwide when HHS Secretary Becerra issued buprenorphine practice guidelines, removing the barrier for providers to treat more patients with buprenorphine. We are proud to report that we have already seen this change increase the number of providers prescribing medication-assisted treatment. More Americans are now able to access evidence-based treatment, allowing them to move into recovery from an opioid use disorder.

SAMHSA has also focused on harm reduction as the first prevention intervention for people who use drugs. Harm reduction programs promote the widespread dissemination and implementation of evidence-based strategies such as syringe service programs aimed at reducing negative consequences associated with drug use. In particular, the distribution

of naloxone and ensuring individuals have access to lifesaving medication is a large focus of SAMHSA's State opioid response grants. Grantees report using naloxone to reverse nearly 200,000 overdoses.

We have lost so much over the COVID-19 pandemic, but tragedy has also forced innovation. The use of telehealth is increasing access to screening, assessment, treatment, crisis support, medication management, and recovery support across diverse behavioral health and primary care settings. SAMHSA looks forward to working with Congress to ensuring access to care is not lost as we move beyond the pandemic.

Thank you for the opportunity to appear before you today and for your attention to this important topic. I welcome any questions that the caucus members might have.

[The prepared statement of Mr. Coderre follows:]

The Chairman. Thank you. For Senators on the panel, Tom Coderre used to be Senator Tom Coderre in the Rhode Island Senate, and then the trajectory that he described took place and crash-dived to rock bottom. And now here he is in front of us in the United States Senate on this panel. So it is a powerful story of what recovery can mean.

Mr. Coderre. Humbling experience, Senator. Thank you.

The Chairman. Yes. Delighted not to have to experience it, but delighted that you came through so well.

Dr. Volkow, please proceed with your testimony. Welcome to you.

[Pause.]

Dr. Volkow. It is not working. Yes.

STATEMENT OF NORA VOLKOW, DIRECTOR,
NATIONAL INSTITUTE ON DRUG ABUSE

Dr. Volkow. Good afternoon, everyone. Chairman Whitehouse, Co-Chairman Grassley, members of the caucus, thanks very much for giving me the opportunity to speak to you.

I represent the component of agencies that does science, and my task here is to try to illuminate some of the solutions that science can bring to the opioid crisis.

You just heard the overdose deaths have been at its highest in the United States from what we have ever been recorded in 2020, and it seems that illicit fentanyls and analogues are presumably mostly responsible for those deaths, though cocaine and methamphetamine and the combination of these drugs is increasingly of greater and greater concern.

We have medications for treating opioid use disorder, and but certainly, there are more options that are sorely needed. With support from the Congress and the funds for the Hill initiative, NIDA research has led to FDA authorization of 16 investigational new drug applications for opioid addiction treatment, including vaccines to prevent opioids from entering the brain.

NIDA is also prioritizing development of treatments for stimulant use disorders, for which there are currently

no FDA-approved medications. We are encouraged by recent research findings that a combination of two FDA-approved drugs for other indications, bupropion and naltrexone, reduce methamphetamine craving and use in patients with moderate to severe disorders, and also by positive safety findings from antibodies that could help reverse methamphetamine overdoses.

Just as important, it is critical to support implementation research to help expand access to treatments that work, for only a fraction of people who need them receive them. Stigma, inadequate reimbursement, poor treatment compliance, policy barriers that limit access to these medications all contribute to this deficit.

New models of care have already started to make treatments more accessible and sustainable. For example, NIDA's Clinical Trials Network has done studies showing that opioid use disorders can be successfully treated in emergency departments, as well as other healthcare settings. NIDA's Justice Community Opioid Innovation Network is testing ways to expand addiction treatment for people in justice settings. And through the Healing Communities Study, we are investigating how the delivery of a battery of evidence-based prevention and treatment approaches, in partnership with multiple agencies, can be used to reduce opioid overdoses by -- and deaths by

40 percent in some of the hardest-hit communities in our country.

NIDA has also helped biotech startups develop innovative technologies that translate addiction science into healthcare and so consumer products. One such example is the development of the first-ever FDA-approved digital medicine, which puts psychosocial treatment for substance use disorders right into the hands of anyone with a smartphone.

Other innovative approaches include digital applications for overdose detection and automatic activation of emergency support, applications to monitor patient medication compliance, and applications to connect individuals to treatment and support groups. Research has also shown that people who use drugs are more vulnerable to getting infected with COVID and, if they get infected, are at greater risk for death. This is especially true for black people, a population that has already been disproportionately affected by the pandemic.

NIDA is supporting more than 100 studies at the intersection of COVID-19 and substance use, including research to examine how healthcare policy changes implemented during the pandemic, such as take-home methadone and increased use of telehealth, affect the outcomes. We are also capitalizing on two large ongoing

longitudinal studies, one in adolescents, the Adolescent Brain Cognitive Development Study, and one in infants, the Healthy Brain and Child Development Study, to examine the impact of COVID on brain and behavioral development.

These studies will also inform our understanding of what is normal child development from prenatal period to young adulthood and how it is affected by biological and environmental factors such as exposure to drugs during pregnancy, during development, being infected with COVID, and pandemic-related stressors. Ultimately, this information will be crucial for tailoring prevention interventions that are necessary to address the crisis.

And finally, it is the close collaboration with all of us that is going to enable us to address the epidemic. I thank you very much for inviting me to be part of this hearing.

[The prepared statement of Dr. Volkow follows:]

The Chairman. Thank you very much, Dr. Volkow.

The order of questioning will be Senator Grassley, Senator Hassan, Senator Cornyn, Senator Blumenthal, Senator Whitehouse, and then we will turn to the second panel.

Senator Grassley. I thank you, Mr. Chairman.

To Director LaBelle, ONDC released an outline this year about policy goals. I feel a number of important issues were mostly absent. So, at your invitation, I sent a letter outlining what I thought ought to have priority. This includes permanently scheduling fentanyl-related substances, dealing with an increased methamphetamine threat, and lastly addressing polydrug trafficking.

Permanently controlling fentanyl-related substances is a priority for me. Currently, they are temporarily placed in Schedule I. That authority ends October. ONDCP is leading the effort to draft legislation to control these drugs. My staff has been in contact with yours on steps forward, but very little information has been shared with Congress, and I am worried that your proposed solution won't permanently schedule these drugs.

Will your legislative proposal permanently schedule fentanyl-related substances?

Ms. LaBelle. Thank you, Senator, for that question. And also thank you very much for your letter, which consisted of many of the items that we are going to cover

in our strategy, which will be released next year.

As to fentanyl scheduling, as you mentioned, we have talked to your staff about this. My staff is working diligently with DOJ, the Drug Enforcement Administration, and HHS to make sure that what we send to the Hill meets the needs of the Hill, but also that it checks all the boxes. So we are doing diligent work right now.

I can't tell you all the details of it because I can't get ahead of the process that we are going through. But I can assure you that we will meet our deadline, and we will work diligently on this matter to make sure what we send to the Hill is a good product.

Senator Grassley. I just don't have a handle on why Congress is so reluctant to be very strong on this issue. But -- and I say that considering how very dangerous fentanyl is. I wish somebody would explain to me that. I am not asking you to.

So last month, you testified before the Senate Judiciary Committee that you were working to present Congress with a legislative proposal sometime this fall. Is that still the case, and do you have any updates on that?

Ms. LaBelle. Yes, sir. We will have legislation to the Hill prior to the expiration of the Fentanyl Scheduling Act, and so we are -- the update is that we are -- I

actually think we are making good progress, and we are going to have something on time to the Hill.

Senator Grassley. In addition to fentanyl, the National Drug Control Strategy must address methamphetamine. That is my second point. According to the CDC, more than almost 17,000 people overdosed from meth 2019, which is a 30 percent increase from 2018. This rate keeps going up.

Senator Feinstein and I introduced a bill that prioritizes stopping this crisis by declaring methamphetamine an emergency drug threat. This bill would also require ONDCP to develop and implement a national plan on meth addiction. So, Director LaBelle, if you agree that methamphetamine is an emerging threat, how does ONDCP plan to address the surge in supply and abuse of meth?

Ms. LaBelle. Thank you, Senator.

As you said, we are seeing methamphetamine crop up in places that had never seen it before. Certainly in the Northeast, we are seeing more in New Hampshire, and methamphetamine has been a direct threat in the State of Iowa for many years. So what we are doing, we are working on a plan. It will be rolled out.

We want to make sure that it includes the public health and the public safety efforts that are important to this. As you mentioned, the meth that we are seeing right

now is not what we used to see. It is coming from Mexico, mostly liquid meth. And so there are law enforcement efforts that need to be undertaken, and that is why our High Intensity Drug Trafficking Areas program, we asked for increased funding for them in the next year so that they can continue to disrupt drug trafficking networks and go after illicit methamphetamine.

Senator Grassley. Polydrug use and trafficking also needs to be central to the strategy. Nowadays, an overdose isn't due to only one drug. As you know, users are often addicted to multiple drugs, and traffickers adapt and sell any drug that makes a dollar. This problem is exacerbated by the influx of constant threat of fentanyl analogues.

So to you again, how is ONDCP addressing polysubstance trafficking and its use, and are you leveraging programs like the Drug-Free Communities and High Intensity Drug Trafficking Areas to deal with the problem? And this will have to be my last question.

Ms. LaBelle. Sure. Thank you, Senator.

So the Drug-Free Communities program and the HIDTA program are two of our programs that ONDCP oversees. We not only kept those programs in the Office of National Drug Control Policy, which is where they belong, but they also -- we requested an increase in those programs.

We strongly support both of them. They show the two

sides, two sides of this issue, which is drug prevention efforts as well as going after supply reduction efforts. The HIDTA program, what is so great about it is that it is a force multiplier for -- it uses the strength of Federal dollars and is matched with State and local efforts to go after drug trafficking networks.

Senator Grassley. Thank you. Thank you, Mr. Chairman.

The Chairman. Thank you, Senator Grassley. Senator Hassan?

Senator Hassan. Well, thank you, Chairman Whitehouse and Co-Chairman Grassley, for holding this hearing. And to our witnesses, thank you for your service and your work. It is really critically important, and as you know, my State of New Hampshire has been hit hard, particularly by fentanyl and now meth, for years now. And so I really appreciate your work, but boy, do we have a lot of work still to do.

Director LaBelle, as Co-Chairman Grassley mentioned, we have seen a disturbing increase in the supply of fentanyl analogues, and we have heard, my colleagues and I, from law enforcement that tracking and regulating various analogues can feel like just an unending game of whack-a-mole.

Director LaBelle, you and the co-chairman have now

mentioned that the current temporary prohibition on fentanyl analogues will expire on October 22nd. The co-chair, along with Senator Feinstein, Senator Ernst, and I recently introduced the bipartisan Stop Importation and Manufacturing of Synthetic Analogues Act to give the Justice Department the power to continue regulating these dangerous analogue drugs.

Now you have mentioned that you will have a strategy, a legislative strategy coming up to the Hill before the October 22nd date, but suppose there isn't action by that date, what steps can the administration take to help combat the trafficking of these extremely dangerous fentanyl analogues?

Ms. LaBelle. Thank you, Senator.

So we intend to have legislation to the Hill well before it is due. That is something that we are working on diligently. My staff meets weekly across the interagency. But, so I will answer hypothetically --

Senator Hassan. Yes.

Ms. LaBelle. -- if that doesn't occur --

Senator Hassan. Right.

Ms. LaBelle. -- you know, the Fentanyl Scheduling Act was -- there were many pieces put into place prior to this year in the last Congress that allow us to go after the financial aspect of fentanyl. So there are many things

that we are doing, including working with the global network of fentanyl trafficking.

So working with China about precursor chemicals, working with the Mexican government and our Drug Enforcement Administration partners to make sure that fentanyl is not coming over the border, that they are disrupting labs that are happening in Mexico. So it is a -- it is a complex issue --

Senator Hassan. Right.

Ms. LaBelle. -- that involves many more agencies than just ONDCP.

Senator Hassan. Okay. Well, thank you, and I look forward to continuing to work with you on that and share our legislation or answer any questions you have about it as well.

I have another question for you, Director. The COVID-19 pandemic changed traditional supply networks for many products, including deadly illicit drugs. During the pandemic, many purchasers started buying these drugs through dark web marketplaces. These networks anonymize transactions to help suppliers evade law enforcement.

I was encouraged to see that the Department of Justice, through the Joint Criminal Opioid and Darknet Enforcement, JCODE, disrupted a number of these dark web marketplaces last fall with Operation Disruptor. Director

LaBelle, how can ONDCP work with other Federal agencies, including DOJ, to help combat drug trafficking on the dark web?

Ms. LaBelle. Thank you, Senator.

So certainly anti-money laundering efforts are significant, and we really appreciate Congress' passing the Anti-Money Laundering Act. That really was a game-changer, and it also allows the Department of Treasury to go after illicit activities and to make sure that they are one step ahead of drug traffickers who are changing their tactics on a regular basis.

So what ONDCP does is a couple of things. One is that we -- because, again, everything we do requires coordination, this issue is very complex, and we need to bring DOJ as well as the Treasury Department in. So we have regular coordinating meetings to discuss tactics and strategy.

And the second thing we do is on the National Drug Control Budget, is to make sure that FinCEN and the Department of Treasury get the resources that they need to enforce these laws.

Senator Hassan. Thank you. One more question to Dr. Volkow and Mr. Coderre.

Earlier this year, I reintroduced bipartisan legislation with Senator Murkowski to expand access to

medication-assisted treatment for those struggling with opioid use disorder. Specifically, our legislation would eliminate completely the outdated waiver requirement that prevents many healthcare providers from prescribing medication-assisted treatment to their patients, the so-called X-waiver that you have all mentioned.

In April, the administration announced steps to remove some of the requirements that this waiver imposes, but there are additional steps that Congress must take to eliminate the remaining barriers.

So, Mr. Coderre, you have spoken in the past about the importance of medication-assisted treatment and barriers to access. How do we fully address these challenges and expand access to medication-assisted treatment? And I will just add what I am looking for here is the waiver that is in place still says that doctors can only treat 30 patients and also doesn't alleviate the training requirements for all practitioners. So how can we make progress here?

Mr. Coderre. Well, thanks so much for your question, Senator.

The spike we have seen, of course, in opioid and violent deaths during the COVID-19 pandemic requires us to do all we can to make treatment more accessible to patients, and Americans with chronic disease need and deserve readily available access to these lifesaving

medications. That is why in April, Secretary Becerra issued --

Senator Hassan. Right. And I am running out of time, and I understand what he did. It isn't everything we need to do, and I think there are still issues of stigma here that are interfering with our ability to integrate substance use disorder treatment into primary care. And that is what I am really looking for is not what you have already done. We all agree on what you have already done. What are we going to do next?

Mr. Coderre. Well, HHS is taking this to the statutory limit that we can, but we are looking forward to working with Congress to find other ways to take this further.

Senator Hassan. Okay. And could I have Dr. Volkow just speak about this for a second, please?

Dr. Volkow. Extremely important issue and -- can you hear me?

Senator Hassan. Yes.

Dr. Volkow. Yes. And it definitely will expand access to clinicians that can prescribe buprenorphine. However, we have to be mindful that it is not the only roadblock, and one of the issues that have become interfering with expansion is reimbursement and that we need to actually evaluate the extent to which this

restricted reimbursement for treatment of opioid use disorder is acting as a barrier and also access to buprenorphine.

We have models of care, which actually take advantage of pharmacies, of primary care physicians that have proven to be as effective as those on specialized treatment programs that are also much less costly. So expanding alternative ways of delivering the treatment is an incredible opportunity that we have.

Senator Hassan. Thank you very much, and thank you for your indulgence, Mr. Chair.

The Chairman. Of course, and now I turn to my partner in the Residential Substance Use Disorder Treatment Act and in our work on crisis intervention in law enforcement, Senator Cornyn.

Senator Cornyn. Thank you, Mr. Chairman.

Ms. LaBelle, you have talked about the coordination that your office does with I believe you said the Department of Justice and others. But what I want to reflect on here or ask you to reflect on here for a moment is the current humanitarian crisis we are experiencing at the Southern border. About a million encounters this year alone with migrants attempting to enter the United States, the vast majority of whom will not qualify for asylum or legal entry.

The Border Patrol tells me that because of the tactics used by the smugglers, they are flooding the border with unaccompanied children, for example. And out of compassion, of course, and necessity, we would want the Border Patrol to take care of those children while they are in our custody. But they also tell me that is when the cartels take advantage of the 40 percent or so of Border Patrol off of the front lines and then move drugs across the border.

So my question is, is ONDCP coordinating with the Department of Homeland Security and the Drug Enforcement Agency to react to the cartels' tactics along the Southern border?

Ms. LaBelle. Thank you, Senator.

So we certainly work very closely with Customs and Border Protection and DEA on the drug trafficking across the border. And it is not solely at the border. We also work with DEA and our other INL, State Department, on drug trafficking that occurs in Mexico, as well as the global network. So China, which is the source of other precursor chemicals, as well as India.

So it is a complex web that at the end, when it comes across the border, Customs and Border Protection does seize the drugs. And then, when it comes into the United States, our High Intensity Drug Trafficking Areas program -- there

are many across the Southwest border -- they also disrupt drug trafficking. So we work very closely across the interagency to make sure that there is this web and this force multiplier so we can enforce the drug trafficking laws.

Senator Cornyn. Well, clearly, we are losing that fight at the border in particular, which would be an ideal place to interdict drugs coming from anywhere around the world. But the fact is that the vast majority of them come from Mexico and south of Mexico, Central and South America. But last year alone, there were 8,500 pounds of fentanyl seized by Customs and Border Protection. It is a huge increase in volume over previous years.

I just -- I wish the administration would look at the business models of the cartels, which include smuggling not only people, but also drugs at the same time. And it seems to me that, again, we are losing that battle.

Ms. LaBelle, let me ask you about the bill that Senator Whitehouse -- and Mr. Coderre, I would like to get your comments as well. We have introduced a bill called the Residential Substance Abuse Disorder Treatment Act of 2021. We have worked together on prison reform and other criminal justice reforms. But it occurs to both of us -- I will let Senator Whitehouse speak for himself. But I think it occurs to both of us that we need to have follow-on

treatment for people who are released from prison, 85 percent of whom will be somehow associated -- either they committed a drug-related crime or they are addicted or using drugs.

And so if they go back to the same neighborhood, the same associates, and the same environment that contributed to them going to prison, talk to me about the importance of this follow-on treatment through the Residential Substance Abuse Disorder Treatment Act and why that is so important to getting people off of addictive drugs.

Ms. LaBelle. Thank you, Senator.

As you mentioned, when people leave incarceration, they not only return to use, they are also at heightened, much heightened risk for overdose, which is why we are also working in our drug strategy to keep people away from incarceration; if they are incarcerated, to make sure they get the treatment; and then upon leaving incarceration, they have a warm handoff to treatment. They may get naloxone, but they get the services they need so they don't return to use.

Senator Cornyn. Dr. Volkow, let me ask you in my remaining time, earlier this year, Senator Feinstein and I, when we were the co-chairs of this caucus, issued a report on marijuana usage and public health and calling for more research into the impact of particularly high

concentrations of THC that are used in vaping and the like.

And because of the unregulated nature of marijuana -- 37 States and D.C. have legalized medical use, 18 States along with D.C. have legalized recreational use -- we simply, I don't believe, have any handle on the concentrations and the impact of these high concentrations of THC on people with perhaps mental health challenges or on the developing juvenile brain.

Do you agree that it is important before we legalize marijuana at the Federal level, should Congress decide to do so, that we get this kind of research performed so we actually know what we are doing?

Dr. Volkow. I think it is 100 percent necessary that we actually have an understanding of the consequences of legalizing marijuana are going to have into the children and adolescent brain and what are the consequences to health to adults. So if they choose to take marijuana, they know what they are taking, just like with cigarettes. The moment that it was clear that they were producing cancer, that changed the choices of people. We owe it to the public to actually provide with that information.

And we do know already that high-content THC marijuana produces significantly higher risk of psychosis. It is also associated with severe medical adverse effects like hyperemesis syndrome and has been also associated with

strokes and pulmonary disorders.

So marijuana is not a benign drug. Some people are more vulnerable to its adverse effects than others.

Senator Cornyn. Thank you.

The Chairman. And I will associate myself with those same concerns.

Ms. Volkow, because we were on this subject, let me just follow up with you because you have pointed out that incarcerated individuals are at a heightened risk of drug overdose following their release. We had a very successful program in Rhode Island that began medication-assisted and support pre-release and then persisted post release to continue the support for the individual, and we saw a dramatic reduction in overdose deaths. I want to say by two-thirds.

And I think it was that number that really drove the downward turn that Rhode Island achieved in overdose deaths before COVID. Any further advice to us on dealing with that cohort? Do you support our bill? Should we modify it in any way?

Dr. Volkow. I think that it was a brilliant move on Rhode Island that serves actually as an example of what can be achieved by providing treatment to people when they leave the prisons or jail systems. The results that you all obtained were basically speaking for themselves, and we

have taken that study to actually get other States to evaluate similar programs through a network that we are working with in justice settings to determine how to optimally bring treatment either during incarceration or at the moment of release.

And importantly, as said before, providing a bridge that will allow those individuals to remain in treatment once they get back into the community. And many of those actions were inspired by the remarkable success that Rhode Island obtained.

The Chairman. Thank you. Mr. Coderre, one of the breakthroughs, if you will, of the Comprehensive Addiction and Recovery Act was its focus on recovery. We have spent a lot of money on prevention. We spent a lot of money on law enforcement. We spent a fair amount of money on treatment and intervention. But for the first time, we have started putting some effort into the recovery piece of the population.

What did we learn from that experience, and what should we be doing going forward on the recovery part?

Mr. Coderre. Well, thank you so much for that question, Mr. Chairman, and for your leadership, of course. Your landmark legislation, the Comprehensive Addiction and Recovery Act, CARA, has certainly set the stage for what President Biden is proposing in his Fiscal Year 2022

budget, which is a 10 percent set-aside for recovery support services.

Recovery support programs provide community-level resources for people with substance use disorder beyond primary prevention and clinical treatment. Currently, there are no dedicated resources to fund these community recovery support programs, and as a result, there is only about 150 of them throughout the country.

This funding, if enacted, of course, would provide a sustainable source of funding directly to community organizations to support the development of community-level recovery infrastructure and would be available for a wide variety of recovery support programs like Recovery Community Centers.

The Chairman. So part of the problem we had that with recovery never having been funded before, there was not much of a record of success or failure, not much of a record of best practices. When an area of Federal spending and intervention has reached a certain amount of maturity, you learn a lot and you know a lot, and you are able to spend the money wisely.

What lessons should we undertake with respect to recovery? What have we learned in this first go since CARA, and what should we be on the lookout for as we invest this additional 10 percent?

Mr. Coderre. Well, the biggest thing we learned, Senator, is that recovery is possible for everybody because of CARA. And this builds upon 20 years of grant programs that SAMHSA started with the Recovery Community Services program, then Building Communities of Recovery, which is in CARA, our Targeted Capacity Expansion Peer-to-Peer programs. What we have learned is that this is a chronic condition.

The Chairman. So keep at it?

Mr. Coderre. We have to keep at it, and we have to support people for the long term in order for them not to fall back into active addiction.

The Chairman. And Ms. LaBelle, Senator Grassley and I, after a long battle that actually ended up in another committee, in the Banking Committee, ended up getting our beneficial ownership legislation passed, which provides a lot more transparency into shell corporations and so forth. President Biden has announced a kleptocracy summit internationally to try to clean up some of the pockets of the dark economy around the world, where usually things that are not good for America ferment.

And I want to flag for you the need to address illicit financial networks. The narcotics business is a business, and that means that your production and your revenues are in balance. But if you look at the effort that we put into

the production side, for a lot of pretty good reasons most of our enforcement effort has been on that side.

But there is a big financial side of this international narco-business. And with these new tools and with this new focus, I think we can do a lot more to address that side of it, and I hope that you will put more focus on that through the national policy as we move forward, now that these new tools are in your hand. And I would like to give you the chance to respond to that.

Ms. LaBelle. Thank you, Senator.

As you mentioned, there are lots of activities that have happened since the Anti-Money Laundering Act was put into place, which was really a game-changer. And what we want to make sure is that the Treasury Department, FinCEN, OFAC, has the resources that they need to implement and execute on these laws.

As you said, these are complicated global networks of cash, and it requires more than just ONDCP. It requires the Treasury Department, the Department of Justice, FBI, working together to address those issues, and we are going -- we plan to address this in the National Drug Control Strategy.

The Chairman. Good. Well, I look forward to working with you on strengthening that side now that we have these new tools.

Unless anybody has an urgent final question, I will excuse this panel, and we will suspend for a few minutes while we call the second panel together. And may I thank you all for your service in this area and for your testimony here before this committee today. We look forward to working with you. We have a lot of work ahead and, as you saw, a lot of bipartisan, good faith interest. So I think we can big things.

Thank you.

Mr. Coderre. Thank you, Mr. Chairman.

Senator Cornyn. Mr. Chairman, while we are changing out the panel, I just thought the -- thought you might like to hear these statistics. And 93,000 Americans died last year of drug overdoses. Twenty thousand Americans died as a result of a gun incident, plus 24,000 more who died as a result of suicide.

So adding those two figures together, that is less than half of the number of people who died by drug overdoses. It strikes me that we are treating those two sort of in a disparate way. In other words, undervaluing the importance of addressing the overdoses. But I know that is your focus and the caucus' focus, and I thank you for that.

The Chairman. And I thank you for that comment.

Let me first introduce our -- let me give them a

second to get in their seats.

So, first, we have Steve Gurdak, a group manager for the Washington/Baltimore HIDTA Northern Virginia Financial Initiative and a member of George Mason University faculty. The Northern Virginia Financial Initiative serves as a model suspicious activity report review team. Mr. Gurdak has over 30 years of law enforcement experience and is a certified anti-money laundering specialist. So he is my kind of guy, and I appreciate very much his testimony here today as we look more at the financial side of this industry.

Next we have Keith Humphreys, who is the Esther Ting Memorial Professor in the Department of Psychiatry and Behavioral Sciences at Stanford University. I hope you didn't come all this way just for this?

Dr. Humphreys. I also had the great pleasure to go to a wedding in your home State.

The Chairman. Ah, wonderful. We have very good locations for weddings in my home State.

He is also a senior research career scientist at the VA Health Services Research Center in Palo Alto and an honorary professor of psychiatry at the Institute of Psychiatry of King's College, London. So he is a very impressive witness as well. We are delighted that he should be here.

And finally, Nicole Alexander-Scott has been the Director of the Rhode Island Department of Health since April 2015. She comes to us electronically from Rhode Island. She is board certified in pediatrics, internal medicine, pediatric infectious diseases, and adult infectious diseases, and she helped guide Rhode Island through the COVID epidemic in really exemplary fashion to the point where we are one of the highest-performing States in the country right now with very high double vaccination rates and schools, businesses, and summer life all reopening.

So I am delighted that she should be here as well.

And perhaps I should lead with Dr. Alexander-Scott since we have her signed in, and I don't want to have the technology here foul up.

So, Dr. Alexander-Scott, please proceed with your testimony.

STATEMENT OF NICOLE ALEXANDER-SCOTT, DIRECTOR,
RHODE ISLAND DEPARTMENT OF HEALTH

Dr. Alexander-Scott. Good afternoon. Thank you so much. It is such an honor to be able to join you. And thank you for all the support that you have been providing to States like Rhode Island as we have continued to battle the public health crisis of substance use disorder.

Over the last 2 years, there have been many, many stories of recovery and hope in Rhode Island that are true inspirations, just like Tom Coderre, to every one of us in this field. We cherish those stories. But the truth is that during this time, there have also been many, many tragic stories of heartbreak and loss, some of which can be preventable.

After working to bring about moderate decreases in our overdose deaths from 2016 to 2019, we started seeing an increase again in 2020. In 2020, overdose deaths increased by 25 percent over what we saw in 2019, making it the first year on record.

And the data in 2021 are not encouraging in the least. At this point, fentanyl and counterfeit pills in cocaine and in other forms is driving the epidemic in our State. Roughly three out of every four overdose deaths in Rhode Island involve fentanyl. There is no doubt that the stressors and isolation of the COVID-19 pandemic have

contributed to the challenges we are experiencing now, but our numbers started climbing in Rhode Island before we had our first patient with COVID-19.

Under the leadership of the Governor of Rhode Island, we have an Overdose Prevention and Intervention Task Force. This is a diverse, cross-sector group that engages every community throughout the State. We are a small State, and we take pride in our direct engagement and "all hands on deck" interdisciplinary approach. The task force is tackling the overdose epidemic head on, as well as addressing the many underlying issues that are fueling the crisis.

We often refer to these as the socioeconomic and environmental determinants of health. Principal among all of them are inequity and discrimination. Every intervention the group the considers is evaluated through a race equity lens. In this regard, we are in strong support of the current priorities of the National Office of Drug Control Policy.

The major focus areas of Rhode Island's Overdose Prevention and Intervention Task Force are prevention, treatment, harm reduction, recovery, and family and intergenerational addiction issues. I am giving you this background on our experience and approach in Rhode Island because it really illustrates why we so strongly support

these three specific pieces of legislation before Congress.

Telehealth has been a critical tool for Rhode Islanders during the COVID-19 pandemic, especially for people already experiencing barriers to care. By expanding telehealth availability and flexibility, the Telehealth Response for E-prescribing Addiction Therapy Services Act would be a major step forward in our work to make treatment as accessible as possible for every Rhode Islander who needs it, regardless of their circumstances.

The Comprehensive Addiction and Recovery Act 3.0 gets at those underlying socioeconomic and environmental determinants of health by committing funds to safe and certified recovery housing, pre-arrest aversion programs equitably conducted, and efforts targeting our veterans. So much of what is in CARA mirrors our commitment to going to where people are instead of waiting for them to come to us. That means mobile treatments, warm handoffs, and focusing the public health response in the community.

By enhancing public health surveillance of fentanyl-related substances and improving efforts to detect and share data on fentanyl, the Support, Treatment, and Overdose Prevention of Fentanyl Act gets directly at the root of the crisis in Rhode Island. And like the other pieces of legislation I referenced, this act similarly ensures that we are investing in treatment and prevention.

I want to wrap up by saying that we are doing everything we can to turn the tide in Rhode Island, but we cannot do it alone. Your support has been tremendous. I only ask you to continue that support and continue investing in the community-focused public health interventions that we know prevent overdoses and save lives.

Thank you very much.

[The prepared statement of Dr. Alexander-Scott follows:]

The Chairman. Thank you, Dr. Alexander-Scott. I appreciate it. It is good to have you with us even electronically.

And I turn now to Mr. Gurdak.

STATEMENT OF STEVE GURDAK, GROUP MANAGER, WASHINGTON/BALTIMORE HIGH INTENSITY DRUG TRAFFICKING AREAS (HIDTA) NORTHERN VIRGINIA FINANCIAL INITIATIVE

Mr. Gurdak. Chairman Whitehouse, Ranking Member Grassley, and other distinguished members of the Senate Caucus, I am honored to be here before you to give you my assessment on the emerging drug threats and money laundering techniques used by drug traffickers and money launderers, including how those threats and techniques have changed as a result of the COVID-19 pandemic.

My position as an initiative supervisor for the Washington/Baltimore HIDTA, High Trafficking Area Program, for over the last 12 years has actually put me in a fairly unique position to have met, associated, consulted, and hung around with some of the best anti-money laundering specialists there are in both the public and private sector.

A number of these experts have appeared before congressional caucuses and committees just like this one. Some had helped to even craft the Bank Secrecy Act and its recent amendments through the Anti-Money Laundering Act of 2020.

Officially, I may only be able to speak for my Washington/Baltimore HIDTA initiative, known as the Northern Virginia Financial Initiative, or NVFI. The NVFI,

however, has created a unique network and reputation known far and wide for our innovative work in anti-money laundering and narcotics investigations based on that. It was created through tests -- through an idea of testing the system that the Bank Secrecy Act had put in place. The logistics, innovation, and latitude provided by the Washington/Baltimore HIDTA for us to do that was incredible.

Additionally, we have benefitted from an incredible support from the U.S. Attorney's Office for the Eastern District of Virginia. Any statistical data I am presenting is primarily derived from the Washington/Baltimore HIDTA Threat Assessment Report for 2022, and the rest is based on my contact knowledge and just reaching out and sharing this information with many of those experts in that field that I have the privilege to know.

I will skim over my remarks pretty much on some of the -- I talk to drug notice in my written statement and the fact that I don't need to convince anybody here of the deadliness that fentanyl is to this country right now and the threat assessment it poses. Both the enforcement sector and the treatment sector will agree with that. It is ranked number one and is now considered, even at ranked number one is now considered kind of understating the idea because fentanyl now is being used as a cutting agent for

almost everything, to include marijuana. And it has, like any other drug, has all the violence associated with it.

The other thing I will mention is the fact that when I was talking to some of the experts is this little kind of forgotten threat that marijuana trafficking seems to be -- the violence threat marijuana trafficking seems to be still creating out there, despite the trend toward legalization and decriminalization. The Washington/Baltimore HIDTA report reported a large increase, as well as the conversation I had, in violence associated with marijuana trafficking, although police and law enforcement are not enforcing it anywhere near the capacity they were before.

It may be initially surprising, but it is not so much if you think of the fact that you have got a lot of novice people entering the market. So you have more dealers, and they are not being confronted by law enforcement as they are being threatened by their competition.

The threat assessment report from Washington/Baltimore HIDTA showed easy availability of all drugs and maybe some slight increases. There were concerns about some of the more -- these more designer drugs out there and their usage, and I can assure you with these designer drugs, a lot of that usage was actually tainted by the addition of fentanyl in the report.

But what I want to get to before anything else is on

the money side of the house. So the money talks out there, and for this purposes, I want to be able to report to you that COVID-19 actually created an actually incentive for us or it actually create a new, unique opportunity to redefine what normal looked like.

With fentanyl out there -- excuse me, with the COVID restrictions out there, a lot of the money laundering techniques had to change. For example, businesses that were pouring a lot of cash through them prior to the epidemic would have a hard time explaining how that cash went through the system. In that sense, to keep my remarks brief, despite all the emerging threats of cybercurrencies and those items out there, cash is -- I have to report to you cash is still king.

The FinCEN reports, various newspaper articles, and everything I have stated in my remarks show that cash is still the number one out there, with a 44 percent increase of the transmissions below $10,000 reporting requirement. I would like to report to you that the Bank Secrecy Act, to include the partnership with the financial organizations, does provide us with a unique opportunity to better track these things. What we do need is more people with knowledge in the anti-money laundering world to attack this problem from that aspect.

[The prepared statement of Mr. Gurdak follows:]

The Chairman. Thank you, Mr. Gurdak.

And we close with the very distinguished Dr. Humphreys. Thank you, sir, for being here and for closing our official testimony.

STATEMENT OF KEITH HUMPHREYS, ESTHER TING MEMORIAL PROFESSOR, STANFORD UNIVERSITY

Dr. Humphreys. Thank you, Chairman Whitehouse, Co-Chairman Grassley, and distinguished members of the caucus. I am honored to speak with you today.

My analysis of the opioid crisis reflects my decades of work as an addiction researcher at Stanford University, as well as my service as a White House drug policy adviser in the administrations of George W. Bush and Barack Obama.

I am going to focus my remarks on three key issues -- tracking the epidemic, preventing it from spreading to other countries, and facing up to the new world of synthetic drugs.

So, first, tracking the epidemic. One of the signs of our Government's productive response to COVID is any of us could pick up our phone right now and find out how many people got COVID and how many died of COVID in any State in our country in the last 24 hours. Contrast that to the fact that opioid overdose data gets to Washington 6 to 12 months after the fact.

Our current survey tools do not provide credible estimates of how many people use heroin or fentanyl or are addicted to these drugs. As a result, we cannot design policy based on the status of the epidemic because we don't know what it is.

It would, therefore, be a wise investment to restore lost public capacities in this area, like the defunded Arrestee Drug Abuse Monitoring Program or the significant data analytic capacity that ONDCP used to have but doesn't have so much anymore. We also could build a national infrastructure using wastewater technology to monitor for new and emerging drug threats.

Point two, we need to stop the opioid epidemic from spreading beyond North America. COVID has taught us the painful lesson that one country's health problems can become the world's problems. That could happen with the opioid crisis.

Federal officials, including members of this very caucus, exposed the role in the opioid crisis of people like the Sackler family and their company, Purdue Pharma. Fines have been levied, along with constraints on various fraudulent practices that were used to promote opioid drugs like OxyContin in the United States.

However, like the tobacco industry before them, some opioid manufacturers have now shifted to expanding opioid prescribing abroad. For example, investigative journalists have documented that the Sackler family is expanding opioid markets through a mirror company of Purdue Pharma known as Mundipharma using the same tactics employed in the U.S.

The Los Angeles Times has reported that among the

countries where Mundipharma is attempting to promote OxyContin are Brazil, Colombia, Egypt, Mexico, and the Philippines. Investigative journalists at the Guardian document Mundipharma is one of the many Western companies promoting opioids in India using tactics pioneered in North America. Without intervention, those countries will suffer as we have suffered.

We have a moral responsibility to people around the world to not be satisfied by simply bringing our own opioid problems under control. I urge the caucus to investigate the international activities of U.S. opioid manufacturers, to warn nations around the world against their conduct, and to do everything possible to ensure that constraints on fraudulent and corrupt practices apply not only in our own country, but in other countries where these corporations are active.

Point three, and finally, we need to rethink drug control in light of the increasing prevalence of synthetic drugs. The increasing availability of fentanyl and of methamphetamine are only the two most prominent demonstrations that global illicit drug markets are increasingly able to produce large volumes of drugs whose production is not dependent on agriculture.

Traffickers reap enormous financial advantages from not having to grow drug-producing plants in politically

volatile regions or secure peasant labor to farm it. Eliminating the risks of drought, crop blight, and bulk shipment interdiction are also attractive to drug traffickers. These economic advantages of synthetic drugs, coupled with the Internet spreading the needed information and technology to synthesize drugs and to facilitate their covert purchase, raises questions about the basic assumptions of global drug control strategy.

As drug production moves increasingly from something that depends on agriculture to something that any chemist can accomplish in their sink, some longstanding policies and programs have diminishing returns, like, for example, trying to reduce drug crops in poor countries. Transnational drug trafficking itself may also diminish as domestic retail sellers can make their own drugs rather than rely on large criminal organizations to import them in bulk. This has substantial implications for where domestic law enforcement and international border control agencies direct their energies.

Dealing with this new world is going to take sustained thought, study, and discussion. If your caucus wishes to use its convening power to lead that process, I know I am only one of many drug policy analysts who would be pleased to assist you in formulating an approach to drug policy that measures up to the challenges posed by widespread

synthetic drug production.

Thank you very much.

[The prepared statement of Dr. Humphreys follows:]

The Chairman. Thanks, Dr. Humphreys.

The order of questioning will be Senator Grassley, Senator Cornyn, Senator Whitehouse, unless others arrive.

Senator Grassley. Thank you.

Mr. Gurdak, you mentioned in your testimony that COVID-19 changed how drug traffickers do business. Drugs are increasingly exchanged online and not on the street corner. Traffickers use the Internet and even door-to-door food delivery services to spread their supply. Obviously, drug dealers are adapting, and so should we.

How can the Federal Government's approach to combating drug trafficking adapt to be more nimble and proactive, or have we already adapted?

Mr. Gurdak. From the drug trafficking side, we have adapted okay. I still -- you know, I come here with firm belief that we have very underused the intelligence information that we can get through the Bank Secrecy Act through things like SARs and the FinCEN information we have out there, just exposing more of law enforcement to the ability to attack these organizations from the money level instead of sometimes from the industry trafficking level.

Senator Grassley. To you also, how do High Intensity Drug Trafficking Area programs respond to emerging and evolving synthetic drugs like fentanyl analogues and methamphetamine?

Mr. Gurdak. It seems like out there, and I think if you look in my testimony -- and in fact, when I was listening to some previous testimonies from this, because this is a very new experience for me, somebody mentioned the fact that, you know, criminals are very agnostic about their crimes. We are seeing over and over again there is no particular drug anybody sells anymore almost exclusively. So we are seeing synthetics as well as the other stuff all mixed together.

So I don't know if you can separate the two because it seems like what our experiences are seeing that, you know, they will deal whatever they can find and whatever they can get a hold of, and it doesn't really matter to try to like target one thing versus the other because they are all over the map with the drugs they will sell and deal with.

Senator Grassley. Lastly, also to you, what common trends have you observed over the past year as it pertains to drug supply and abuse, and what successful law enforcement efforts should mimic post pandemic?

Mr. Gurdak. Well, I said like in my remarks, I am a big believer, one of the people out there waving the flag that we are vastly underusing the resources being presented to us by the Bank Secrecy Act and getting that information or the idea of following the money brought down from the macro level of the international trafficking to the micro

level of the local drug dealer in our area.

And even better, identify that even from the overdose thing. Not necessarily charging people with money laundering at lower levels, but using that as a key form of evidence to try to go after some of the other dealers and preventing some of these overdoses.

Senator Grassley. Dr. Humphreys, you have stated that we ought to rethink our drug policy in light of increasing prevalence of synthetic drugs. Obviously, I agree with that point. Synthetic drugs pose an enormous risk because they can be easily manufactured, imported, and trafficked.

I am working on bipartisan legislation to proactively control synthetics. Right now, we are playing a deadly game of whack-a-mole as law enforcement tries to keep pace with drug trafficking organizations, and that ought to stop. So my only question to you is how can the Federal Government proactively detect and stop the flood of synthetic drugs, and what strategy should this caucus consider in approaching the unique challenges of synthetic drug use?

Dr. Humphreys. So it is a big question, and I would not claim to have all the answers to it. Certainly we have had success with synthetics with precursor chemical interdiction. There were successes with methamphetamine that could be exploited and also could be relevant with

fentanyl.

There also might be things to do over the Internet. For example, creating spoof sites that do denial of service attacks to Internet-based sellers or setting up fake sites that block off people's credit cards or block off cryptocurrency transactions. But it is going to take a lot of thought and a lot of work, and I would be very pleased to work with you and your staff on that in the years ahead, sir.

Senator Grassley. Thank you, and I will yield back my time.

The Chairman. Thank you very much, Senator Grassley. And include me in that conversation.

Dr. Humphreys. Yes, sir.

The Chairman. Let me start with Dr. Alexander-Scott. Part of the traumatic effect of COVID was that it required breakthroughs in certain areas, and one breakthrough was in the area of telehealth. And in one particular area in telehealth, we got emergency regulations that allowed providers to prescribe medication-assisted treatment by audio and video after an initial audio-only in some cases -- after an initial in-person or visual appointment and then to go ahead and bill Medicare.

That has been, I think, very successful. And Dr. Alexander-Scott, if I could ask you whether you think

that should be continued? If there is a temporary --

Dr. Alexander-Scott. Thank you, Senator.

The Chairman. If there is a temporary program right now, should we make it permanent and why?

Dr. Alexander-Scott. We absolutely should make it permanent. Telehealth provides another venue. When we really look at the focus that we have of meeting people where they are, we want to be able to access every tool that is possible. Whatever door you enter, that is the door we want to make sure that treatment is available.

And so if that is your primary care provider and if it is engaging just via telephone, as opposed to traveling to a healthcare facility, we absolutely have to have that as one of our resources available in the toolbox.

The Chairman. We have in Rhode Island done a number of things. We have already talked about the medication-assisted treatment delivered through transition out of our ACI, our penal facility. We have not mentioned that in Rhode Island if you overdose and are taken to an emergency department, you get prescribed a peer recovery mentor. You may not take him up on it, but you are not going to leave without a connection.

That addiction professionals have been embedded in a number of our police departments to do follow up on the night calls and to make sure that if there is an addiction

issue, it is highlighted early. And we have made fire and police stations points of entry for people who need treatment that don't know where to go.

Those, I think, have been very effective interventions, and I would like you, Dr. Alexander-Scott, to comment on which ones you think were the most effective and how they work together as a group.

Dr. Alexander-Scott. Thank you, Chairman.

One of the parts that is critical to our response that I shared earlier is the interdisciplinary "all hands on deck" approach. While we know that there is not one whole solution, we do know that when many effective, evidence-based solutions work together, we can have the greatest impact. And given in particular how significantly COVID and other elements of the syndemic that we are in have impacted the opioid epidemic that we are dealing with, we want to for sure continue these elements.

We have established the levels of care within our hospitals, which are voluntary designations that require certain qualifications of standard bare minimum elements of care applied to every individual who comes into the hospital. And so, as you mentioned, that not only includes providing a peer recovery coach being -- or peer recovery specialist being offered to that individual, it also involves screening for drugs if someone comes in with other

scenarios. It also involves being able to be referred to treatment and other referral services, as well as being offered naloxone along with many other elements, including access to mediation-assisted treatment, which we know is critical as well.

With the other lifesaving interventions that you relayed, it is really all about meeting people where they are. So ensuring that people have access and can just walk in to one of our local law enforcement or first responder or fire stations that are available and automatically be able to be connected to treatment and, importantly, recovery services is critical.

And then, certainly, a focus that we have really begun to build out is targeting upstream more so. Addressing determinants of health, making sure that people have access to sustainable housing, making sure that we are addressing our race equity concerns, discrimination and other challenges that exist for communities of color, making sure that people have access to jobs and employment, transportation, and other elements that we know are critical to not only prevention, but also building recovery capital.

The Chairman. Thank you very much, Dr. Alexander-Scott.

Mr. Gurdak, to use your phrase, on the money side of

the house, cash is still king, and cryptocurrency and dark web exchanges have not caught up yet. Do you think they will? What is your projection?

Mr. Gurdak. I think the fear -- well, right now, I think you see in my written remarks that the fear right now out there is that the acceptance of those currencies at that macro level, that transnational drug organization level. We are seeing it at a kind of like a local, micro level is people are testing those things out to use it, but I have done a lot of -- and I have mentioned in my remarks. I looked into one case about even a transnational level. And when you get to the bottom line, everything seems to originate with cash being dumped into the system at the smaller level that an SAR review team like my own, the NVFI, is capable of using with the right people knowledgeable in how to use it.

You know, there has been obviously some growing pains in trying to use the Bank Secrecy Act properly, but I am one of these people that just loves the Bank Secrecy Act and what it could provide us if properly applied out there. So --

The Chairman. Well, if you don't mind, I would love to ask you to follow up on that with a question for the record. Just to get your advice, you also said that you think we are dramatically underutilizing our capabilities

with the Bank Secrecy Act and the new Money Laundering Act.

Let me get your advice on what we should be looking at to try to amplify that. As I pointed out in my earlier remarks, as big a business as the drug business is on the drug side, it is an equally big business on the financial side. Otherwise, it doesn't work.

Mr. Gurdak. Oh, we fully agree with that.

The Chairman. So you got to get after the financial side, too, and I appreciate your service in that respect. And if you could follow up with like a written list of recommendations, I would really be grateful to you.

Mr. Gurdak. Yes. No, you saw my passion is that side of the house, and I just think it is very underutilized. I have called the lack of knowledge within law enforcement about what the Bank Secrecy Act can do the broken window in that approach.

The Chairman. Yes.

Mr. Gurdak. I think that was an appropriate analogy to it because I am just seeing good investigators who can be trained but just haven't trained in that aspect, and I think there are great things we could do if we had that.

The Chairman. Well, I am with you. And I had the FBI take me for a spin a few years ago on the dark web in a secure computer that they run, and that is a pretty astonishing place, too, when you look at what is just

flagrantly for sale right in front of you.

So look forward to working with you.

Mr. Gurdak. Yes, sir.

The Chairman. Dr. Humphreys, as I saw your testimony about what the opioid manufacturers and marketers are up to in foreign countries, I had a real sense of, you know, deja vu all over again because I was around through the litigation with the tobacco industry over the fraud that the tobacco industry committed in marketing its product. I was an attorney general, and I was an attorney general who filed with the broad litigation that caused the generic settlement.

But the U.S. Department of Justice did its own thing by bringing a civil RICO lawsuit against the tobacco industry and getting a very solid judgment. I mean, well over 1,000 pages. The judge just nailed them. That what they were doing was, in fact, fraud, and they were put under order to knock it off.

And what you saw after that was that they did, in fact, knock it off in the U.S., where everybody was watching. But they took what seemed to be the exact same marketing tactics and they went to other countries and deployed exactly what had been described to be fraudulent and illegal in the United States and did that exact same stuff elsewhere. And I think Brazil was one of the

countries that was one of the targets, and it showed up in your testimony as one of the targets.

So here we are, what, 20 years plus later from that, and it seems that the opioids are up to the same thing. You have looked at this for a long time. How would you describe the analogy between the tobacco export of its wrongful U.S. conduct and the opioid export of its wrongful conduct?

Dr. Humphreys. As it happens, I use that very same analogy, Senator. It is exactly parallel. Tightening regulation and end of corrupt, misleading practices in our country as well as in Europe, they just then went to, you know, poor nations that they could push around with their enormous wealth.

I think it is critical in this, you know, moment where we are finally holding companies to account that the restrictions that are placed on them in these lawsuits do not have U.S. limitations on them. In other words, if you are a family who owns one such company here and another somewhere else, the same things like covertly paying doctors, saying OxyContin is not addictive when you know, in fact, that it is, incentive bonuses, overshipment -- all the things we saw here -- they have to be prevented entirely. Otherwise, we will be letting our friends down around the world, and a lot of suffering that I would like,

I am sure you would like other countries to not go through as we have gone through.

The Chairman. Well, I look forward to working with you on this as we proceed. I appreciate very much your attention to this.

There is a movie called "Casablanca," and at the end, Humphrey Bogart and Claude Rains walk off through the airport in the rain, and one says to the other, "Louis, I think this is a start of a beautiful friendship." So maybe this is a start of a beautiful friendship with us, Dr. Humphreys. I certainly hope so. We have a lot of work to do.

The record of the hearing will remain open for 1 week. So if anybody has anything to add to the record of the proceedings, that week is what you will take. That gives you a week, Mr. Gurdak, to try to get your advice in to us. I appreciate very much you are willing to do that.

I thank all of the witnesses for participating and my colleagues for participating. And we are off to a good start, and I hope that we can do a lot of good work ahead to end this scourge.

Thank you all very much. The hearing is concluded.

[Whereupon, at 4:02 p.m., the caucus was adjourned.]

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

Hearing entitled,
"The Federal Response to the Changing Drug Overdose Epidemic"

Caucus on International Narcotics Control
United States Senate

Tuesday, July 20, 2021
2:30 p.m.

Statement of
Regina M. LaBelle
Acting Director
Office of National Drug Control Policy

For Release Upon Delivery

Chairman Whitehouse, Co-Chairman Grassley, and members of the Caucus on International Narcotics Control, it is my pleasure to join you today to talk about the Office of National Drug Control Policy's (ONDCP) role in the Federal response to the changing drug overdose epidemic. I am honored to testify as the Acting Director of the agency where I served for eight years under the Obama Administration.

ONDCP coordinates drug policy through the development and oversight of the *National Drug Control Strategy* and the National Drug Control Budget. We develop, evaluate, coordinate, measure, and oversee the international and domestic drug-related efforts of Executive Branch agencies and, to the extent possible, ensure that those efforts complement State, local, and Tribal drug policy activities. As Acting Director, I act on critical current and emerging drug issues affecting our Nation by facilitating close coordination of Federal agency partners on drug interdiction and public health efforts; and by overseeing our budget authorities, through which I ensure that adequate resources are provided to our drug policy priorities.

The work of ONDCP is critically important at this moment in time. Provisional overdose deaths reported by the Centers for Disease Control and Prevention (CDC) show that an estimated 93,331 people died of an overdose in the 12-month period ending in December 2020.[1] Synthetic opioids other than methadone, a category that includes illicitly manufactured fentanyl and its analogues, were specifically involved in 62 percent of these overdose deaths. In addition, overdose deaths involving psychostimulants, including methamphetamine, have increased 46 percent from 2019 to 2020. Cocaine-involved overdose deaths also increased 21 percent in the same period, likely driven by an increase in cocaine overdose deaths where synthetic opioids other than methadone were also involved.

President Biden has made it clear that addressing addiction and the overdose epidemic is an urgent priority for his Administration. In the first six months of his Administration, he has taken immediate steps to expand access to critical services for people with substance use disorders.

1) The American Rescue Plan invested nearly $4 billion to allow the Department of Health and Human Services' (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources and Services Administration to expand access to vital mental health and substance use disorder services. The funding also included $30 million in supports for harm reduction services—a historic amount that will enhance interventions like syringe services programs that build trust and engagement with people who use drugs, and serve as a connection to care.

[1] Centers for Disease Control and Prevention, National Center for Health Statistics. *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts* through the 12-month period ending in December 2020. Available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#source, accessed on July 14, 2021.

2) HHS released the *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*, which exempt eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives from Federal certification requirements related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine. Submission and approval of a notification of intent to HHS remains necessary in order to use buprenorphine in the treatment of patients with opioid use disorder. This action expands access to evidence-based treatment by removing a critical barrier to buprenorphine prescribing.

3) The Drug Enforcement Administration (DEA) announced a new rule, effective July 28, to streamline registration requirements for opioid treatment programs that want to include a mobile component. This rule change—which was years in the making—will help provide treatment to rural and other underserved communities, including people in correctional facilities.

4) CDC and SAMHSA announced that Federal funding may now be used to purchase rapid fentanyl test strips in an effort to help curb the dramatic spike in drug overdose deaths largely driven by the use of strong synthetic opioids, including illicitly manufactured fentanyl.

5) And the President's Fiscal Year (FY) 2022 Budget includes an historic $41 billion investment for the National Drug Control Program agencies, with the most significant increases dedicated to treatment and prevention efforts.

This funding and these actions are just the start of the Biden Administration's historic commitment to ensure that the Federal Government promotes evidence-based public health and public safety actions to address this epidemic amidst a changing drug environment.

The drug environment that we currently face is considerably different than it was in the past. For instance: when the overdose epidemic began, the primary concern was prescription opioids. Today, the number of drug overdose deaths involving synthetic opioids other than methadone (which is dominated by illicit fentanyl and fentanyl analogs) has risen more than six-fold since 2014.[2] In addition to facing a different environment, the situation we face today requires an urgent response grounded in evidence and an understanding that addiction and overdoses today are driven by polysubstance use.

The COVID-19 pandemic has exacerbated addiction and the overdose epidemic. Overdose deaths were

[2] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2019 on CDC WONDER Online Database, released December 2020. Extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on December 22, 2020.

rising prior to COVID-19, but provisional data from the CDC show during the 12-months ending in December 2020 there were 54 percent more overdose deaths involving synthetic opioids other than methadone, like fentanyl, than in the 12-month period ending in December 2019.[3] One of the most dramatic and important innovations implemented during COVID-19 was the temporary lifting of barriers to treatment so that people with substance use disorder could access necessary care. As a result, we have seen the high utilization of telehealth services. For example, a buprenorphine program in Oregon was able to transition over 90 percent of its patients to telephone counseling and remote prescribing because of changes enacted during COVID-19 by the DEA that permitted telephone induction of buprenorphine and, to some extent, changes permitting billing for these services made by the Centers for Medicare & Medicaid Services.[4] Given the increases in patient reliance on these telehealth services, it will be important to find a long term solution after the pandemic emergency declaration formally ends.

As we move forward, the Biden-Harris Administration will use our first-year drug policy priorities,[5] which were released in April, as guiding principles in our policy response while we formulate the *National Drug Control Strategy*, which is due to Congress in February 2022. These first-year drug policy priorities represent a focused approach to reducing overdoses; creating more opportunities to engage people with substance use disorders; targeting and disrupting drug trafficking networks at home and abroad, including through anti-money laundering efforts; and ultimately saving lives. The priorities provide guideposts to ensure that the Federal Government promotes evidence-based public health and public safety interventions, which includes directly addressing racial equity in drug policy and embracing a full continuum of interventions, including harm reduction. The priorities, which I will detail further, are:

- Expanding access to evidence-based treatment;
- Advancing racial equity in our approach to drug policy;
- Enhancing evidence-based harm reduction efforts;
- Supporting evidence-based prevention efforts to reduce youth substance use;
- Advancing recovery-ready workplaces and expanding the addiction workforce;

[3] Ahmad, FB, Rossen, LM, & Sutton P (2021). Provisional drug overdose death counts. National Center for Health Statistics. Available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm. Accessed on July 14, 2021.
[4] Buchheit BM, Wheelock H, Lee A, Brandt K, Gregg J. Low-barrier buprenorphine during the COVID-19 pandemic: A rapid transition to on-demand telemedicine with wide-ranging effects [published online ahead of print, 2021 Apr 29]. J Subst Abuse Treat. 2021;131:108444. doi:10.1016/j.jsat.2021.108444
[5] Executive Office of the President of the United States, Office of National Drug Control Policy. (2021). The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One. https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf

- Expanding access to recovery support services; and
- Reducing the supply of illicit substances.

Expanding Access to Evidence-based Treatment

One of the most important steps we can take is ensuring that people with substance use disorders can access evidence-based treatment, which can include medications for opioid use disorder (MOUD) and contingency management services. Substance use disorder is a chronic – not acute – condition that requires long-term solutions, and treatment is a first step in the journey of recovery. Already, the Administration has taken several important strides to increase access to treatment.

- In April, the Administration announced new buprenorphine practice guidelines.[6] The guidelines exempt eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives from Federal certification requirements related to training, counseling and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine. This makes care more accessible.
- In June, the Administration announced a new rule that eases restrictions on opioid treatment programs that seek to operate mobile methadone treatment clinics.[7] I recently traveled to Atlantic County, New Jersey, to see firsthand how a mobile clinic is expanding access to methadone treatment for individuals experiencing incarceration at the Atlantic County Jail.

ONDCP continues to review emergency provisions established under COVID-19 that increased patient access to MOUD treatment. SAMHSA and DEA issued guidance that exempts opioid treatment programs from the requirement to conduct an in-person evaluation to begin treating patients with buprenorphine.[8] SAMHSA also granted state requests for blanket exceptions so that some patients receiving treatment at an opioid treatment program could receive take-home medications for opioid use disorder.[9]

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[6] Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. Department of Health and Human Services. April 28, 2021. Accessed on July 3, 2021. https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder

[7] Registration Requirements for Narcotic Treatment Programs With Mobile Components, 86 FR 36681 (June 28, 2021). https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components

[8] FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency. Substance Abuse and Mental Health Services Administration. April 21, 2020. Accessed on July 3, 2021. https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf

[9] *Ibid.*

Polysubstance use among persons who use opioids is common,[10] and as previously noted, overdoses involving stimulants have increased in recent years, escalating the urgency to offer access to treatment for stimulant use disorders. Currently, the Food and Drug Administration has not approved a drug for treating stimulant use disorder.

There are psychotherapies and behavioral therapies that can help some people recover from stimulant use disorders, but these require rigorous training, practice, and active supervision to ensure fidelity to the clinical model. One particularly effective treatment for treating stimulant use disorder is contingency management therapy, sometimes called "motivational incentives." Research has shown that, unlike psychotherapy, contingency management is easily learned by community therapists, and it helps them yield better outcomes.[11]

However, despite the promising data that underlie these therapies, the federal anti-kickback statute (AKS), which is a criminal statute, and the civil monetary penalty provision prohibiting inducements to beneficiaries (codified at 42 U.S.C. §§ 1320a-7b(b) and 1320a-7a(a)(5), respectively) may constrain the ability of providers to offer contingency management program incentives to Federal health care program beneficiaries. These statutes, respectively, prohibit offering anything of value to induce a person – including a patient – to purchase or use items or services paid for by a Federal health care program and offering anything of value to influence the patient's selection of a particular provider for Medicare or Medicaid items or services. Because contingency management programs often involve payments to the patient in the form of the opportunity to earn vouchers, gift cards, or even, in some models, salaries, these statutes may be implicated. However, any assessment of the application of these laws requires a case-by-case analysis of the facts specific to the applicable contingency management program.

The HHS Office of Inspector General (OIG) has the authority to issue regulations designating specific "safe harbors" for various payment and business practices that, while potentially prohibited by broad reach of the AKS, would not be unlawful. A number of existing safe harbors could apply to contingency management programs. However, ONDCP intends to begin work with the interagency to explore needed modifications to safe-harbor rules to ensure that providers can offer incentives, in connection with a contingency management program, that do not violate these laws, since providers are unlikely to widely use these

[10] Jones CM, McCance-Katz EF. Co-occurring substance use and mental disorders among adults with opioid use disorder. *Drug Alcohol Depend*. 2019;197:78-82. doi:10.1016/j.drugalcdep.2018.12.030
[11] Petry NM, Alessi SM, Ledgerwood DM. A randomized trial of contingency management delivered by community therapists. *J Consult Clin Psychol*. 2012;80(2):286-298. doi:10.1037/a0026826

interventions without further clarity. ONDCP is also looking at other opportunities to expand access to contingency management interventions and digital therapies that provide care for people with methamphetamine use disorder. These efforts fall within ONDCP's development of a broader framework to address methamphetamine use, in which our efforts are focused on expanding access to the evidence-based treatments we know exist, as well as addressing the supply of methamphetamine.

In addition, ONDCP is focused on reducing barriers for pregnant and postpartum persons with substance use disorders to safely access prenatal care and evidenced-based treatments. Sometimes these barriers may be prior to initiating treatment, as pregnant persons are less likely than nonpregnant persons to get an appointment with a buprenorphine-waived prescriber.[12] Other barriers may exist after treatment is initiated, such as policies that punish pregnant and postpartum persons merely for acknowledging their substance use disorder, sometimes by removing their children or imposing criminal penalties. These actions are unacceptable, discriminatory, and may discourage those who are struggling with substance use from seeking treatment.

Reducing the Supply of Illicit Substances

In addition to our efforts to expand access to treatment, supply reduction is an important part of the United States' drug policy and efforts to bend the curve on the overdose epidemic.

The Biden-Harris Administration is actively taking steps to reduce the supply of illicit substances in the United States. While synthetic opioids, such as illicitly manufactured fentanyl, its analogues, and non-fentanyl synthetic opioids, have driven up overdose deaths since 2015,[13,14,15] the United States is also seeing increased availability and use of methamphetamine and other synthetic drugs. Methamphetamine is available in the Western and Midwest United States, and recently has become more prevalent in the

[12] Patrick SW, Richards MR, Dupont WD, et al. Association of Pregnancy and Insurance Status With Treatment Access for Opioid Use Disorder. *JAMA Netw Open*. 2020;3(8):e2013456. Published 2020 Aug 3. doi:10.1001/jamanetworkopen.2020.13456

[13] Gladden, R. M., Martinez, P., & Seth, P. (2016). Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid-Involved Overdose Deaths – 27 States, 2013–2014. *Morbidity and Mortality Weekly Report (MMWR), 65*(33), 837–843. https://doi.org/10.15585/mmwr.mm6533a2.

[14] Peterson, A. B., Gladden, R. M., Delcher, C., Spies, E., Garcia-Williams, A., Wang, Y., Halpin, J., Zibbell, J., McCarty, C. L., DeFiore-Hyrmer, J., DiOrio, M., & Goldberger, B. A. (2016). Increases in Fentanyl-Related Overdose Deaths – Florida and Ohio, 2013–2015. *Morbidity and Mortality Weekly Report (MMWR),* 65, 844–849. http://dx.doi.org/10.15585/mmwr.mm6533a3.

[15] O'Donnell, J. K., R. Gladden, R. M., & Seth, P. (2017). Trends in Deaths Involving Heroin and Synthetic Opioids Excluding Methadone, and Law Enforcement Drug Product Reports, by Census Region – United States, 2006–2015. *Morbidity and Mortality Weekly Report (MMWR), 66*(34), 897–903 https://doi.org/10.15585/mmwr.mm6634a2.

Northeast.[16] Moreover, the use of cultivated drugs such as heroin and cocaine, often adulterated by synthetic opioids, continues to pose a risk of overdose for people who use drugs.[17]

The majority of illicit drugs that enter the United States are smuggled across the Southwest border. Seizures of illicit drugs on the Southwest border show that the total quantity of all drugs seized by U.S. Customs and Border Protection (CBP) at the Southwest border decreased in April 2020, but rebounded in May to pre-pandemic levels, where it remained until October 2020 when seizures at the Southwest border reached 61,326 pounds. They have since started to decline to 37,677 pounds in May of this year. Specifically, fentanyl seizures on the Southwest border increased, from 245 pounds in March 2020 to a peak of 1,171 pounds in October 2020. Fentanyl seizures on the Southwest border have declined since then to 934 pounds in May of this year, but still remain above pre-pandemic levels.[18]

That's why this Administration has moved quickly to work with key partners in the Western Hemisphere, such as Mexico and Colombia, to shape a collective and comprehensive response to illicit drug production that includes bilateral efforts to stem the flow of illicit substances, expand effective state presence, develop infrastructure, and respect the rule of law. In Mexico, for example, we are working closely with them to improve port security, strengthen their ability to detect and seize synthetic opioids, and counter transnational organized crime groups. We expect to continue collaborating with Mexico, including in the upcoming Cabinet-level security dialogue. Meanwhile, in Colombia, we are working to address historic coca cultivation and potential production numbers through a holistic approach that emphasizes development, rural security, interdiction, and eradication efforts.

We are also engaging with Mexico and Canada through regional forums such as the North American Drug Dialogue to share information and best practices on public health and public safety approaches. Additionally, we are establishing multilateral and bilateral forums to engage with China, India, and other source countries to disrupt the global flow of synthetic drugs and their precursor chemicals.

Further, ONDCP is strengthening the U.S. Government's capacity to disrupt the manufacture, marketing,

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[16] https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf

[17] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division. (2020). Tracking Fentanyl and Fentanyl-Related Compounds Reported in NFLIS-Drug, by State: 2018–2019. *National Forensic Laboratory Information System, Special Maps Release*. https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLISDrugSpecialRelease-Fentanyl-FentanylSubstancesStateMaps-2018-2019.pdf.

[18] U.S. Customs and Border Protection. Drug Seizure Statistics. Department of Homeland Security. Updated June 3, 2021. Accessed July 6, 2021. https://www.cbp.gov/newsroom/stats/drug-seizure-statistics

money, and movement of synthetic drugs by addressing illicit Internet drug sales and the continually evolving techniques in illicit financial transactions. Illicit and diverted drugs enter the United States from global suppliers as the result of a long and complex process involving manufacture, concealment, movement, purchase, and delivery, and are bought and sold in communities across America. The illicit drugs change hands several times during the process, which often necessitates the transfers of money either as payment for services or for delivery of the final product. Traditionally, street-level sales of illegal drugs have been, and for the most part still are, conducted with cash, creating immediately liquid assets that are almost impossible to track. Drug Trafficking Organizations (DTOs) employ various techniques to move and launder drug proceeds into, within, and out of the United States. Preferred methods used by DTOs to launder illicit proceeds are Bulk Cash Smuggling, Trade-Based Money Laundering, unlicensed Money Service Businesses, and through the banking sector. Additional money laundering vulnerabilities DTOs exploit include real estate, casinos, and third-party money launderers.[19]

According to the El Paso Intelligence Center's (EPIC) National Seizure System, in 2019 there were over 3,000 bulk currency seizures in the United States. This represents more than $368 million US seized, a 62 percent increase from 2018. Between 2010 and 2018, the volume of bulk currency seized has steadily dropped, with 2019's increase being an outlier to this trend. The number of seizure events in 2019 (3,454) was a 39 percent increase from the previous year (2,487).[20]

Virtual currencies like Bitcoin have been increasing in popularity, due in part to the ability of virtual currencies to change hands rapidly without limits on the amount being transferred. There are over 2,000 distinct virtual currencies in circulation, with more being developed every year; however, Bitcoin continues to be the most widely used due to its status as one of the original virtual currencies. Bitcoin is sometimes a stand-in term for virtual currency as a whole. In recent years, virtual currency exchangers have emerged to ease the conversion of fiat currency into virtual currency, and vice versa.

ONDCP believes that in order to counter these DTO's illicit financial structures, a whole-of-government approach is needed. Focused initiatives such as the Department of the Treasury's (Treasury) Office of Foreign Assets Control Foreign Narcotics Kingpin Designation Act (Kingpin Act) continue to aggressively target narcotics traffickers, and powerful tools such as Treasury's Financial Crimes Enforcement Network's (FinCENs) use of Geographic Targeting Orders assist law enforcement and FinCEN in gathering information necessary to combat money laundering and other illicit financial activity by DTOs. These

[19] Drug Enforcement Administration, 2020 National Drug Threat Assessment. 2020 National Drug Threat Assessment (NDTA) (dea.gov)
[20] Ibid.

targeted orders under the Bank Secrecy Act (BSA) impose additional recordkeeping or reporting requirements on domestic financial institutions or other businesses in a specific geographic area.

On June 30, 2021, FinCEN announced the first set of government-wide anti-money laundering/countering the finance of terrorism (AML/CFT) priorities, as required by the Anti-Money Laundering Act of 2020. Consistent with the National Strategy for Combating Terrorist and Other Illicit Financing, the AML/CFT priorities reflect a mix of new and long-standing threats to the U.S. financial system and national security. These threats involve attempts to exploit perceived legal, regulatory, supervisory, or enforcement vulnerabilities in the U.S. financial system that may be associated with a particular product, service, activity, or jurisdiction.[21]

Within the next six months, new financial institution regulations will be issued by FinCEN and Federal and state institutions to implement the new AML/CFT priorities. Those regulations will require financial institutions to integrate into their BSA compliance programs the emerging and long-standing threats to the U.S. financial system and national security identified in the AML/CFT priorities.[22]

FinCEN's announcement aligns with President Biden's National Security Study Memorandum, issued on June 3, 2021, making anticorruption efforts a core national security interest, and indicating that domestic and foreign corrupt actors and their financial facilitators seek to take advantage of vulnerabilities in the U.S. financial system to launder their assets and obscure the proceeds of crime.[23]

As for interagency mechanisms, strategically placed coordination centers continue to be great examples of information sharing tools focused on illicit financial activities. For example, High Intensity Drug Trafficking Areas (HIDTAs) supported by ONDCP; the Department of Justice's Organized Crime Drug Enforcement Task Forces (OCDETF); DEA Task Forces; the EPIC, jointly operated by DEAs and CBP; U.S. Immigration and Customs Enforcement's (ICEs) Trade Transparency Units; and ICE's Border Enforcement Security Taskforces (BESTs) allow agencies to pool confidential sources, intelligence, resources, and investigations to use evidence-based approaches to disrupt and dismantle entire organizations which create long-term gain and build a systemic means to longitudinally target DTO's illicit financial activities.

[21] Ledbetter, Lisa M., et al. FinCEN Issues First U.S. Priorities For Anti-Money Laundering And Counter-Terrorism Financing. *Mondaq*. https://www.mondaq.com/unitedstates/money-laundering/1090524/fincen-issues-first-us-priorities-for-anti-money-laundering-and-counter-terrorism-financing.
[22] Ibid.
[23] Ibid.

Advancing Racial Equity in our Approach to Drug Policy

As we work on efforts to expand access to treatment and reduce the supply of illicit substances, an important part of our work is to incorporate the cross-cutting issue of advancing racial equity in our approach to drug policy.[24] We know that existing racial inequalities result in disproportionate rates of arrest, conviction, and incarceration, disparate access to care, differential treatment in health care systems, and overall poorer health outcomes. That's why the Biden-Harris Administration supports the "Eliminating a Quantifiably Unjust Application of the Law (EQUAL) Act" and its complete elimination of the unfair sentencing disparity between crack cocaine and powder cocaine.

Additionally, for many people with substance use disorders, access to quality care in the United States is inadequate, but for Black, Indigenous, and People of Color (BIPOC), the situation is worse. A recent study showed that Black individuals generally entered addiction treatment four to five years later than white individuals, a disparity that remained even when controlling for socioeconomic status.[25] In Latino communities, those who needed treatment for substance use disorders were less likely to access care than non-Latinos.[26] This discrepancy in treatment access is important to address at a time when overdose rates are increasing for some communities of color.[27]

Our first-year actions are focused on acknowledging decades of harms to BIPOC communities and taking the steps necessary to begin correcting them. We are working to establish a research agenda to meet the needs of historically underserved communities which includes identifying data gaps related to drug policy.

ONDCP supports allocating Federal resources to advance fairness and opportunities consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government." ONDCP's FY 2023 funding guidance will direct agencies to identify opportunities to

[24] Mendoza, S., Rivera-Cabrero, A., & Hansen, H. (2016). Shifting blame: Buprenorphine prescribers, addiction treatment, and prescription monitoring in middle-class America. *Transcultural Psychiatry*, *53*(4), 465–487. https://doi.org/10.1177/1363461516660884

[25] Lewis, B., Hoffman, L., Garcia, C., & Nixon, S. (2018). Race and socioeconomic status in substance use progression and treatment entry. *Journal of Ethnicity in Substance Abuse*, *17*(2), 150–166. https://doi.org/10.1080/15332640.2017.1336959

[26] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (October 25, 2012). *The NSDUH Report: Need for and Receipt of Substance Use Treatment among Hispanics.* Rockville, MD. https://www.samhsa.gov/data/sites/default/files/NSDUH117/NSDUH117/NSDUHSR117HispanicTreatmentNeeds2012.pdf.

[27] U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. (2020). *Multiple Cause of Death 1999-2019*. CDC WONDER Online Database, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. http://wonder.cdc.gov/mcd-icd10.html

promote equity in their budgets. ONDCP will use the results of the Executive Order and our collaboration with National Drug Control Program agencies for allocating Federal drug control resources in a manner that increases investment in underserved communities.

Enhancing Evidence-based Harm Reduction Efforts

Harm reduction organizations provide an opportunity to build connections between people who use drugs and healthcare systems, often through peer support workers. Regular engagement between harm reduction staff and people who use drugs builds trust,[28] allowing for an ongoing exchange of information, resources, beneficial contact, and the potential to develop connections to healthcare systems.

As previously mentioned, access to quality healthcare is essential, but often inaccessible for people with substance use disorders. For many people who use drugs, their first point of contact may be outside of the mainstream healthcare system and through harm reduction programs. For example, critical services offered at syringe service programs (SSPs) may include providing the overdose reversal drug naloxone, sterile syringes, drug testing strips, and testing for the human immunodeficiency virus (HIV) and viral hepatitis, including hepatitis C. Research has shown that SSPs reduce HIV prevalence in conjunction with other support services.[29,30,31]

ONDCP is integrating and building linkages between funding streams to support SSPs, and is working to find ways to support the use of Federal funds to purchase syringes and other critical harm reduction services. In April, CDC and SAMHSA announced that Federal funds may now be used to purchase rapid fentanyl test strips.[32] In addition to this effort, ONDCP is working to identify opportunities to expand access, awareness, and training in naloxone in communities with the highest rates of overdose.

The Administration is encouraging additional research on the clinical effectiveness of emerging harm reduction practices in real-world settings and test strategies for implementing established evidence-based

[28] Bartlett, R., Brown, L., Shattell, M., Wright, T., & Lewallen, L. (2013). Harm reduction: compassionate care of persons with addictions. *Medsurg nursing: official journal of the Academy of Medical-Surgical Nurses*, *22*(6), 349–358. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4070513/
[29] Hurley, S., Jolley, D., & Kaldor, J. (1997). Effectiveness of needle-exchange programmes for prevention of HIV infection. *The Lancet (British Edition)*, *349*(9068), 1797–1800. https://doi.org/10.1016/S0140-6736(96)11380-5
[30] World Health Organization. (2004). *Effectiveness of sterile needle and syringe programming in reducing HIV/AIDS among injection drug users.* Geneva, Switzerland. http://www.who.int/hiv/pub/idu/e4a-needle/en/
[31] National Institutes of Health. (1997). *Consensus Development Statement: Interventions to prevent HIV risk behaviors, February 11-13, 1997*:7-8 Rockville, MD. https://consensus.nih.gov/1997/1997PreventHIVRisk104html.htm
[32] Federal Grantees May Now Use Funds to Purchase Fentanyl Test Strips, CDC and SAMHSA Press Release, April 7, 2021. https://www.cdc.gov/media/releases/2021/p0407-Fentanyl-Test-Strips.html

practices. We are developing and evaluating the impact of educational materials featuring evidence- based harm reduction approaches that link people who use drugs with harm reduction, treatment, recovery support, health, and social services and evaluate their effectiveness. It is important to note that this is the first time that strengthening harm reduction activities has been identified by the Executive Branch as a top drug policy priority.

Supporting Evidence-based Prevention Efforts to Reduce Youth Substance Use

Preventing youth substance use, including the use of alcohol, tobacco, and illicit drugs, is essential to young people's healthy growth and development. Delaying substance use until after adolescence also decreases the likelihood of developing a substance use disorder later in life.[33]

Scaling up science-based, community-level interventions to prevent and reduce youth and young adult use through ONDCP's Drug-Free Communities (DFC) Support Program can be an essential element of a comprehensive approach to prevention policy.

In the first year of this Administration, ONDCP is using its budget authorities to call on prevention programs that receive Federal funding to use evidence-based approaches to deliver and monitor the fidelity to and outcomes of those approaches through continuous quality improvement. Connected to this, we will conduct an inventory of prevention programs developed with Federal funding, and identify evaluations and assessments of their outcomes and effectiveness.

In order to advance the adoption of evidence-based prevention models, ONDCP is looking at specific opportunities for its DFC program and CDC to enhance culturally competent prevention programming, specifically to identify opportunities for prevention programming in communities with high rates of adverse childhood experiences. Additionally, we will work to update evidence-based prevention curricula for families of school-aged children, including options that can be administered at home; identify grants or other opportunities to increase substance use disorder/ mental health screenings through school nurses, school-based health centers and back-to-school physicals; encourage more widespread use of interventions and linkage to care and treatment, as clinically appropriate; and support the adoption of evidence-based care approaches for adolescents in juvenile justice programs.

[33] Rioux, C., Castellanos-Ryan, N., Parent, S., Vitaro, F., Tremblay, R., & Séguin, J. (2018). Age of Cannabis Use Onset and Adult Drug Abuse Symptoms: A Prospective Study of Common Risk Factors and Indirect Effects. *Canadian Journal of Psychiatry*, *63*(7), 457–464. https://doi.org/10.1177/0706743718760289

Advancing Recovery-ready Workplaces and Expanding the Addiction Workforce

While the Americans with Disabilities Act of 1990 provides some protections for people with substance use disorders, employers are often reluctant to hire a person with a history of substance use disorder.[34] This reluctance may be based on misconceptions and fears, negative attitudes, and even misplaced beliefs that discrimination against people with substance use disorders (either in recovery or not) is acceptable.[35]

At the same time as people in recovery are being excluded from employment, the Nation's addiction workforce is experiencing staffing shortages,[36] and we need to address future needs for various behavioral health occupations.[37] Hiring diverse practitioners who reflect the communities and cultures they serve is also an important workforce issue.[38] The United States needs skilled addiction care providers to provide the array of services necessary to meet the needs of those with behavioral health conditions, especially in light of the significant Federal Government investments in the addiction treatment infrastructure and belief in both the short-term and long-term benefits of these investments.

ONDCP promotes the adoption of recovery-ready workplace strategies by conducting a landscape review of existing programs, as well as outreach to State, local, and Tribal governments, employers, and members of the workforce, including opportunities that support recovery in the workplace and remove hiring and employment barriers. We also provide recommendations to ensure that all communities (including rural and underserved areas) have access to these programs, as well as identifying a research agenda to examine existing recovery-ready workplace models. We are identifying ways in which the Federal Government can remove barriers to employment and expand employment opportunities for people in recovery from addiction, and we are producing guidelines for Federal managers on hiring and working with people in recovery from a substance use disorder. ONDCP intends to lead by example: several ONDCP employees are people in long-term recovery who are using their experience to improve our policies and make treatment and

[34] See 29 C.F.R. § 1630.3(a) and (b) (regulations implementing Title I of the Americans with Disabilities Act of 1990. https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title29/29cfr1630_main_02.tpl.
[35] Barry, C., McGinty, E., Pescosolido, B., & Goldman, H. (2014). Stigma, Discrimination, Treatment Effectiveness, and Policy: Public Views about Drug Addiction and Mental Illness. *Psychiatric Services, 65*(10), 1269–1272. https://doi.org/10.1176/appi.ps.201400140
[36] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Workforce, National Center for Health Workforce Analysis. (2018). State-Level Projections of Supply and Demand for Behavioral Health Occupations: 2016-2030. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/state-level-estimates-report-2018.pdf.
[37] U.S. Department of Health and Human Services, Health Resources and Services Administration, Health Workforce. (2020). Behavioral Health Workforce Projections, 2017-2030. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf.
[38] Ma, A., Sanchez, A., & Ma, M. (2019). The Impact of Patient-Provider Race/Ethnicity Concordance on Provider Visits: Updated Evidence from the Medical Expenditure Panel Survey. Journal of Racial and Ethnic Health Disparities, 6(5), 1011–1020. https://doi.org/10.1007/s40615-019-00602-y

recovery easier for those who follow. In addition, we continue to engage persons with "lived experience" in the development of all levels of drug policy.

Expand Access to Recovery Support Services

We know that addiction is a chronic condition, and that providing support for people in recovery is an essential part of the continuum of care for substance use disorders. Recovery support services are offered in various institutional- and community-based settings and include peer support services and engagement, recovery housing, recovery community centers, and recovery programs in high schools and colleges. Scaling up the capacity and infrastructure of these programs will create strong resource networks to equip communities to support recovery for everyone. The required infrastructure includes a safe, reliable, and affordable means of transportation to access recovery support services.

ONDCP will work with Federal partners, State, local, and Tribal governments, and recovery housing stakeholders to begin developing sustainability protocols for recovery housing, including certification, payment models, evidence-based practices, and technical assistance.

CONCLUSION

Addressing addiction and the overdose epidemic is an urgent issue facing the Nation that has only been made worse during the COVID-19 pandemic. We have lost close to one million people to overdose since this epidemic began.[39] The Biden-Harris Administration's drug policy priorities look at addiction and overdose broadly, and are designed to bend the curve of overdose deaths by improving our addiction infrastructure and address shortcomings in how our country treats addiction. Critically, these priorities are based on science and evidence. We need to follow the science, because the science will lead us to the right answers. We look forward to working with Congress on these important issues to turn the tide on an epidemic that has lasted far too long and taken too many lives.

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[39] From 1999 through 2019, 840,565 Americans died from drug overdose. [Centers for Disease Control and Prevention. (2020). Multiple Cause of Death, 1999-2019. *CDC WONDER*. Extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on January 22, 2021].

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Testimony before the

United States Senate Caucus on International Narcotics Control

Hearing Titled:

"The Federal Response to the Drug Overdose Epidemic"

Tom Coderre

Acting Deputy Assistant Secretary for Mental Health and Substance Use

July 20, 2021

Good Afternoon and thank you Chairman Whitehouse and Co-Chairman Grassley for inviting me to testify during this hearing held by the Caucus on International Narcotics Control on the subject of "The Federal Response to the Drug Overdose Epidemic."

My name is Tom Coderre and I am currently serving as the Acting Deputy Assistant Secretary for Mental Health and Substance Use at the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA's mission is to reduce the impact of substance use and mental illness on America's communities. The drug overdose epidemic and drug threats that have emerged or changed as a result of COVID-19 have been at the forefront of our work over the past year. I will be describing changes in use patterns, trends with psychostimulants and synthetic opioid such as fentanyl, and provide an overview of SAMHSA's efforts toward the opioid crisis.

Changes in Drug Misuse and Overdose Patterns

Treatment and prevention programs must evolve with the patterns of drug misuse, and over the past 40 years, this has been complicated by rapid changes in prescribing practices, supply chains, and patterns of use. Ain describing the history of the opioid crisis, the early opioid epidemic of the 1990s was characterized by an increased supply of prescription opioids.[1] By 2010, however, we began to see rapid increases in overdose deaths involving heroin[2] and then by 2013, the misuse of synthetic opioids – such as fentanyl – contributed to a further rise in overdose-related deaths.[3,4] This shift in types of opioid used has informed many of the strategies we now employ such as naloxone distribution and fentanyl test strip utilization as we are also more focused on overdose prevention. Since the 1980s, there has also been fluctuating mortality from

[1] Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR MorbMortal Wkly Rep. 2011 Nov 4; 60(43):1487-1492.
[2] Rudd RA, Paulozzi LJ, Bauer MJ, Burleson RW, Carlson RE, Dao D, Davis JW, Dudek J, Eichler BA, Fernandes JC, Fondario A. Increases in heroin overdose deaths—28 states, 2010 to 2012.MMWR MorbMortal Wkly Rep. 2014 Oct 3; 63(39):849.
[3] Gladden RM, Martinez P, Seth P. Fentanyl law enforcement submissions and increases in synthetic opioid-involved overdose deaths—27 states, 2013–2014. MMWR MorbMortal Wkly Rep. 2016; 65:837–43.
[4] O'Donnell JK, Gladden RM, Seth P. Trends in deaths involving heroin and synthetic opioids excluding methadone, and law enforcement drug product reports, by census region—United States, 2006–2015. MMWR MorbMortal Wkly Rep. 2017; 66:897–903.

methamphetamine and stimulant use.[5] Overdose deaths involving methamphetamine started rising steeply in 2009, and November 2020 data from the Centers for Disease Control and Prevention (CDC) show they had increased almost 10-fold by 2019.[6] It is also important to note the impact of alcohol and tobacco, which carry significant mortality when used alone, or in combination with other substances.[7]

The issue of concurrent use of multiple substances known as polysubstance misuse – complicates treatment and interventions further. Indeed, the rise in overdose deaths from methamphetamine has been linked to the co-administration of opioids such as heroin or fentanyl, or using products that have been contaminated by fentanyl without the user's knowledge. Fentanyl is a powerful synthetic opioid which is 50 to 100 times more potent than morphine. According to a recent study, there are increasing numbers of individuals injecting methamphetamine and opioids together.[8] Of the 16,167 drug overdose deaths involving psychostimulants in the United States in 2019, 53.5 percent also involved an opioid.[9] There is also emerging thoughts hat individuals may be substituting opioid for methamphetamines due to availability.[10] Some individuals will combine substances, such as methamphetamine and opioids, to achieve a synergistic high or to balance out their effects.[11] However, the combination can enhance the drugs' toxicity and lethality, by exacerbating their individual cardiovascular and pulmonary effects as well as inherent increased risk of fatal overdose in those without opioid tolerance.

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[5] Jalal H, Buchanich JM, Roberts MS, Balmert LC, Zhang K, Burke DS. Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016. Science. 2018 Sep 21;361(6408):eaau1184. doi: 10.1126/science.aau1184.

[6] NIDA. 2020, November 12. Rising Stimulant Deaths Show that We Face More than Just an Opioid Crisis. Retrieved from https://www.drugabuse.gov/about-nida/noras-blog/2020/11/rising-stimulant-deaths-show-we-face-more-than-just-opioid-crisis on 2021, June 25

[7] Baggett, T. P., Chang, Y., Singer, D. E., Porneala, B. C., Gaeta, J. M., O'Connell, J. J., & Rigotti, N. A. (2015). Tobacco-, alcohol-, and drug-attributable deaths and their contribution to mortality disparities in a cohort of homeless adults in Boston. American journal of public health, 105(6), 1189–1197.

[8] Jones CM. Syringe services programs: An examination of legal, policy, and funding barriers in the midst of the evolving opioid crisis in the U.S. Int J Drug Policy. 2019 Aug;70:22-32.

[9] NCHS Data Brief, Number 406, April 2021 (cdc.gov)

[10] ibid

[11] Ellis MS, Kasper ZA, Cicero TJ. Twin epidemics: The surging rise of methamphetamine use in chronic opioid users. Drug Alcohol Depend. 2018 Dec 1;193:14-20. doi: 10.1016/j.drugalcdep.2018.08.029. Epub 2018 Oct 10.

We have seen further rises in opioid, stimulant, and polysubstance use over the course of the COVID-19 pandemic. Provisional CDC data indicate that there were more than 93,000 drug overdose deaths in 2020.[12] Synthetic opioids (primarily illicitly manufactured fentanyl) appear to be the principal driver, increasing 51.2 percent in 2020.[13] Overdose deaths involving cocaine also increased by 19.4 percent. This increase in deaths is likely linked to co-use or contamination of cocaine with illicitly manufactured fentanyl or heroin.[14] Of the 15,883 overdose deaths involving cocaine in 2019 in the United States, 75.5 percent also involved an opioid.[15]

Changes in drug misuse patterns complicate treatment. Treating people who use fentanyl, for example, is made difficult by disparity in access to agonist treatment. There is limited scientific evidence and a lack of consensus on the optimal treatment approaches for polysubstance misuse. Research cannot keep up with rapid changes in drug use patterns. Beyond this, medical schools have not uniformly implemented comprehensive curricula to improve the ability of graduates to recognize and treat substance misuse and to improve their attitudes toward this condition.[16] This potentiates stigma and may reduce the effectiveness of interventions at the health system level.[17]

State Patterns in Fentanyl and Methamphetamine Use

Drug overdose deaths rates involving synthetic opioids and methamphetamine have shifted geographically over the past several years.[18] Understanding geographic distributions allows for more resources to be allocated to the areas most affected.

[12] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[13] ibid
[14] ibid
[15] NCHS Data Brief, Number 406, April 2021 (cdc.gov)
[16] Polydorou S, Gunderson EW, Levin FR. Training physicians to treat substance use disorders. Curr Psychiatry Rep. 2008;10(5):399-404.
[17] van Boekel LC, Brouwers EPM, van Weeghel J, Garretsen HFL. Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review. *Drug and Alcohol Dependence.* 2013;131(1):23-35.
[18] Mattson CL, Tanz LJ, Quinn K, Kariisa M, Patel P, Davis NL. Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019. MMWR Morb Mortal Wkly Rep 2021;70:202–207.

- From 2018 to 2019, the largest relative increase in the death rate involving synthetic opioids occurred in the West (67.9 percent).While the largest relative increase in the death rate involving psychostimulants occurred in the Northeast (43.8 percent).
- Within the past two years, the East had the highest increases in deaths involving synthetic opioids, and the Midwest had the highest increases in deaths involving psychostimulants.
- Most striking is that no state experienced a significant decrease in the age-adjusted synthetic opioid overdose death rate from 2018-2019.
- From 2013 to 2019, the age-adjusted rate of deaths involving synthetic opioids other than methadone increased by 1,040 percent, and the age-adjusted rate of deaths involving psychostimulants increased 317 percent.

Engagement Strategies and Solutions

Ensuring access to treatment for individuals who misuse substances requires that issues regarding treatment capacity and barriers to treatment seeking be addressed. SAMHSA is addressing these issues in several ways, which are described below. This section also discusses other strategies that can improve engagement in treatment.

Treatment Capacity: Workforce projections estimate a shortage of behavioral health providers. Treatment capacity could be increased through the use of peer providers in a wide variety of integrated and specialty care settings. will be required.

DATA Waivers: To expand access to treatment, HHS issued the "*Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*"[19] These guidelines permit eligible practitioners to treat up to 30 patients without obtaining a waiver. The revised guidelines may help reduce geographic barriers to treatment, especially in rural areas. We have seen an uptick in evaluations overall and over 1000 providers have applied for the exemption in the first two months.

[19] 86 FR 22439 (Apr. 28, 2021)

SAMHSA provides direct support and technical assistance to practitioners seeking to treat and currently treating people with Opioid Use Disorder (OUD) through its university-based Provider Clinical Support System.

Certification of Opioid Treatment Programs (OTPs): SAMHSA certifies OTPs and provides direct support (information and technical assistance) to OTPs regarding certification, accreditation and treatment. These services include:

- Assisting potential sponsors in establishing new OTPs.
- Reviewing and approving exemptions to the federal regulations where needed, such as developing flexibilities for use of telehealth and take-home prescription medication during the COVID-19 pandemic.
- Providing technical assistance and support for prisons seeking to assure continuation of Medications for Opioid Use Disorder (MOUD) for people who are incarcerated and/or preparing for re-entry.

Comprehensive Opioid Recovery Centers (CORC): SAMHSA provides direct support for the development of comprehensive centers which provide a full spectrum of treatment and recovery support services to address the opioid epidemic through its Comprehensive Opioid Recovery Centers grants. These Centers have played a key role in allowing people receiving MOUD to live as residents of sober homes and to participate in inpatient rehabilitation services.

Supporting Providers, Healthcare Systems and States: SAMHSA meets regularly with the state opioid treatment authorities (SOTAs) to provide technical assistance and support in the oversight opioid treatment programs (OTPs), and it oversees the work of the Accrediting Bodies in maintaining accreditation standards. Examples of issues SAMHSA addresses with SOTAs include:

- Assisting in evaluating state requirements and their adherence to the Federal regulations for Opioid Treatment Programs (OTPs).
- Promoting evidence-based treatment through discussion of scientific strategies and OTP accreditation standards.
- Use of social media as a means of engaging younger people in treatment.

Our oversight of the accreditation bodies enables SAMHSA to promote culturally appropriate treatment for specific populations (e.g. American Indians and Alaska Natives, Latinx communities, women, youth, and people involved in the criminal justice system). We do this by requiring that the capacity to deliver culturally appropriate services is included in the accreditation standards for OTPs.

Providers Clinical Support Systems-Universities (PCSS-U): SAMHSA manages the PCSS-U through which medical, physician assistant and nurse practitioner students receive the training needed to obtain a DATA waiver . This grant promotes incorporation of substance use disorder (SUD) education into the core curriculum of graduate-level medical education for physicians and mid-level providers and prepares these students to obtain a waiver upon becoming licensed.

Decreasing Barriers: Research reveals geographic and sociodemographic barriers to receiving treatment.[20] Indeed, many treatment facilities are found in urban and suburban areas, and there is disparity in access to buprenorphine providers and OTPs.[21] Recent policy changes, such as *The Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*, remove barriers to obtaining a DATA-2000 Waiver and eliminate the need to do so for eligible practitioners providing MOUD to 30 or fewer patients. On June 28, 2021, the U.S. Drug Enforcement Administration published the final rule allowing OTPs the option of adding a mobile component (or van) to their existing registration. We anticipate these new flexibilities in the use of mobile units to provide methadone for the treatment of OUD will expand the reach of methadone providers, improving geographic access.

Wrap-around Services: These services not only improve the treatment experience, but also provide support to clients during their recovery. For example, research demonstrates that women's SUD treatment outcomes are improved when women-specific needs are addressed through wrap-around services, such as the provision of childcare, employment assistance, or

[20] Sharma RN, Casas RN, Crawford NM, Mills LN. Geographic distribution of California mental health professionals in relation to sociodemographic characteristics. Cultur Divers Ethnic Minor Psychol. 2017 Oct;23(4):595-600.
[21] Goedel WC, Shapiro A, Cerdá M, Tsai JW, Hadland SE, Marshall BDL. Association of Racial/Ethnic Segregation With Treatment Capacity for Opioid Use Disorder in Counties in the United States. JAMA Netw Open. 2020;3(4):e203711. Published 2020 Apr 1. doi:10.1001/jamanetworkopen.2020.3711

mental health counseling.[22] Additionally, the receipt of basic needs, child care, educational, family, and medical services is associated with improvements in several post-treatment outcomes.[23] These services provide an important opportunity to address social determinants of health that could otherwise lead to a poor prognosis. SAMHSA supports the provision of wraparound services in most of its major grant programs.

Telehealth: The recent pandemic has demonstrated the utility of telehealth in ensuring access to care despite geographic or other barriers. Telehealth is a mode of service delivery that has been used in clinical settings for over 60 years and empirically studied for just over 20 years.[24] Telehealth is not an intervention itself, but rather a mode of delivering services. This mode of service delivery increases access to screening, assessment, treatment, recovery supports, crisis support, and medication management[25] across diverse behavioral health and primary care settings. For example, State Opioid Response (SOR) grantees have implemented telehealth in various ways. Another outreach strategy is the use of mobile healthcare services include HIV testing, hepatitis testing, vaccinations, buprenorphine medication, harm reduction supplies, connections to follow-up appointments with doctors, naloxone training, housing services, and treatment. Telehealth has also increased access to MOUD, particularly in rural and other hard to reach areas. SOR grantees have reported a significant increase in client engagement, satisfaction, and retention in treatment due to the increased use of telehealth.

State Opioid Response (SOR) Grants: The SOR program aims to address the opioid crisis by increasing access to MOUD using the three FDA-approved medications for the treatment of opioid use disorder, reducing unmet treatment needs, and reducing opioid overdose deaths. This program was expanded recently to address stimulant use, including cocaine and

[22] Oser C, Knudsen H, Staton-Tindall M, Leukefeld C. The adoption of wrap-around services among substance abuse treatment organizations serving criminal offenders: The role of a women-specific program. Drug Alcohol Depend. 2009;103 Suppl 1(Suppl 1):S82-S90. doi:10.1016/j.drugalcdep.2008.12.008

[23] Pringle, J, et al. The Role of Wrap Around Services in Retention and Outcome in Substance Abuse Treatment: Findings From the Wrap Around Services Impact Study. Addict Disord Their Treatment 2002;1:109–118.

[24] Bashshur, R. L., Shannon, G. W., Bashshur, N., & Yellowlees, P. M. (2016). The empirical evidence for telemedicine interventions in mental disorders. Telemedicine and e-Health, 22(2), 87-113.

[25] Substance Abuse and Mental Health Services Administration. (2015). Using technology-based therapeutic tools in behavioral health services. Treatment Improvement Protocol (TIP) Series 60

methamphetamine. The SOR program is helping reduce opioid morbidity and mortality, and expanding overdose prevention and naloxone distribution, treatment, and recovery support services. SOR grantees have utilized peer support specialists assist individuals with OUD and/or stimulant use disorder(s) to initiate and/or maintain recovery. Peers work across settings, collaborating closely with medical professionals, criminal justice personnel, treatment providers, child welfare workers, and others to provide education, assistance accessing treatment, and recovery support services. SOR grantees have reported increased numbers of peer-certified specialists in the workforce with streamlined training and certification as well as improved child welfare outcomes when family peer mentors are paired with child welfare workers.

SOR grantees have implemented several programs that offer MOUD and wrap-around services, including housing assistance, transportation to treatment, job training, and peer recovery support services. Grantees report improved ability to integrate wrap-around recovery support services not traditionally provided in office-based opioid treatment (OBOT) as a result of grant funding. Further, SOR-funded services that target pregnant and post-partum women have demonstrated positive outcomes. These programs provide access to safe housing, MOUD, medical and behavioral health care, employment and educational services, and case management services related to childcare and transportation. Outcome data suggests an overall reduction in the days of use of substances and a greater percentage of clients housed from intake to 6-month follow-up. Additional outcomes include infants with healthy birth weights, no or shorter stays in the neonatal intensive care units (NICU), fewer infants born with neonatal abstinence syndrome (NAS), fewer infants with feeding and respiratory issues, and many mothers in recovery at the time of birth.

SOR grantees implement coordinated SUD prevention, treatment, and recovery support efforts to address the opioid and stimulant crisis. Grantees' strategies must include evidence-based practices (EBPs). Among EBPs commonly implemented by SOR grantees are: MOUD, "hub and spoke" models, cognitive behavioral therapy, motivational interviewing, contingency management, peer recovery support services, and overdose education and naloxone distribution.

SOR grantees report increased utilization of evidence-based behavioral health treatment models and recovery supports because of grant-funded trainings.

Services: SOR grantees have implemented several harm reduction activities, including innovative approaches to distribution of naloxone and fentanyl test strips as well as access to HIV/HCV testing, street-based outreach, and support of SSPs. These approaches aim to reduce the harms of active drug use, including reducing the spread of infectious disease as well as providing important connections to treatment and other community supports.

Education: SOR grantees are required to make use of SAMHSA-funded opioid technical assistance/training (TA/T) resources, including the opioid response network (ORN),in providing training and technical assistance to healthcare providers. The SOR grant program also hosts monthly webinars for states to share effective use of grant funds in addressing the opioid and stimulant use crises. Additionally, many grantees provide ongoing educational opportunities to providers in their state through Project ECHO. Various webinars and training events are also offered through SOR grantees to ensure the workforce has the most up-to-date information.

Reducing Stigma: SOR grantees focus on the need to reduce stigma surrounding not just OUDs but also medications for OUD, also known as MOUD. This is accomplished through various training and education initiatives, focused on directly addressing myths and stigma. Other effective approaches include the implementation of media campaigns, as described below.

Street-Based Outreach: SOR grantees have implemented various street-based outreach initiatives as a means of providing harm reduction services. These projects often target underserved areas. Services include distribution of naloxone, fentanyl test strips, hygiene kits, and provision of wound care. Information about how to access treatment and other relevant resources is also shared. The approach for this outreach style is rooted in harm reduction and overdose prevention, often emphasizing education on fentanyl and latest drug trends.

Another example of SOR-funded street-based outreach occurs in post overdose support teams (POST). This is a model that partners harm reduction programs with first responders to provide

outreach and support after a 911 call for overdose. These teams visit overdose survivors and their families in the days or weeks following the overdose event. During these visits, individuals are provided access to naloxone, referrals to mental health counseling, and information about treatment and recovery support services. These efforts have been shown to be effective in reducing the likelihood that the overdose survivor will experience a second, fatal overdose.

Partnering with Public Safety Officials and Community Organizations: SOR grantees continue to work with law enforcement, community groups, patients, and treatment teams to address the overdose epidemic. SOR grantees are required to provide treatment transition and coverage for patients reentering communities from criminal justice or rehabilitative settings. Approaches include working within criminal justice settings to offer access to MOUD for incarcerated individuals, training incarcerated individuals to become peer support specialists, and collaborating with various agencies to improve transitions into the community. SOR grantees report improved transitions for clients reentering communities from criminal justice settings or other rehabilitative settings through close partnerships of "hub" locations and "spoke" providers.

Increasing Public Awareness: Many SOR grantees sponsor evidence-based media campaigns to reduce stigma, provide education on OUD and MOUD, and increase awareness of available treatment options. Millions of people have been reached through television, radio, social media, and print campaigns. Many grantees have been able to show an increase in the number of individuals seeking treatment because of these public awareness campaigns.

Harm Reduction Activities: The promotion and distribution of naloxone and fentanyl test strips represents an opportunity to not only promote life-saving interventions, but to also provide education on drug potency and mortality.[26] This can be achieved in partnership with public safety agencies, providers, community organizations and the public. A comprehensive and coordinated approach must incorporate innovative and established overdose prevention and response strategies, including those focused on polysubstance use. We have seen earlier success

[26] Han JK, Hill LG, Koenig ME, Das N. Naloxone Counseling for Harm Reduction and Patient Engagement. Fam Med. 2017 Oct;49(9):730-733.

with syringe services programs reducing the spread of infectious diseases such as HIV and Hepatitis C and expect similar results with other harm reduction measures.

SAMHSA's Community-Based Substance Use Disorder program, supported through the American Rescue Plan Act, promotes the widespread dissemination and implementation of evidence-based strategies aimed at reducing the negative consequences associated with drug use. Community-based overdose prevention programs, syringe services programs, and other harm reduction services will be expanded under this effort. Funding will be used to prevent and control the spread of infectious diseases and the consequences of such diseases for individuals with, or at risk of developing SUD, support distribution of opioid overdose reversal medication to individuals at risk of overdose, connecting individuals at risk for, or with, a SUD to overdose education, counseling, and health education, and encouraging such individuals to take steps to reduce the negative personal and public health impacts of substance use or misuse. Grants will strengthen harm reduction programs by helping establish strategies for referral to appropriate treatment and recovery support services, and for increasing safety around fentanyl, fentanyl analogs, and other dangerous drugs. Harm reduction grants are intended to promote widespread dissemination and implementation of harm reduction activities and stigma reduction efforts. Grant funding is intended for states; local, tribal, and territorial governments; tribal organizations; nonprofit community-based organizations; and primary care and behavioral health organizations to support community-based overdose prevention programs, SSPs, and other harm reduction services.

Naloxone and Fentanyl Test Strips: Distribution of naloxone is a large focus of SOR grantees. Ensuring individuals have access to this life-saving medication is a cornerstone of the grant program. Implementation includes widespread distribution of naloxone kits to peers, first responders, people who use drugs, and various community-based organizations. Grantees report having distributed approximately 2,571,381 naloxone kits and using naloxone to reverse approximately 197,084 overdoses through March 31, 2021.

Vending machines are one innovative approach to the distribution of naloxone kits and fentanyl test strips 24/7. After receiving their own unique card/PIN, participants can use the machines to

access a number of harm reduction supplies including: sharps boxes, naloxone, fentanyl test strips, hygiene kits, first-aid kits, pregnancy tests, and safe sex kits. The vending machines allow for increased naloxone and fentanyl test strip distribution in communities with high overdose rates. These machines can also be placed in commercial areas to allow for easier access to naloxone.

Another innovative approach to increasing access to naloxone was inspired by the proliferation of automated external defibrillators (AEDs) for heart attacks. Like fire extinguishers or defibrillators, wall-mounted kits with doses of naloxone are placed in common areas of various public buildings. This allows bystander rescuers to save the lives by reversing opioid overdose with publicly available naloxone.

Naloxone and fentanyl test strips are also distributed by peer support specialists, through street-based outreach, emergency medical service (EMS) leave-behind models, mobile unit distribution, and mail delivery. The "Text to Live" program allows individuals to use their phones to receive an interactive map of naloxone distribution sites and a series of follow-up messages encouraging naloxone use and providing information about accessing treatment.

HIV/HCV Testing: SOR grantees have partnered with local harm reduction organizations and coalitions to provide various harm reduction services aimed at reduction of infectious disease. These include access to free HIV and hepatitis C Virus (HCV) testing, as well as referrals to treatment as needed. SOR grantees have partnered with harm reduction organizations to administer hepatitis A and hepatitis B vaccines, distribute many types of clean and safe injection supplies, with the exception of syringes, and to refer individuals to treatment. Grantees also offer PrEP to at-risk individuals.

Syringe Service Programs (SSPs): Other SOR grantees have partnered with syringe service programs (SSPs) to implement various harm reduction approaches within these settings. SOR grantees have provided support to SSPs in order incorporate low-barrier opioid treatment

services into these settings. Other grantees have worked to expand SSPs operating hours. These approaches increase access to treatment for individuals who may utilize SSPs.

Medication Assisted Treatment- Prescription Drug and Opioid Addiction (MAT-PDOA): The purpose of MAT-PDOA grants are to expand/enhance access to MOUD and psychosocial services for persons with an OUD seeking or receiving MOUD. The desired outcomes for this program are: 1) an increase in the number of individuals with OUD receiving MOUD; and 2) a decrease in illicit opioid drug use and prescription opioid misuse at six-month follow-up. MOUD is evidenced based and is an integral component of harm reduction strategies and helps to prevent overdose deaths.

MAT-PDOA grantees are currently purchasing fentanyl test strips to help mitigate potential overdoses among their patients who still use. MOUD combined with psychosocial services provides a channel to help patients engage in recovery support services and gain access to primary care services while providing a pathway to gainful employment and significant benefits in reducing STI transmission and other infectious diseases.

Education: Recent medical school graduates play a pivotal role in educating their patients and colleagues; screening, diagnosing, and treating patients; and modeling positive attitudes to reduce the stigma attached to SUDs. Research demonstrates that SUD educational interventions, using various approaches and durations, produce a positive impact on medical students' knowledge, skills, and attitudes.[27] Studies also show that simply increasing exposure to patients with SUD does not equip providers to identify, treat or prevent SUD. A concurrent, comprehensive didactic curriculum is necessary to accomplish that.[28] Even as the opioid crisis deepens, there remains wide variability in SUD curricula across medical schools.[29] This adversely impacts patient care - a lack of preparedness has been identified as a barrier in the

[27] Muzyk A, Smothers ZPW, Akrobetu D, Ruiz Veve J, MacEachern M, Tetrault JM, Gruppen L. Substance Use Disorder Education in Medical Schools: A Scoping Review. Acad Med. 2019 Nov;94(11):1825-1834. doi: 10.1097/ACM.0000000000002883. PMID: 31663960.

[28] Tetrault, J. Improving Health Professions Education to Treat Addiction: The Time Has Come. The Josiah Macy Jr Foundation, News and Commentary. May 2018.

[29] Blanco, C., Wiley, T.R.A., Lloyd, J.J. et al. America's opioid crisis: the need for an integrated public health approach. Transl Psychiatry 10, 167 (2020). https://doi.org/10.1038/s41398-020-0847-1

provision of buprenorphine to patients with opioid use disorder by early career family physicians.[30] Appropriate education "would help legitimize opioid use disorder as a chronic disease, and destigmatize its treatment."[31] This impacts patient-physician dialogues and contributes to the under-treatment of SUDs by primary care and specialty providers.[32]

Reducing Racial Disparities in Outcomes: Opioid-involved overdose death rates in the United States differ by demographic and geographic characteristics.[33] From 2015 to 2017, nearly all racial/ethnic groups and age groups experienced significant increases in opioid-involved and synthetic opioid–involved overdose death rates, particularly Black persons aged 45–54 years (from 19.3 to 41.9 per 100,000) and 55–64 years (from 21.8 to 42.7) in large central metro areas.[34] In 2019, the age-adjusted drug overdose death rate in the Black population surpassed that in the White population for the first time in many years. From 2016 to 2019, Black persons saw a 43 percent increase in drug induced deaths, Latinx saw a 33 percent increase, Asian persons saw a 30 percent increase, and White persons saw a 5 percent increase.[35] The increased involvement of synthetic opioids in overdose deaths is changing the demographics of the opioid overdose epidemic. The differential impact of overdose rates in some populations has highlighted inequities and disparities in access to general healthcare, substance use disorder services, and vital ancillary services that must be addressed. Additionally, culturally competent interventions are needed to target populations at risk; these interventions include increasing awareness about synthetic opioids in the drug supply and expanding utilization of evidence-based interventions, such as naloxone distribution and MOUD.

Stigma can reduce willingness of providers in non-specialty settings to screen for and address problems with substances, and may limit willingness of individuals with such problems to seek

[30] DeFlavio JR, Rolin SA, Nordstrom BR, Kazal LA Jr. Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians. Rural Remote Health. 2015;15:3019.
[31] Tong ST, Hochheimer CJ, Peterson LE, Krist AH. Buprenorphine Provision by Early Career Family Physicians. Ann Fam Med. 2018;16(5):443-446. doi:10.1370/afm.2261
[32] Kennedy-Hendricks A, Busch SH, McGinty EE, et al. Primary care physicians' perspectives on the prescription opioid epidemic. Drug Alcohol Depend. 2016;165:61-70.
[33] Lippold KM, Jones CM, Olsen EO, Giroir BP. Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid–Involved Overdose Deaths Among Adults Aged ≥18 Years in Metropolitan Areas — United States, 2015–2017. MMWR Morb Mortal Wkly Rep 2019;68:967–973.
[34] ibid
[35] https://www.tfah.org/wp-content/uploads/2021/05/2021_PainInTheNation_Fnl.pdf ?

treatment.[36] All of these factors may help explain why so few individuals with SUDs receive treatment. Public education that reduces stigma and provides information about treatment is needed. This represents an opportunity to engage across multiple disciplines and modalities.

Supporting Providers, Healthcare Systems, and Payers: The production of treatment guidelines, advisories and informational materials represents an opportunity to not only promote best-practice, but to also inform decision making at the health system level. Furthermore, appropriate support of DATA-Waivered providers affords an opportunity to promote increased rates of treatment.[37] These activities encourage collaboration across disciplines, organizations, agencies, and centers. In a study of data from 24 states plus DC in 2019, the CDC found that in 62.7 percent of drug overdose deaths there was at least one opportunity for intervention prior to the fatal overdose.[38]

Partnering with Public Safety Officials and Community Organizations: Working with law enforcement, community groups, patients, and treatment teams to address the growing drug epidemic has the potential to channel new ideas, data sources, and efforts towards reducing mortality and use of illicit substances. Such engagement promotes cross collaboration and encourages patients and providers to work with law enforcement to create innovative and community focused interventions.

Increasing Public Awareness: Public awareness campaigns, such as Public Service Announcements (PSAs) and information sharing through social media promote safety and knowledge among community members.[39] Such activities also offer a means of promoting harm reduction practices among those already misusing substances.[40] The creation of these resources

[36] Yang LH, Wong LY, Grivel MM, Hasin DS. Stigma and substance use disorders: an international phenomenon. Curr Opin Psychiatry. 2017;30(5):378-388.
[37] Andrilla CHA, Coulthard C, Larson EH. Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder. Ann Fam Med. 2017 Jul;15(4):359-362.
[38] Vital Signs: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants — 24 States and the District of Columbia, January–June 2019 | MMWR (cdc.gov)
[39] Makkai, T., Moore, R., & McAllister, I. (1991). Health education campaigns and drug use: The "drug offensive" in Australia. Health Education Research, 6(1), 65–76.
[40] Harm reduction: An approach to reducing risky health behaviours in adolescents. Paediatr Child Health. 2008;13(1):53-60. doi:10.1093/pch/13.1.53

affords an opportunity to work with community members, technology experts and media strategists.

Recovery Supports

True success with substance use disorder also involves enduring efforts, many of which are through recovery supports.

RCSP-RN, BCOR, TCE-PTP and Workforce Support Programs: Recovery Support efforts have been in the forefront at SAMHSA since the late 1990s. SAMHSA first launched the Recovery Community Support Program, later the Recovery Community Services Program (RCSP) in 1998. This grant helped launch and supported the development and strengthening of recovery community organizations (RCOs). Later iterations of the grant supported their efforts to establish statewide networks. Their focus has been emphasizing the critical importance of as a bi-directional bridge between communities and formal systems, including SUD treatment, and the criminal justice and child welfare systems. RCOs are peer-led organizations that advocate, educate, and may provide peer recovery support services to individuals with or in recovery from SUDs or co-occurring substance use and mental health disorders (CODs).

The most recent advancement of the SAMHSA recovery portfolios feature two new grant initiatives, the RCSP 5-year grant program and the Treatment, Recovery and Workforce Support Grants (Workforce Support). The 5-year RCSP grants build peer recovery support services capacity through recovery community centers , and the Workforce Support grants enhance employment opportunities for individuals in recovery from SUDs by addressing gaps in services and providing opportunities for veterans, homeless individuals, and those reentering the community after incarceration.

Moreover, understanding the critical role peers play, SAMHSA developed the targeted capacity expansion-peer to peer (TCE-PTP) grant portfolio forging the path for the extensive ongoing training of peers towards certification and expanding the workforce. This portfolio has provided state recognition for peer support service providers in the workplace and, in some states where allowable, Medicaid reimbursement for their services. It has been demonstrated that peer

recovery support services (PRSS) are invaluable in assisting individuals to establish and maintain their recovery.

Since 2017, SAMHSA allocated over 60 million dollars to recovery support initiatives, including the further development of RCOs, strengthening the peer recovery workforce, and advancing de-stigmatization efforts regarding addiction and recovery. Additionally, housing and employment opportunities have been supported, and SAMHSA's recovery support initiatives have served almost 8000 individuals. However, we can and must do more to build out the continuum. President Biden's FY 2022 Budget contains a 10 percent set aside for recovery support services in the Substance Abuse Prevention and Treatment Block Grant which would provide states with funding to further invest in building out recovery support services.

SAMSHA is also partnering with NIDA in the HEALing Communities Study. This study is an implementation research study investigating coordinated approaches for deploying evidence-based strategies to prevent and treat opioid misuse and OUD tailored to the needs of local communities. The partnership will ensure that this research is best poised to impact service delivery toward ameliorating the opioid crisis in hard hit areas.

Thank you for the opportunity to share SAMHSA's activities to combat the addiction crisis in America. I welcome any questions that Caucus members might have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Testimony before the

Senate Caucus on International Narcotics Control

Hearing Title

The Federal Responses to the Drug Overdose Epidemic

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Director

National Institute on Drug Abuse

July 20, 2021

Chairman Whitehouse, Co-Chairman Grassley, and members of the Senate Caucus on International Narcotics Control, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this hearing. Our mission at NIDA is to use science to address addiction in all its complexity, and I am glad for the opportunity to speak to you today about the collision of our nation's addiction and overdose crises with the COVID-19 pandemic.

Impact of the COVID-19 Pandemic on Drug Use and Overdose

The twin addiction and overdose crises have collided with the COVID-19 pandemic, each exacerbating the deleterious effects of the other, resulting in increased rates of substance use and overdose, and increased risk for serious effects of COVID-19 illness. Large increases in many kinds of drug use and overdose have been recorded since March 2020, when a national emergency was declared and our lives radically changed due to lockdown and the closure of businesses and schools. Several reports have revealed increases in the number of positive urine drug screens for fentanyl, cocaine, heroin, and methamphetamine.[1,2,3] There have also been increases in cannabis and alcohol use, especially among people with anxiety and depression and those experiencing COVID-19-related stress.[4,5,6] Further, state and local data suggest substantial increases in emergency visits for drug overdose, including nonfatal overdose, despite a decline in overall non-COVID emergency department visits.[7,8,9,10,11,12]

Provisional data from the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths reached an estimated 93,000 deaths in 2020, a nearly 30 percent increase over the previous year and the highest number ever recorded in a 12-month period. Death rates increased by nearly fifty-five percent for fentanyl-category involved overdoses, by forty-six percent for methamphetamine-category involved overdoses, and over twenty-one percent for cocaine-involved overdoses.[13]

Social isolation and pandemic-related stress are likely contributing factors to the rise in substance use and overdose. Social isolation can make people with substance use disorders (SUD) more vulnerable to negative outcomes because it interferes with many of the support systems that can help them to reach

[1] Millennium Health's Signals Report™ COVID-19 Special Edition Reveals Significant Changes in Drug Use During the Pandemic (prnewswire.com)
[2] Analysis of Drug Test Results Before and After the US Declaration of a National Emergency Concerning the COVID-19 Outbreak | Emergency Medicine | JAMA | JAMA Network
[3] The Opioid Epidemic Within the COVID-19 Pandemic: Drug Testing in 2020 | Population Health Management (liebertpub.com)
[4] Alcohol Consumption during the COVID-19 Pandemic: A Cross-Sectional Survey of US Adults (nih.gov)
[5] Increased alcohol use during the COVID-19 pandemic: The effect of mental health and age in a cross-sectional sample of social media users in the U.S. - ScienceDirect
[6] Changes in Alcohol Consumption Among College Students Due to COVID-19: Effects of Campus Closure and Residential Change: Journal of Studies on Alcohol and Drugs: Vol 81, No 6 (jsad.com)
[7] Patterns of alcohol and drug utilization in trauma patients during the COVID-19 pandemic at six trauma centers | Injury Epidemiology | Full Text (biomedcentral.com)
[8] Patterns of alcohol and drug utilization in trauma patients during the COVID-19 pandemic at six trauma centers | Injury Epidemiology | Full Text (biomedcentral.com)
[9] Brief Report: The Impact of COVID-19 on Emergency Department Overdose Diagnoses and County Overdose Deaths - Shreffler - - The American Journal on Addictions - Wiley Online Library
[10] Nonfatal Opioid Overdoses at an Urban Emergency Department During the COVID-19 Pandemic | Emergency Medicine | JAMA | JAMA Network
[11] Nonfatal Opioid Overdoses at an Urban Emergency Department During the COVID-19 Pandemic | Emergency Medicine | JAMA | JAMA Network
[12] Injury Center | CDC
[13] Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)

and sustain recovery. Researchers have long recognized the strong correlation between stress and substance use, particularly in prompting relapse. Although exposure to stress is a common occurrence for many of us, it is also one of the most powerful triggers for relapse to substance use for people with SUD, even after long periods of abstinence. Notably, there are increased reports of mental distress since the COVID-19 pandemic emerged, including among individuals with no history of mental disorders and among younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers.[14,15,16,17]

SUD and Risk for Serious COVID-19 Illness

SUDs are among the health conditions identified by the CDC as increasing a person's risk for becoming severely ill from COVID-19. Drugs themselves negatively influence human physiology, and data have demonstrated that those who use drugs are more vulnerable to getting infected with SARS-CoV-2, the virus that causes COVID-19 infection, and more vulnerable to worse outcomes; this is especially true for Black people and those with opioid use disorder (OUD).[18,19,20,21]

Chronic cardiovascular or respiratory conditions related to substance use may mediate this higher vulnerability. Because it attacks the lungs, the coronavirus that causes COVID-19 could be an especially serious threat to those who smoke tobacco or marijuana or who vape. Smoking or vaping drugs - including tobacco/nicotine, marijuana, heroin, or crack cocaine - has been shown to worsen chronic lung conditions, which can make a person more likely to get severely ill from COVID-19. People with OUD are also vulnerable because opioids act in the brainstem to slow breathing, increasing risk for long-term damage to the lungs, heart, and brain.[22] This may be among the reasons that people with OUD are more susceptible to COVID-19, and their illness may be more severe. In addition, the use of stimulants such as cocaine, methamphetamine, and amphetamine constricts the blood vessels and may increase the risk for stroke, heart attacks, abnormal heart rhythm, seizures, and other conditions that may lead to more severe heart or lung damage in someone with COVID-19.[23]

Importance of Vaccination for People with SUD

Due to the compounding injurious effects of COVID-19 and SUD, it is especially important that people who use or have an addiction to drugs become vaccinated. As individuals with SUD are also more likely to experience homelessness or incarceration than those in the general population, they may face circumstances that pose additional unique challenges regarding COVID-19 transmission. Nevertheless, fears around vaccines and misinformation are preventing many people from taking the potentially life-saving measure of getting vaccinated. Reasons cited include distrust of the government, wariness about

[14] Mental Health - Household Pulse Survey - COVID-19 (cdc.gov)
[15] Early Release of Selected Mental Health Estimates Based on Data from the January–June 2019 National Health Interview Survey (cdc.gov)
[16] Mental distress during the COVID-19 pandemic among US adults without a pre-existing mental health condition: Findings from American trend panel survey - ScienceDirect
[17] Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020 | MMWR (cdc.gov)
[18] COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States | Molecular Psychiatry (nature.com)
[19] :: JKMS :: Journal of Korean Medical Science
[20] Association of substance use disorders and drug overdose with adverse COVID-19 outcomes in New York City: January–October 2020 (nih.gov)
[21] The Impact of Substance Use Disorder on COVID-19 Outcomes | Psychiatric Services (psychiatryonline.org)
[22] Mechanisms of fatal opioid overdose - PubMed (nih.gov)
[23] Mechanisms of fatal opioid overdose - PubMed (nih.gov)

the rapidity with which vaccines were developed, and skepticism about being at higher risk.[24] Vaccine hesitancy could be a particular problem for people who may have experienced previous mistreatment in healthcare settings due to their drug use. Because people with a history of experiencing stigma from the healthcare system due to an addiction may be hesitant, community leaders, healthcare providers, and others in the community must play a role in encouraging and facilitating vaccination for people who use drugs. As trusted messengers, health professionals are in the best position to help patients understand vaccine safety and the many important benefits of becoming vaccinated.[25]

Effects of the COVID-19 Pandemic on SUD Treatment

Treatment Policy Changes

While the COVID-19 pandemic has presented enormous challenges for people with SUD, the altered realities of healthcare have created both barriers to SUD treatment as well as opportunities to reach more people with services and to potentially increase the reach of recovery support systems. There are many anecdotal reports of people with SUDs having to wait longer to obtain treatment as centers had to reduce in-person services in response to social distancing policies. There are reasons to expect that lower-income people and minorities could be especially affected; despite implementing widespread COVID-19 testing, community health centers, which predominantly serve disadvantaged populations, have seen declines in patient visits and have experienced staffing problems.[26] The good news is that pandemic-related policy changes facilitating telehealth and expanding access to medications for OUD may help ameliorate these problems. During the COVID-19 public health emergency, people with OUD can now begin treatment with buprenorphine with a telehealth appointment rather than the initial in-person doctor visit that was previously required. In addition, methadone treatment previously mandated daily supervised dosing with tightly controlled take-home options, but patients deemed stable may now obtain 28 days of take-home doses; others may receive 14 days of doses. Changes to Medicare and Medicaid rules are also enabling telemedicine consultations for SUD to be reimbursed more easily. These developments may particularly benefit people who live in rural areas or who otherwise have had trouble accessing treatment in the past.

Racial Inequities

The COVID-19 pandemic has also highlighted the large racial health disparities in the United States. Black Americans have experienced worse outcomes during the pandemic, continue to die at a greater rate than white Americans, and also suffer disproportionately from a wide range of other acute and chronic illnesses.[27,28.29] These disparities are particularly stark in the field of addiction, where entrenched punitive approaches have exacerbated stigma and made it hard to implement appropriate medical care. Abundant data show that Black people and other communities of color have been disproportionately harmed by decades of addressing drug use as a crime rather than as a matter of public health.[30] Not only does incarceration fail to address SUD treatment needs, but congregate settings increase risk for COVID-19 transmission and other harms.[31]

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[24] Trust in a COVID-19 vaccine among people with substance use disorders (nih.gov)
[25] Safety of COVID-19 Vaccines | CDC
[26] Impact of Coronavirus on Community Health Centers | KFF
[27] Racism and Health | Health Equity | CDC
[28] Racial Disparities in COVID-19 Testing and Outcomes : Retrospective Cohort Study in an Integrated Health System - PubMed (nih.gov)
[29] National Disparities in COVID-19 Outcomes between Black and White Americans - PubMed (nih.gov)
[30] Examining Racial Disparities in Drug Arrests: Justice Quarterly: Vol 32, No 2 (tandfonline.com)
[31] Release from Prison — A High Risk of Death for Former Inmates | NEJM

NIDA Research Addressing SUD and Overdose

For the past nearly five decades, NIDA-supported research has led to the development of effective prevention and treatment interventions for SUD, providing hope for the more than 20 million people in the United States diagnosed with SUD and their loved ones. Although significant strides in establishing-evidence-based practices have been made, there is far more work to be done to develop new prevention and treatment interventions and to implement existing effective interventions with fidelity, for diverse populations, and at scale. In particular, developing strategies to prevent and treat opioid and stimulant use, addiction, and overdose will continue to be key priorities for NIDA.

Prevention

Preventing the initiation of substance use and minimizing the risks of harmful consequences are essential components of addressing SUD. NIDA prevention research aims to understand and intervene upon risk and resilience mechanisms for addiction and common comorbidities. Under the Helping to End Addiction Long Term℠ or HEAL Initiative℠, NIDA leads prevention research aimed at adolescent and young adult populations that are at highest risk for opioid misuse and OUD.[32] Goals of the program include preventing individuals with low-severity OUD from developing a more serious OUD; building strategies to keep people in medication treatment for opioid addiction; understanding the role of sleep dysfunction in OUD and recovery; stopping at-risk adolescents from developing OUD; and exploring collaborative care for people with OUD and mental health conditions. Seven pilot studies were completed and are continuing across a variety of prevention strategies including: modifying an existing alcohol and drug prevention intervention designed for American Indian/Alaska Native (AI/AN) youth to be appropriate for opioid prevention in young adults; preventing OUD among homeless adolescents/young adults ages 18-24 years, exploring whether providing housing in addition to opioid and related risk reduction services could improve outcomes; and leveraging technology that is appealing to adolescents and young adults to facilitate delivery of an emergency-department-based intervention via health coaches. Preventing harms related to substance use is another critical priority and includes strategies to prevent overdose and other medical consequences of substance use such as infectious diseases.

Medication Development

Developing effective medications for SUDs is one of our highest priorities and is critical to improving treatment for people with addiction. While effective medications exist for OUD, these medications are underutilized. Suboptimal patient retention in treatment regimens, policy barriers that limit opioid prescribing, and stigma around opioid agonist medications all contribute to their underutilization. More options are needed to help people with OUD achieve long-term recovery. Under the HEAL Initiative, NIDA is supporting research on medications development for OUD and overdose. Since HEAL began, 16 Investigational New Drug applications were filed with the FDA and authorized for human studies. These studies focus on a variety of drug targets, as well as vaccines that could prevent opioids from entering the brain. Others are repurposing existing medications for OUD indications, such as the FDA-approved insomnia medication, suvorexant, based on known overlaps between brain signaling systems involved in sleep and addiction. We are also prioritizing the development of medications to treat stimulant use disorders for which there are currently no FDA-approved medications. Numerous compounds are being tested and approaches span novel biological targets for new medications, to anti-cocaine and anti-meth vaccines, to the repurposing of existing medications. The recently completed Accelerated Development

[32] Preventing At-Risk Adolescents from Developing Opioid Use Disorder | NIH HEAL Initiative

of Additive Pharmacology Treatment (ADAPT-2) trial demonstrated that bupropion (used to treat depression) plus naltrexone (used to treat OUD) was effective for reducing methamphetamine use and craving in individuals with moderate to severe methamphetamine use disorder. We continue to place a high priority on medications development for SUD, including new and improved overdose reversal medications, particularly those that are effective for opioid overdoses involving other drugs such as methamphetamine. More coordinated and targeted approaches to incentivize drug development related to addiction are sorely needed. The pharmaceutical industry has historically underinvested in research and development of addiction treatments, due to the biological complexity of this disorder, the stigma that surrounds it, and concerns around the profitability potential of the market for addiction medications.

Translating Research into Practice in Diverse Settings

Effective provision of prevention and treatment services across health care, justice, and community settings is key to addressing SUD and is the most promising way to improve access to treatment. NIDA places a high priority on implementation research in diverse settings, providing major infrastructure through our Clinical Trials Network (CTN) in healthcare settings, Justice Community Opioid Innovation Network (JCOIN) in justice settings, and HEALing Communities Study (HCS) in community settings.

Clinical Trials Network

NIDA's CTN allows medical and specialty treatment providers, treatment researchers, patients, and NIDA to cooperatively develop, validate, refine, and deliver new treatment options to patients. The CTN comprises 16 research nodes across the country in academic medical centers and large health care networks, and more than 240 community-anchored treatment programs. This unique partnership enables the CTN to conduct studies of behavioral, pharmacological, and integrated treatment interventions in multisite clinical trials to determine effectiveness across a broad range of settings and populations, including hard-to-reach rural settings. The CTN is conducting studies to evaluate strategies for integrating OUD screening and treatment into emergency departments, primary care clinics, infectious disease programs and rural and AI/AN communities. It also tests alternative models of care for SUD such as the use of pharmacies for delivering medication for OUD and the integration of telehealth for support of treatment. The CTN also supports research based on data relevant to SUD by taking advantage of electronic health record (EHR) systems. It is currently developing and testing a clinical decision support tool that integrates with EHR systems to help doctors diagnose OUD and provide treatment or refer patients to appropriate care. The primary goal of CTN is to bridge the gap between the science of drug treatment and its practice, through the study of evidence-based interventions in real world settings.

Justice Community Opioid Innovation Network

NIDA's JCOIN, which is part of NIH HEAL initiative, is testing strategies to expand effective OUD treatment and care for people in justice settings in partnership with local and state justice systems and community-based treatment providers.[33] JCOIN includes a national survey of addiction treatment delivery services within the justice system; studies on the effectiveness and adoption of new medications, prevention and treatment interventions, and technologies; and use of existing data sources in novel ways to understand care in justice populations. Together, these studies are generating real-world evidence to address the unique needs of individuals with OUD in justice settings. JCOIN also

[33] Justice Community Opioid Innovation Network | NIH HEAL Initiative

responded in real time to the COVID-19 pandemic with additional research to study COVID testing protocols in justice-involved populations.

HEALing Communities Study

The HEALing Communities Study, also part of the HEAL Initiative, is a multisite implementation research study investigating coordinated approaches for deploying evidence-based strategies to prevent and treat opioid misuse and OUD tailored to the needs of local communities. Research sites are partnering with 67 communities highly affected by the opioid crisis in four states to measure the impact of these efforts.[34] The ambitious goal of the study is to reduce opioid-related overdose deaths by 40 percent over three years. Despite the impacts of COVID-19 on research, the HEALing Communities study was able to launch a key aspect of its program, a diverse communications campaign to increase awareness and demand for evidence-based practices and to reduce stigma against people with OUD and those taking medications for OUD.[35]

Driving Solutions through Technological Innovation

NIDA leverages the federal government's small business innovation research (SBIR) and small business technology transfer (STTR) programs and other funding mechanisms to help biotech startups develop innovative technologies that translate addiction science into healthcare and consumer products. These tools help provide more timely information about substance use in communities, connect people to care, provide or support treatment, help individuals sustain their recovery from SUDs, and even facilitate overdose prevention. For example, wastewater-based epidemiology is a novel approach being used to study substance exposure at the community level in order to help public health officials better understand and respond to the current opioid crisis in the United States. In the past, researchers seeking to directly measure opioid exposure were often limited by the fact that they only had access to people who had contact with the health care system; this approach excluded people who use these drugs and have no interaction with the health care system. Now researchers are using this robotic technology to sample both substances and SARS-Cov-2 in wastewater from municipal sewers. Other products deliver evidence-based therapies to people with SUDs in novel ways. For example, a smartphone app originally designed to connect patients to open acute care beds has been adapted to facilitate referrals to addiction treatment facilities and is currently being used by several state governments and hospital systems. NIDA has also helped small businesses develop tools that put evidence-based psychosocial treatment for SUDs right in the hands of anyone with a smartphone. For example, reSET and reSET-O are apps that deliver cognitive behavioral therapy (CBT) and contingency management (i.e., reinforcement) to people with non-opioid SUDs (reSET) and OUD (reSET-O), and were the first mobile medical applications, "digital medicines," to receive FDA approval for the treatment of addiction. A NIDA SBIR grant is now being used to make these apps more accessible by converting them into a game. To prevent overdose, another app turns a user's smartphone into a portable respiratory monitor capable of detecting changes in breathing associated with an overdose, sounding an alarm and alerting emergency services. Other apps help doctors and patients monitor and maintain their OUD medication, and connect individuals to behavioral therapies, peer support groups, and community interventions. In addition, NIDA supports the development of entirely novel technologies. One is a hospital bassinet pad that applies gentle vibrations to soothe babies born dependent on opioids, which is currently seeking FDA approval. Another technology uses virtual reality as an alternative form of pain relief to opioids. These

[34] HEALing Communities Study | NIH HEAL Initiative
[35] Introduction to the special issue on the HEALing Communities Study - PubMed (nih.gov)

and other innovative products demonstrate that pairing sound science with biotechnology entrepreneurship has great potential benefit for our underserved patient population.

NIDA Research on the Intersection of SUD and COVID-19

In March 2020, NIDA responded to the urgent research need posed by the pandemic by issuing a Notice of Special Interest to solicit research at the intersection of COVID-19 and substance use. We've funded more than 100 supplemental research studies under this announcement, which was renewed this year. One of the areas of research NIDA is prioritizing is to understand how changes in healthcare policies implemented due to the pandemic, such as telehealth expansion and changes in the methadone take-home dose policy, have affected addiction treatment access and outcomes. Recognizing that many people with SUDs do not have computers or smartphones, NIDA is also focusing on other innovative methods, such as combining telemedicine with street outreach to help ensure that all people receive the care they need.

Through supplements to the HEALthy Brain and Child Development (HBCD) and Adolescent Brain Cognitive Development (ABCD) studies, we have been able to capitalize on existing infrastructure for longitudinal studies to examine the impact of COVID-19 on child development. HBCD, part of the HEAL Initiative, will add to our understanding of early brain development trajectories from the prenatal period through ages 9-10 by determining how environmental factors, including maternal drug exposure, substance use, and COVID-19 influence early brain development and clinical outcomes such as mental illnesses and addiction. ABCD is following nearly 12,000 children from age 9-10 through the subsequent decade, a period likely to capture the initiation of substance use behaviors. This study will determine how childhood experiences interact to affect brain development and social, behavioral, academic, and health outcomes, including substance use and COVID-19. Together, these studies will lead to a better understanding of typical brain and cognitive development and how they are affected by drugs and other environmental exposures.

NIDA is also pleased to be participating in several of the large trans-NIH COVID-19 initiatives made possible with the generous support of Congress. For example, NIDA is participating in the Rapid Acceleration of Diagnostics Underserved Populations, or RADx-UP, Initiative, which aims to expand COVID-19 testing among underserved and medically and/or socially vulnerable populations; NIDA has ensured that people with SUD are recognized as one such population and are included in this research. We are also leading a program under the RADx-Radical initiative to accelerate methods for detecting SARS-CoV-2 in wastewater as a means of improving community-level surveillance of the virus. This project takes advantage of knowledge and expertise NIDA has developed through research on wastewater surveillance of drug use.

Building Partnerships

Partnerships are critical for NIDA research to make a positive impact on public health. NIDA's commitment to synergistic cooperation takes many different forms, designed to better respond to emergent issues or chronic needs in the public health arena. This includes working with a wide range of partners including state and local governments; sister agencies within the Department of Health and Human Services such as SAMHSA, FDA, and CDC; the Department of Justice; the White House Office on National Drug Control Policy (ONDCP); and with private industry.

Some of the largest projects under the HEAL initiative rely on such collaboration. The HEALing Communities Study is led by NIDA in close partnership with SAMHSA to ensure that this research is best poised to impact service delivery toward ameliorating the opioid crisis in hard hit areas. JCOIN fosters collaboration between investigators, justice, and behavioral health stakeholders in search of creative ways for improving the capacity of the justice system to respond to the opioid crisis. Similarly, our work on medication development aims to de-risk promising compounds so that the pharmaceutical industry can develop them into products and obtain their approval for clinical use.

Along with ongoing collaboration to improve the medication treatment development process, NIDA and FDA work closely together on the Population Assessment of Tobacco and Health (PATH) Study, a nationally representative longitudinal study of tobacco use and health in the United States. By following study participants over time, the PATH Study helps scientists learn how and why people start using tobacco products, quit using them, and start using them again after they've quit, as well as how different tobacco products affect health outcomes, such as cardiovascular and respiratory health, over time. Findings from this study and others inform FDA's regulatory actions. For example, results from NIDA's Monitoring the Future study revealed that a large proportion of teens vaped because they liked the taste which prompted the FDA to finalize their enforcement policy on flavored vaping (e-cigarette) products.[36]

In addition to these specific research examples, NIDA partners with agencies across HHS to ensure that research findings are effectively communicated to support evidence-based policymaking. Ongoing NIDA projects, along with the existing evidence base, support the development of HHS's coordinated overdose prevention strategy and the development of ONDCP's National Drug Control Strategy.[37] These collaborations provide valuable and complementary perspectives and infrastructures that NIDA leverages to maximize potential benefit for the populations we serve.

Conclusion

The COVID-19 pandemic has upended every facet of our society and exacerbated the ongoing public health crisis of drug addiction and overdose. As our nation continues to grapple with the pandemic, we must preserve a laser focus on effective prevention and quality treatment of addiction, and enhanced support of people in recovery. NIDA appreciates the support of Congress for our mission, and NIDA research will continue to pursue scientific solutions to the addiction and overdose crisis as it has evolved due to COVID-19.

[36] FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint | FDA

[37] ONDCP Releases 2020 National Drug Control Strategy and Rural Toolkit - Capitol Connector (thenationalcouncil.org)

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Written Testimony of Nicole Alexander-Scott, MD, MPH to the Senate Caucus on International Narcotics Control
July 20, 2021

Thank you for the opportunity to participate in this hearing of the Senate Caucus on International Narcotics Control. Thank you as well to Caucus Chair Senator Sheldon Whitehouse, for his strong leadership nationally and in Rhode Island in ensuring that our response to the addiction and overdose crisis remains rooted in public health.

Rhode Island Background
For the past six years, Rhode Island has been experiencing an addiction epidemic. Our overdose deaths increased from 290 in 2015 to 336 in 2016, and then, with decisive action from our cross-agency overdose response team in Rhode Island, decreased 8.3% to 308 in 2019. However, as COVID-19 began to ravage our state, overdose deaths rose again, back up to 384 in 2020 with a 25% increase compared to 2019, resulting in a syndemic – a pandemic and an epidemic being experienced by our simultaneously, each exacerbated by the other.

At the end of 2020, we carried out an Evidence Update and Strategic Program Review and determined that the rising number of deaths was driven by increases in the use of illicit, potent fentanyl, from COVID-19 social isolation, and from untreated behavioral health conditions, and by structural racism.

These deaths are not just numbers. Each one represents a beloved Rhode Islander – a parent, a child, a brother, sister, or friend. And so, our drive to address the addiction and drug overdose crisis is personal to us. We have a commitment to do whatever we can to enhance existing prevention, treatment, recovery, and harm reduction strategies with the aim of preventing overdoses and saving lives.

Our commitment is based on the data. We track all the components of the addiction and overdose crisis using multiple surveillance systems. These data inform the development of all of our policies, as does our use of a race equity lens, to ensure that our work addresses structural racism and health disparities.

We rely on subject matter experts throughout the state, from our academic partners at Brown University and other institutes of higher education, to our physicians and behavioral health providers, to the professionals who carry out street outreach, talking to the people grappling with the addiction crisis in homeless shelters, bus stops, and other locations in the community. And most importantly, we talk to Rhode Islanders with lived experience – people who are using drugs, and their family members, who can give us the most insight on how to address the syndemic. We have evolved our strategic

plans as the crisis has changed, and we're very pleased to be able to share this information with your Senate Caucus today.

Governor's Overdose Prevention and Intervention Task Force

Governor McKee's Overdose Prevention and Intervention Task Force is a coalition of professionals and community members statewide with the goal of preventing overdoses and saving lives. The Governor's Task Force was developed in 2015. The group of diverse stakeholders is the driving force behind Rhode Island's life-saving efforts. In July 2017, then-Governor Gina M. Raimondo signed an Executive Order that enhanced the existing core strategies of prevention, treatment, rescue, and recovery within the Task Force's Action Plan.

The structure of the Task Force is a key component of its success. It is an interagency body, with participation from throughout State government. Co-Chaired by the Directors of the Rhode Island Department of Health (RIDOH) and the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities, and Hospitals (BHDDH), its membership includes representation from other agencies throughout the Rhode Island Executive Office of Health and Human Services (including the Office of Veterans Affairs) as well as the Rhode Island Department of Labor and Training and the Rhode Island Department of Corrections. Each of the Task Force Work Groups includes both public and private members, and focuses on recruiting diverse memberships. Work Groups are led by two chairs a community member and a State agency leader. We also encourage the recruitment of family and community members for the Work Groups and a broad range of experts, as noted above.

Task Force's Accomplishments

Prevention:

- One key focus for the Task Force's Prevention Work Group has been changing prescribing practices to decrease the number of Rhode Islanders receiving opioid prescription pain medications and benzodiazepines. For example, the number of people receiving new opioid prescriptions reduced from 41,820 in the first quarter of 2017 to 26,025 in the first quarter of 2021 and the number of overall opioid prescriptions prescribed in the same time period was reduced from 153,025 to 103,228, a reduction of 33%. The ability to track these data came from Rhode Island's implementation of our Prescription Drug Monitoring Program, supported by Congressional funds.
- Rhode Island also pursues prevention programs within our Recovery-Friendly Workplace Initiative activities. Led by Governor Dan McKee, Rhode Island's "Recovery Friendly Workplace Initiative" promotes individual wellness for Ocean Staters by empowering workplaces to provide support for people recovering from substance use disorder.
- Our Regional Prevention Coalitions and our Health Equity Zones (HEZ) Initiative bring prevention activities to local communities. Rhode Island Regional Coalitions strive to create a community that encourages healthy lifestyle choices and a deeper understanding of the complexities of mental health and substance use. HEZs encourage and equip neighbors and community partners to collaborate to create healthy places for people to live, learn, work, and play. By addressing these social determinants of health, HEZs help families prevention addiction. Both the Rhode Island Regional Prevention

Coalitions and HEZs lead statewide efforts to educate the public about the importance of safely storing and disposing of all medicines, especially opioid prescription pain medications.

- And our Community Overdose Engagement (CODE) project uses overdose-related data to help local communities address dangerous increases in overdoses at the local level. RIDOH and BHDDH use 48-Hour Opioid Overdose Reporting System data to alert stakeholders of increased overdose activity within a region and send "Public Health Advisories" to educate stakeholders about overdose prevention and harm reduction resources across the state t so that they are empowered to reach out and help prevent additional overdoses.

Treatment:

- One major treatment focus has been to increase the number of people receiving Medication Assisted Treatment (MAT). Medication Assisted Treatment is an evidence-based approach for opioid addiction that reduces the risk of death, relapse, and incarceration and is most effective as a long-term treatment.
- Rhode Island's goal was to increase the number of physicians trained and waivered to prescribe some of the most effective treatments, and we have been successful. Buprenorphine treatment capacity in Rhode Island has more than doubled since 2014. In the first quarter of 2017, we had 308 trained and DATA-waivered practitioners and in the first quarter of 2021, we now have 635.
- In April2020, during COVID-19, Rhode Island launched a new 24/7 telehealth buprenorphine hotline to connect individuals to healthcare providers who can conduct a health evaluation and prescribe buprenorphine over the phone.
- Rhode Island believes that it is critical to meet people where they are at and find ways to engage individuals we have not engaged before. To that end, BHDDH is also working to duplicate Connecticut's successful Imani Breakthrough Recovery Project, to collaborate with faith-based communities and enhance connections with more diverse populations. This faith-based recovery initiative takes place in houses of worship and is designed to be culturally, spiritually, and trauma-informed, to assist individuals recovering from opioid use and other substance use conditions.

Harm Reduction:

- Rhode Island understands that there are some people who are not yet ready for treatment, and so we believe it is critical that we help provide services and supports to help save their lives.
- In December 2020, Rhode Island launched the 10,000 Chances Project, a statewide initiative to get more than 10,000 intranasal naloxone kits into the hands of Rhode Islanders at risk of overdose, as well as their loved ones. Eligible non-profit organizations received $5,000 grants to support naloxone distribution efforts. Priority was given to applicants that distributed naloxone kits to individuals at high risk of overdose and families and friends of people who are at risk. A multi-channel public awareness campaign in English and Spanish was launched in parallel to this statewide initiative, leveraging social media, television, radio, and community-level messaging to deliver harm reduction messaging.

AIDS Care Ocean State's ENCORE Needle Exchange Program is the state's long-standing, harm reduction organization and only needle exchange program. ENCORE's goal is to reduce the risk of HIV transmission among injecting drug users (IDUs), through counseling, HIV prevention and education, and referrals to substance use treatment and

Testimony Provided by Steve Gurdak

Senate Caucus on International Narcotics Control
"The Federal Response to Changing the Drug Overdose Epidemic"
July 20, 2021

Chairman Whitehouse, Ranking Member Grassley, and other distinguished members of the Senate Caucus on International Narcotics Control, I am honored to appear before you to discuss my assessment of the emerging drug threats and money laundering techniques used by drug traffickers and money launderers, including how those threats and techniques have changed as a result of the COVID-19 pandemic.

My position as an initiative supervisor for the Washington/Baltimore High Intensity Drug Trafficking Area Program for 12 years has offered me the unique opportunity to meet, collaborate, consult, and associate with many of the top anti-money laundering (AML) experts in both the public and private sectors. A number of these experts have appeared before congressional caucuses and committees much like this one. Some even helped craft the Bank Secrecy Act (BSA), and its recent amendments through the Anti-Money Laundering Act of 2020 (AMLA2020).

Officially, I may only be able to speak for my W/B HIDTA initiative, known as the Northern Virginia Financial Initiative, or the NVFI. The NVFI; however, has created a network and reputation known far and wide for its innovations in anti-money laundering and narcotics trafficking investigations. It was created through consultation with many of those AML experts I mentioned with the goal of "testing the system" the BSA put in place. The logistics, innovation, and latitude the W/B HIDTA has provided in allowing the NVFI members to aggressively use and test the attributes of the BSA is probably why I'm here today. Additionally, we have benefitted from the incredible support of prosecutors at the U.S. Attorney's Office for the Eastern District of Virginia (EDVA) in those endeavors.

The statistical and empirical data I am presenting is primarily derived from the *W/B HIDTA's Threat Assessment for Program Year 2022*, and the rest of my testimony is based on knowledge acquired through my reaching out and sharing information with various experts, as part of my job and my passion.

I. The Drug Nexus.

Fentanyl is now the foremost drug threat the country faces. The *W/B HIDTA Threat Assessment* states that both its law enforcement initiative supervisors (61%) and treatment initiative leaders (75%) ranked it the number one drug threat. In my conversations with experts in the field, even that assessment is often described as being understated. Rather, they report that fentanyl is now a common "cutting agent" for nearly all the other dangerous drugs, even including marijuana. It is also now commonly used as part of growing counterfeit prescription pill market. Fentanyl is also ranked highest by all in the threat of violence associated with the distribution of it.

Despite the trend towards legalization and decriminalization, several of my law enforcement sources have expressed a concern about the increase in violence associated with marijuana trafficking. Further, 33 percent of the law enforcement officials surveyed for the *W/B HIDTA Threat Assessment* reported that marijuana was considered to be a major contributor to community problems. Although this might

initially seem surprising, it may be attributed to more dealers entering the market who no longer fear law enforcement, but are confronting more threats from increased competition.

The W/B HIDTA Threat Assessment reported that the availability of nearly all major illicit drugs seem to have remained constant, but prices did increase during COVID-19. It noted the emergence of the drugs Xylazine, a veterinary sedative for large animals, and Eutylone, a synthetic stimulant that is considered to be a "designer drug." Eutylone started becoming widespread with the ban on the compound ethylene. Concerningly, yet not surprisingly, the *W/B HIDTA Threat Assessment* cited information that both of these emerging drugs are being mixed with fentanyl.

According to the *W/B HIDTA Threat Assessment*, Xylazine is commonly used with heroin and fentanyl, and its use increases the risk of overdose. It is also frequently found in combination with heroin and cocaine, which is referred to as a "speedball." Though Narcan can save a person's life who has overdosed on an opioid drug, when Xylazine is used as an adulterant in the opioid the person has taken, it does not respond to the naloxone to reverse its effects because it is not an opioid. There is no known antidote or reversal agent for Xylazine, and users may not even be aware that they are taking it.

On July 14, 2021, the U.S. Centers for Disease Control and Prevention released data showing that there was a 30 percent increase in overdose deaths from all types of drugs in 2020. Officials cited a number of COVID-19 restrictions that resulted in isolation as the reason for this increase.

During the COVID-19 pandemic, drug traffickers changed their distribution methods as a result of the restrictions put in place to contain it. Even before COVID-19 came into existence, drug dealers were using more socially-distanced text messages and holding more clandestine meetings. The emergence of rapid, inexpensive, worldwide shipping and mailing services had already opened international drug markets to nearly anyone with an internet connection. Dark web and foreign internet sources had been replacing many distribution methods, much like Amazon has changed our everyday shopping. The emergence of door-to-door delivery services for food delivery and other businesses also provided ideal cover for mores the localized delivery of drugs and other contraband.

From an enforcement perspective, the most common problem expressed during the COVID-19 restrictions was the ability to meet with prosecutors and the courts to obtain warrants and other legal process documents. Task forces and initiatives like mine that rely on multi-agency collaboration and cooperation also experienced difficulties during COVID-19, as the restrictions were causing confusion in assembling personnel for many enforcement actions.

Finally, the W/B HIDTA Threat Assessment found that drug trafficking organizations (DTOs) commonly distributed/dealt multiple types of drugs. This is similar to what I will note later in my testimony about money laundering organizations (MLOs), which is that MLOs launder funds for a variety of criminal activities.

II. The Money Talks

COVID-19 restrictions and their implications for money launderers created unique opportunities for investigators to re-define normal practices. A key principle in money laundering investigations has been to "define normal" and then to identify activities that are abnormal. Essentially that is what the Bank Secrecy Act (BSA) requires financial institutions to do when they file suspicious activity reports, or SARs. The changes, adjustments, and adaptations to the COVID-19 response required in the legitimate world

have the potential to expose and unmask illicit monies that were not similarly impacted during this time. By way of example, explaining how cash was still flowing in through closed doors created challenges for money launderers, yet it created new opportunities for investigators for better identifying them.

An emerging concern at the cartel or transnational MLO levels is the greater acceptance of cyber currencies, such as bitcoin. Our local SAR review team, the NVFI, is seeing more of a curiosity and experimental use of these cyber currencies. As many money launderers are both inexperienced and relatively unfamiliar in using or trading in these products, their cyber currency activities regularly result in creating easy to investigate money trails that we can disrupt with the use of existing money laundering and financial laws.

There is little doubt that the emergence and use of various peer-to-peer payment systems was accelerated by a need for non-contact financial transactions during the COVID-19 restrictions. We expected that illicit markets would find ways to take advantage of this trend. Just like with cyber currencies, MLOs are quite often inexperienced and unfamiliar with these emerging virtual payment systems. Their errors can readily expose their illicit activities to knowledgeable investigators.

While COVID-19 isolations provided an opportunity and time for investigators to analyze these systems, taking enforcement actions at times also exposed sources and methods. By way of example, cyber specialists described for me communications found on the dark web and other sites different methods that are used to test various systems abilities to avoid law enforcement detection.

One of the virtues touted with these virtual payment systems is the ability to include messages or comments with the transactions. These messages often blatantly included texts and emojis which clearly indicated that they were associated with illicit activities. These messages result in so many SARs that SAR review teams have a difficult time allocating investigative resources to address all of them. By way of example, the NVFI did not review any SARs filed on “Square” payment activities in March 2020. Now, however, we are reviewing over 100 SARS filed monthly since March of 2021. That is just for our isolated area of the Eastern District of VA.

III. Cash is Still King

While virtual and cyber currency seem to draw more attention and headlines, behind the scenes, currency is still king. From FinCEN reports, to the *Wall Street Journal,* and even a recent interview of the CEO of Brinks, all reflected that currency usage has actually increased amid the pandemic, despite the increased use of virtual banking.

FinCEN records reported a 44 percent increase in SAR filings from 2019-2020 for “Transactions Below the Cash Transaction Report (CTR) Threshold.” This activity is more commonly known as “structuring” or “smurfing.” A *Wall Street Journal* report attributed this increase to difficulties in smuggling bulk cash across closed borders and other international COVID travel restrictions. Notably, this type of information is a prime example of the emerging new indicators and intelligence being produced by the Bank Secrecy Act as a result of COVID-19 restrictions.

As a result of COVID-19 restrictions, many financial institutions made policy and procedure changes to better allow for more contactless banking. That included currency transaction levels. While contactless banking makes sense for virus avoidance, it also reduces risk for money launderers. The *W/B HIDTA*

Threat Assessment also reflected "cash structuring" as one of the primary money laundering methods in the Washington/Baltimore HIDTA region.

Earlier this year I consulted and debated with several associates about a December 3rd, 2020 *Reuters* story outlining a concerning emerging money laundering trend of Chinese brokers assisting with laundering money for Mexican drug organizations. However, when I dug deeper into this trend, I viewed it as a large portion of the money originating with multiple cash deposits into otherwise small, community based-businesses. There are opportunities for SAR review teams and other enforcement efforts to interdict or disrupt the currency flow at a grass roots or community level before it reaches the transnational money laundering organization or cartels. As such, one of the key takeaways when I provide training on SAR-based investigations I stress that "SARs don't care about your jurisdiction or specialty."

IV. Summary.

The Bank Secrecy Act, to include the partnership with financial institutions, is providing law enforcement with valuable information and intelligence to combat money laundering and related financial crimes. Properly done, "following the money" rarely fails as an investigative strategy. From that perspective, COVID-19 responses actually provide law enforcement with many new valuable investigative opportunities to better identify the legitimate from the illegitimate. The new normal is exposing money laundering and financial criminal activities. Our challenge is having enough trained investigators to discourage this activity by taking away the financial rewards recognized by successful MLOs.

Key points:

- Fentanyl is now the top drug threat. It is now a common "cutting agent" for nearly all the other dangerous drugs, including marijuana; and is commonly used as part of the growing counterfeit prescription pill market.

- Among law enforcement, there is a perceived increase in violence among marijuana traffickers. This may be attributed to more dealers entering the market who no longer fear law enforcement, but are confronting more threats from increased competition.

- During the COVID-19 pandemic, the availability of nearly all major drugs seem to have remained constant, but prices did increase. Two drugs, Xylazine and Eutylone, have emerged during 2020, and both have been mixed with fentanyl.

- The emergence of rapid, inexpensive, worldwide shipping and mailing services has already opened international drug markets to nearly anyone with an internet connection, and dark web and foreign internet sources have been replacing many traditional distribution methods.

- The use of currency usage has increased amid the pandemic, despite the increased use of virtual banking.

- There has been an almost 50 percent increase in the number of suspicious activity report (SAR) filings from 2019-2020 for "Transactions Below the Cash Transaction Report (CTR) Threshold." This

activity is more commonly known as “structuring” or “smurfing.”

- COVID-19 responses actually provides law enforcement with new, valuable investigative opportunities to better identify legitimate and illegitimate financial transactions. The new normal is exposing money laundering and financial criminal activities. We just need more human resources with proper training to avail ourselves of this opportunity for our country.

I appreciate having this honor to present my testimony to the Caucus. I would be happy to answer any questions or respond to further inquiries from its Members.

Written Submission of Professor Keith Humphreys to the Senate Caucus on International Narcotics Control for July 20, 2021 hearing entitled "The Federal Response to the Drug Overdose Epidemic"

I am grateful to Chairman Whitehouse, Co-Chairman Grassley, and their fellow members of the Senate Drug Policy Caucus for the opportunity to submit testimony related to our nation's tragic crisis of addiction and overdose. My analysis of the crisis reflects my decades of work as an addiction researcher at Stanford University and my experiences serving as a White House drug policy advisor in the Administrations of Presidents Obama and Bush. I focus on five key areas where the federal government can make fundamental improvements in the national response to addiction and overdose in the era of COVID-19.

Invest in State of the Art Data Science

COVID-19 has obviously been traumatic for our country, but it has also shown what our nation and government can do when they make a commitment to respond to a major public health challenge. One concrete indicator of that commitment is that any of us can look on our computer or phone right now and find out exactly how many Americans in every state tested positive for COVID-19 or died of it as recently as 24 hours ago. Contrast that achievement with our decades-long failure to do anything comparable for addiction and overdose. Overdose fatality data from around the country take 6-12 *months* to arrive in Washington. Our current survey tools cannot provide credible estimates of how many Americans use heroin and fentanyl, how many are addicted to these drugs, or what percentage of the addicted population receives treatment.[1] The ADAM program, which was our best source of data on the link between drug use and crime and provided vital information on illicit drug markets, was defunded. Similarly, the White House Office of National Drug Control Policy's capacity to assemble and analyze data on drug epidemics has withered in recent decades.

As a result, Congress and The White House cannot design policy based on the status of the epidemic today because they don't know what it is. Even data that it is only a few years old can be misleading, as we can see in the recent and rapid expansion of fentanyl into the Western United States.[2] Nor can policymakers tell whether new policies are working until years after the fact when the data finally come in. Data collection can seem like a low priority in comparison with providing direct public health and safety services, but without it we are literally blind and lost in the opioid crisis.

Given that technology companies have extraordinary capacity to know about so many domains of American behavior in real time and that the Internet fora with which humans constantly interact produces an avalanche of data on drug use, attitudes, and intentions, this would be an ideal moment for federal drug control officials to partner with the private sector to develop an opioid-related epidemiological monitoring system. It is also a propitious moment to create a national infrastructure in a representative sample of locations regularly monitoring the content of wastewater for the presence of known and emerging drugs. As part of this overall effort, Congress should fund a small team of data scientists at White House ONDCP to integrate all available data sets and to provide timely and user-friendly reporting to state, local, non-profit, and private sector organizations working to address the drug problem. The COVID experience with real-time, accurate data collection shows that if we make the commitment we can develop a system that accurately estimates how many Americans use opioids, how many are addicted to them, and how many are dying from them in a dashboard based on recent data.

Mainstream the Financing of Addiction Treatment

Another success of the U.S. COVID response was how rapidly health services were established within the existing health care system. We would benefit enormously from copying this model in our approach to addicted patients.

The addiction treatment system includes many dedicated staff members and volunteers who save many lives. It is also segregated from the rest of health care, unstably funded, and of inconsistent quality. There are many reasons this is so, but the fundamental one is that addiction treatment is financed differently than the rest of the health care system. My time in the White House convinced me that when funding for addiction-related care is placed in a silo with no connection to mainstream financing mechanisms like Medicaid and Medicare, that same segregation is reflected in American communities, creating a fragmented, difficult to access care system. Quality of care also suffers because addiction treatment has more difficulty attracting skilled providers and is not subject to the more rigorous quality assurance systems of the rest of health care. Put simply, if we want a quality addiction care system that is a seamless, enduring, part of medical practice, we need to finance it adequately through the same mechanisms as everything else in health care. Over the past 15 years, Congress and successive administrations have made strides in this area, but more work remains to be done.

On the public financing side, this can be best accomplished by ensuring that addiction treatment benefits in Medicaid and Medicare are comprehensive in scope and offer adequate reimbursement. This should be the goal whether the benefits are provided by the government directly or a participating private insurer.

On the private financing side, Congress passed "parity" legislation by an overwhelming bipartisan majority in 2008 and expanded it in 2010. It strengthened the law further only 6 months ago (Public Law 116-260). The principle that insurance benefits for addiction and psychiatric problems should be comparable to those for other disorders is settled policy and is also popular with the public. But it is not consistently adhered to in practice. Congress has given the executive branch critical tools to implement the principle of parity and should now provide both the resources and the oversight to ensure these tools are fully utilized. Specifically, the Departments of Labor, Treasury, and HHS should be encouraged to embark on a major campaign of education of insurers, employers, and the public to explain the requirements of the law coupled with stricter enforcement where it is not followed.

Foster an Explicit, Sensible Division of Responsibility Between Law Enforcement and Public Health

COVID-19 has co-occurred with a national debate about the role of police in American life, and both of these forces shape the national response to the worsening opioid epidemic. There is now substantial disagreement and confusion about what role law enforcement should play regarding drugs and what role public health should play. In any complex, multi-sector endeavor – and the response to the opioid crisis is certainly one – confusion and disagreement about who is capable of and responsible to do what substantially lessens the likelihood of success.

The idea, dominant in the 1980s and 1990s, that enough enforcement would suppress drug problems without significant collateral damage, was wrong. Equally wrong is the idea which is getting popular out where I live, namely that if we just get the police out of the way and offer extensive health and human services, the drug problem will wane. Some people who say, correctly, that "We cannot

arrest our way out of drug problems" believe that we can treat our way out of them, which is also untrue. The opioid crisis illustrates this with painful clarity. When supply control is absent, as was the case when the health care system was churning out a quarter billion opioid prescriptions a year, increases in addiction and death always follow no matter how much is spent on health services for addicted people.

One of the most useful things anyone with a platform – certainly including Members of Congress and officials in the Biden Administration – could do is to articulate a clear division of responsibility between law enforcement and health professionals that honored both of their missions, respected their capacities, and did not ask them to do things they cannot do well. This would then have to be matched in policy design and programmatic decisions. The division I would propose goes something like this.

For the individual experiencing addiction and not committing non-drug felonies (e.g., assault), health professionals should be in the lead and law enforcement should be available as backup. Addiction is a legitimate medical disorder to which our first response should be an offer of treatment, not punishment. Yet we still need law enforcement to be available as backup because addicted individuals can pose threats to public safety (e.g., intoxicated driving, family violence) that health professionals cannot handle on their own.

For the production and distribution of illegal drugs, the roles are reversed: Law enforcement is in the lead and health care professionals are available as backup. Disrupting drug trafficking, money laundering, and transnational criminal organizations for whom drugs is just one line of business can only be done by law enforcement. Such enforcement is a major contributor to public safety and to public health. That said, sometimes health care professionals are needed as backup. For example, when the DEA shuts down a pill mill, hundreds of addicted individuals may respond to having their supply of pills cut off by seeking opioids in heroin and fentanyl markets. Coordinated action making treatment immediately available for such individuals can lower the adverse short-term side-effects of disrupting drug supply.

Stop the Opioid Epidemic from Spreading Abroad

COVID-19 has re-taught us the painful lesson that one nation's health problems can spread throughout the globe. One of the global public health tragedies of my lifetime was that as wealthy countries like ours finally started to adequately regulate the tobacco industry, we let them pivot to expanding their business to low and middle income countries, where they have been dealing death ever since. We are at risk of making the same mistake with opioid manufacturers.

Federal officials -- including members of the Senate Drug Policy Caucus – have managed to expose the role in the opioid crisis of people like the Sackler Family and their company Purdue Pharma[3]. Fines have been levied and more are to come, along with constraints on various fraudulent practices that were used to promote opioid drugs like OxyContin in the United States.

However, like the tobacco industry, some opioid manufacturers have now shifted to expanding opioid prescribing abroad. For example, investigative journalists have documented that the Sackler family is expanding opioid markets through a mirror company of Purdue Pharma -- known as Mundipharma -- using the same tactics as they employed in the U.S. In an ongoing criminal investigation in Italy for example, two Mundipharma executives have been sentenced for involvement

with a leading physician who promoted opioids allegedly in exchange for laundered large cash payments from Mundipharma and another opioid manufacturer.[4]

Most of opioid manufacturers' expansion efforts are targeted at developing nations. Among the countries where Mundipharma is attempting to promote OxyContin for example, according to a *Los Angeles Times* investigation, are Brazil, China, Colombia, Egypt, Mexico, and The Philippines.[5] Investigative journalists at The Guardian document that Mundipharma is one of many Western companies promoting opioids in India using tactics pioneered in North America.[6]

We have a responsibility to our friends around the world to not be satisfied simply by bringing our own prescription opioid problems under control. I urge the caucus to investigate the international activities of U.S. opioid manufacturers, to warn our allies against their conduct, and to do everything possible to ensure that constraints on fraudulent and corrupt practices apply not only in our own country, but in other countries in which these corporations are active.

Rethink Drug Policy in Light of the Increasing Prevalence of Synthetic Drugs

The increasing availability of fentanyl and of methamphetamine are only the two most prominent demonstrations that global illicit drug markets are increasingly able to produce drugs that are entirely synthetic, meaning their production is not dependent on agriculture. The advantages to traffickers of not having to grow drug-producing plants in politically volatile regions and secure peasant labor to farm them are enormous. Eliminating the risks of drought, crop blight, and bulk shipment interdiction are also attractive to drug traffickers. These economic advantages of synthetic drugs, coupled with the Internet spreading the needed information and technology to synthesize drugs, and facilitating their covert purchase, raise questions about the basic assumptions of global drug control strategies.[7]

As drug production moves increasingly from something that depends on agriculture to something that any chemist can accomplish in their sink, some long-standing policies and programs have diminishing returns, e.g., trying to reduce drug crops in poor countries through eradication or alternative livelihood programs. Transnational drug trafficking itself may also diminish as domestic retail sellers can make their own drugs rather than rely on large criminal organizations to import them in bulk. This has substantial implications for where law enforcement directs energy, including on our strategy for border control.

I can't predict all the ways the expansion of synthetic drugs will change drug use, addiction, and drug policy, but I am quite sure it's enormously important. I have some ideas about how to proceed and so do some other people in the field, but fundamentally this change is so profound that we can be safe in saying that any one person who thinks they have a simple answer is wrong. Dealing with this new world is going to take sustained thought, study, and discussion. If the Senate Caucus on International Narcotics Control wishes to use its convening power to lead that process, I know I am only one of many drug policy analysts who would be pleased to assist it in formulating an approach to drug policy that measures up to the challenges posed by synthetic production.

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