

AN EPIDEMIC WITHIN A PANDEMIC: UNDER-
STANDING SUBSTANCE USE AND MISUSE IN
AMERICA

VIRTUAL HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

APRIL 14, 2021

Serial No. 117-20



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H.R. 1384, the Mainstreaming Addiction Treatment Act of 2021, submitted by Ms. Esho ¹
H.R. 1910, the Federal Initiative to Guarantee Health by Targeting Fentanyl Act, submitted by Ms. Eshoo ¹
H.R. 2051, the Methamphetamine Response Act, submitted by Ms. Eshoo ¹
H.R. 2067, the Medication Access and Training Expansion Act, submitted by Ms. Eshoo ¹
H.R. 2355, the Opioid Prescription Verification Act, submitted by Ms. Eshoo ¹

¹The proposed legislation has been retained in committee files and is available at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=111439>.

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¹ The proposed legislation has been retained in committee files and is available at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=111439>.

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²The report has been retained in committee files and is available at <https://docs.house.gov/meetings/IF/IF14/20210414/111439/HHRG-117-IF14-20210414-SD021.pdf>.

AN EPIDEMIC WITHIN A PANDEMIC: UNDERSTANDING SUBSTANCE USE AND MISUSE IN AMERICA

WEDNESDAY, APRIL 14, 2021

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:29 a.m., via Cisco Webex online video conferencing, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Members present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Cárdenas, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio), Guthrie (subcommittee ranking member), Upton, Burgess, Griffith, Bilirakis, Long, Bucshon, Mullin, Hudson, Carter, Dunn, Curtis, Joyce, and Rodgers (ex officio).

Also present: Representatives Tonko, O'Halleran, and Latta.

Staff present: Joe Banez, Professional Staff Member; Jeffrey C. Carroll, Staff Director; Waverly Gordon, General Counsel; Tiffany Guarascio, Deputy Staff Director; Perry Hamilton, Clerk; Mackenzie Kuhl, Digital Assistant; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Chloe Rodriguez, Clerk; Kimberlee Trzeciak, Chief Health Advisor; Caroline Wood, Staff Assistant; C.J. Young, Deputy Communications Director; Sarah Burke, Minority Deputy Staff Director; Theresa Gambo, Minority Financial and Office Administrator; Grace Graham, Minority Chief Counsel, Health; Caleb Graff, Minority Deputy Chief Counsel, Health; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Olivia Shields, Minority Communications Director; Michael Taggart, Minority Policy Director; and Everett Winnick, Minority Director of Information Technology.

Ms. ESHOO. The Subcommittee on Health will now come to order. And due to the COVID-19, today's hearing is being held remotely. All Members and witnesses will be participating via video conferencing.

As part of our hearing, microphones will be set on mute to eliminate background noise. Members and witnesses need to remember to unmute your microphone each time you wish to speak. Docu-

ments for the record should be sent to Meghan Mullen at the email address that we provided to your staff, and all documents will be entered into the record at the conclusion of the hearing.

The Chair now recognizes herself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

According to recently reported data from the CDC, overdose deaths spiked after the start of the pandemic. From September 2019 through August 2020, there were over 88,000 overdose deaths, with 2020 being the deadliest year for overdoses on record. These are really stunning numbers. So we are in an addiction crisis during a COVID crisis.

In 2016 Congress passed the 21st Century Act and CARRA, CARRA, and the SUPPORT Act in 2018 to stem the tide of addiction and the devastation that the opioid crisis has created. Congress also provided over \$8 billion—with a B—to address opioid use and mental and behavioral healthcare through the American Rescue Plan in the fiscal year 2021 Appropriations Act.

Yet despite our legislative efforts to increase access to evidence-based treatment, according to a National Academies of Science report, more than 80 percent of the 2 million people with opioid use disorder are not receiving medication-assisted treatment.

Today we are going to hear from the Acting Director of the Office of National Drug Control Policy about where and why previous efforts have fallen short and what the Biden-Harris administration believes we need to do to save lives.

We will also consider 11 bills, many bipartisan, to address the opioid crisis. According to the CDC, three in five people who died from overdose had an identified opportunity for care or other life-saving actions.

And we know that Representative Tonko and Trahan's bipartisan bills will ensure more doctors are trained and able to prescribe the medication-assisted treatment that we know saves lives.

Those who are released from prisons and jails are 12 times more likely to die of an overdose than the general public, because they often have no access to treatment upon release. The bipartisan Medicaid Reentry Act addresses these inequities by extending Medicaid eligibility to incarcerated individuals 30 days before release.

And lastly, we are considering bills to address the upcoming expiration of the temporary placement of all fentanyl-related substances in schedule I. Despite the temporary scheduling, deaths from fentanyl analogues rose by 10 percent. So clearly, scheduling is not the silver bullet and Congress has to consider alternatives to stop synthetic opioids.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

According to recently reported data from the CDC, overdose deaths spiked after the start of the pandemic. From September 2019 through August 2020, there were over 88,000 overdose deaths, with 2020 being the deadliest year for overdoses on record. We're in an addiction crisis amid the COVID-19 crisis.

In 2016 Congress passed the 21st Century Cures Act and CARA, and the SUPPORT Act in 2018 to stem the tide of addiction and devastation that the opioid crisis has created. Congress also provided over \$8 billion to address opioid use and mental and behavioral healthcare through the American Rescue Plan and the FY 2021 Appropriations Act.

Yet, despite our legislative efforts to increase access to evidence-based treatment, according to a National Academies of Science report, more than 80 percent of the 2 million people with opioid use disorder are not receiving medication-assisted treatment.

Today we will hear from Acting Director of the Office of National Drug Control Policy (ONDCP) about where and why previous efforts have fallen short, and what the Biden-Harris administration believes we need to do to save lives.

We'll also consider 11 bills, many bipartisan, to address the opioid crisis. According to the CDC, 3 in 5 people who died from overdose had an identified opportunity for care or other life-saving actions.

Representative Tonko and Trahan's bipartisan bills will ensure more doctors are trained and able to prescribe the medication-assisted treatment that we know saves lives.

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And lastly, we're considering bills to address the upcoming expiration of the temporary placement of all fentanyl-related substances in schedule I. Despite the temporary scheduling, deaths from fentanyl analogues rose by 10%, so clearly scheduling is not the silver bullet and Congress has to consider alternatives to stop synthetic opioids.

I yield the rest of my time to the sponsor of the STOP Fentanyl Act of 2021, Representative Annie Kuster.

Ms. ESHOO. I now yield the rest of my time—I don't know how much is left—to the sponsor of the STOP Fentanyl Act of 2021, Representative Annie Kuster.

Ms. KUSTER. Thank you so much, Chairwoman Eshoo. As we are all too well aware, the pandemic has exacerbated the already dire addiction and mental health crises in our country. From August 2019 to August 2020, 88,000 Americans died of an overdose, the highest number ever recorded over a 12-month period.

But we also know the addiction and overdose crisis in this country did not occur overnight. It has devastated communities in my State of New Hampshire and across the U.S. for decades. What began as an opioid crisis has evolved to an epidemic that knows no bounds. It impacts every community, no matter the race. It is cross-regional and intergenerational.

The complexity of this epidemic is urgent. Overdose deaths due to synthetic opioids such as fentanyl and fentanyl analogues have continued to rise. And what we have learned in New Hampshire is there is no silver bullet. It is an all-hands-on-deck approach, and any serious solution must look at comprehensive reforms to both public health and our criminal justice system.

And that is why I am so pleased to see my bill, the Support, Treatment, and Overdose Prevention of Fentanyl Act, included in today's hearing. I look forward to discussing it more, and thank you, Chairwoman Eshoo, for this time and I—including my bill to support public health and public safety efforts into responding to fentanyl. It will be a real game changer.

[The prepared statement of Ms. Kuster follows:]

PREPARED STATEMENT OF HON. ANN M. KUSTER

Thank you, Chairwoman Eshoo.

As we are all too well aware, the pandemic has exacerbated the already dire addiction and mental health crises in our country.

From August 2019 to August 2020, 88,000 Americans died of an overdose. This is the highest number ever recorded over 12 months.

But we also know the addiction and overdose crisis in this country did not occur overnight: It has devastated communities in New Hampshire and across the US for over a decade.

What began as an opioid crisis has evolved to an epidemic that knows no bounds: It impacts every community, no matter the race. It is cross-regional, and it is inter-generational.

The complexity of this epidemic is urgent: overdose deaths due to synthetic opioids such as fentanyl and fentanyl analogues have continued to rise, and what we have learned in New Hampshire is that there is no silver bullet—it's an all hands on deck approach, and any serious solution must also look at comprehensive reforms to both our public health and criminal justice system.

That is why I am pleased to see my bill, the Support, Treatment, and Overdose Prevention of Fentanyl Act, included in today's hearing.

I look forward to discussing it more, and hope that all of my colleagues recognize the urgency of this crisis.

Thank you, Chairwoman Eshoo, for the time, and including my bill to support both public health and public safety efforts in responding to fentanyl. This can be a real game changer, and I am grateful for the opportunity to discuss this legislation today.

Ms. KUSTER. And I yield back.

Ms. ESHOO. Well, thank you, Annie. You have been and continue to be an important leader on the whole issue of opioids, and we are all very grateful to you.

The Chair is now pleased to recognize Mr. Guthrie, the ranking member of the Subcommittee on Health, for 5 minutes for his opening statement.

Good morning to you.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Good morning. Good morning, Chair Eshoo, and thank you for holding this important hearing today.

It is devastating that we have lost more than 550,000 Americans due to COVID-19. Sadly, we have another epidemic that has claimed around the same number of lives over the past two decades: the opioid crisis. We are hearing from public health providers that the COVID-19 pandemic has exacerbated this crisis. The CDC recently reported that—over 88,000 overdose deaths over the past year, ending in May of 2020, which is the highest number of overdose deaths in a 12-month time.

In 2019 addiction and substance use disorders affected over 20 million Americans, 10 million of which experienced opioid misuse. Last year we sadly saw that number increase even more. According to the CDC, we have had three waves of the opioid epidemic. First we saw the rise in prescription opioids. Then in 2010 we began to see the rise in heroin. And currently we are in the third wave, which includes the rise of synthetic opioids, which often includes deadly forms of fentanyl.

My home State of Kentucky has seen some of the highest numbers of substance use disorder deaths. One Kentucky substance abuse provider group that my office spoke to shared that they have lost more patients to overdose during the pandemic than they had in the last 5 years. CDC compared the death by drug overdose

rates over a 12-month period between August 2019 and August 2020. In August 2019, Kentucky had 1,307 overdose deaths; one year later, that number was 1,874. Unfortunately, Kentucky is not alone with these increases.

This committee has worked in a bipartisan way to authorize many programs to decrease overdose deaths. But more work needs to be done. Specifically, the Energy and Commerce Committee authorized the 21st Century Cures Act, the Comprehensive Addiction Recovery Act, and the SUPPORT Act for Patients and Communities—Communities Act to combat the opioid epidemic. Included in the final SUPPORT Act was my bill, the Comprehensive Opioid Recovery Act Centers of 2018, which authorized the creation of comprehensive opioid recovery centers throughout the Nation. This program is currently being implemented and provides evidence-based comprehensive care for those with substance use disorders.

Overall, these laws continue to provide critical funding and authorizations to help address substance use disorder treatment, recovery, and prevention.

I think it is important for us to look back and fully examine these laws and evaluate where we are and where we are headed. And while we have 11 new bills before us today, we must also examine current authorizations.

One of these current authorizations is the extension of the temporary emergency scheduling of fentanyl analogues. Synthetic opioids, which includes fentanyl analogues, were involved in 744 deaths in Kentucky in 2018. Fentanyl analogues are very dangerous, due to their potency, and often come across our borders illegally only to harm Americans. Just last month a 2-year-old in Kentucky died from exposure to fentanyl. One healthcare provider group who treats patients with substance use disorders told my office that almost all of their patients have some sort of fentanyl in their system. Many of the patients are not aware of it themselves. I recently heard from another local healthcare provider in Kentucky who said it is almost rare to have an overdose that does not have some traces of synthetic opioids, such as fentanyl.

This provider also shared that they have certain individuals using substances in their own parking lot in case they overdose or anything were to happen, because they know the provider is equipped with Narcan.

We must protect Americans from these harmful drugs that ruin lives and families. I look forward to continuing the bipartisan work to combat the substance abuse disorder crisis in America. I appreciate this hearing, and the witnesses before us, and the Members present.

[The prepared statement of Mr. Guthrie follows:]

PREPARED STATEMENT OF HON. BRETT GUTHRIE

Chair Eshoo, thank you for holding this important hearing today.

It is devastating that we have lost more than 550,000 Americans due to COVID-19. Sadly, we have another epidemic that has claimed around the same number of American lives over the past two decades: the opioid crisis. We're hearing from public health providers that the COVID-19 pandemic has exacerbated this crisis. The CDC recently reported over 81,000 overdose deaths over the past year ending in May 2020, which is the highest number of overdose deaths in a 12-month time. In 2019, addiction and substance use disorders affected over 20 million Americans, 10

million of which experienced opioid misuse. Last year, we sadly saw that number increase even more. According to the CDC, we have had three waves of the opioid epidemic. First, we saw the rise in prescription opioids, then in 2010 we began to see a rise in heroin, and currently we are in the third wave, which includes the rise in synthetic opioids, which often includes deadly forms of fentanyl.

My home State of Kentucky has seen some of the highest numbers of substance use disorder deaths. One Kentucky substance use provider group that my office spoke to shared that they have lost more patients to overdose during the pandemic than they have in the last 5 years. CDC compared the death by drug overdose rates over a 12-month period between August 2019 and August 2020. In August 2019, Kentucky had 1,307 overdose deaths. One year later that number was up to 1,874. Unfortunately, Kentucky is not alone with these increases.

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I look forward to continuing the bipartisan work to combat the substance use disorder crisis in America. I yield back.

Mr. GUTHRIE. And, Madam Chair, I will yield back.

Ms. ESHOO. The gentleman yields back, and I thank him for his opening statement.

The Chair is now pleased to recognize Mr. Pallone, the chairman of the full committee, for his 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairwoman, and thanks to the ranking member, as well.

This committee has a long history of working on a bipartisan basis to combat the threat of opioids and substance use and misuse. And together we are making significant progress.

But, unfortunately, the COVID-19 pandemic and the resulting economic downturn over the last year has weighed heavily on the American people and has only exacerbated substance use and misuse. And so today we are continuing our work to address the epidemic within the pandemic, essentially.

The statistics are alarming. In 2019, prior to the pandemic, more than 20 million Americans experienced a substance use disorder, and half of those involved opioids. Tragically, there were nearly 71,000 drug overdose deaths. And recent data shows that the pandemic has accelerated overdose deaths. From August 2019 to August 2020, 88,000 overdose deaths were reported, the highest ever recorded in a 12-month period.

The primary driver of these deaths was a dramatic increase in the availability of synthetic opioids derived from fentanyl. These low-cost substances can be 50 to 100 times more potent than morphine and are frequently mixed into other drugs like cocaine and methamphetamine.

To combat the opioid epidemic the committee advanced major pieces of legislation that became law. These laws expanded critical substance use disorder services and supports for communities around the country. But our efforts have not ended there. And since the beginning of the pandemic we pushed for the inclusion of funding aimed at the dual public health threats of the virus and rising rates of overdose deaths, substance use and misuse, anxiety, and depression. And I look forward to hearing from our panelists about the implementation of these laws, how the pandemic is impacting people suffering from substance use, and what more can be done to help aid in response to these threats.

Now, on our first panel we will hear from the Acting Director of the White House Office of National Drug Control Policy, or ONDCP, who recently released the Biden administration's first-year drug policy priorities. And I commend the administration for taking an evidence-based public health approach to the drug epidemic. I also applaud them for their plans to expand evidence-based treatment, reduce youth substance use, enhance recovery services, and advance racial equity. Their work falls squarely within the jurisdiction of this committee. I look forward to hearing more from ONDCP about how we can work together.

And our second panel is composed of experienced providers, public health experts, advocates for justice, and Federal law enforcement professionals. This group is on the front lines of the epidemic, and their insight on the impact of Federal policy is invaluable. And I thank all the witnesses for their selfless dedication to this cause.

Now, throughout our discussion it is important to remember that substance use disorder is complex but treatable. Regardless of a patient's personal history or healthcare coverage, they deserve compassion and help, just like any other patient with a diagnosable disease. And we have to approach this substance use epidemic as a public health crisis and take the lead on destigmatizing effective treatments.

The 11 pieces of legislation we are considering today tackle the epidemic in multiple ways, and many of them take a public health approach. And we have considered some of these policies before, and they remain a critical component of a comprehensive response to the crisis. So we have to continue our work in a bipartisan fashion to combat the epidemic. Millions of lives depend on it.

And I commend the sponsors of these bills for their leadership and look forward to our continued work to address this devastating epidemic in the months ahead.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

This committee has a long history of working on a bipartisan basis to combat the threat of opioids and substance use and misuse. Together, we were making significant progress, but unfortunately the COVID-19 pandemic and the resulting economic downturn over the last year has weighed heavily on the American people and has only exacerbated substance use and misuse. Today, we are continuing our work to address the epidemic within the pandemic.

The statistics are alarming. In 2019—prior to the pandemic—more than 20 million Americans experienced a substance use disorder, and half of those involved opioids. Tragically, there were nearly 71,000 drug overdose deaths.

Recent data shows that the pandemic has accelerated overdose deaths. From August 2019 to August 2020, 88,000 overdose deaths were reported, the highest ever recorded in a 12-month period. The primary driver of these deaths was a dramatic increase in the availability of synthetic opioids derived from fentanyl. These low-cost substances can be 50 to 100 times more potent than morphine and are frequently mixed into other drugs like cocaine and methamphetamine.

To combat the opioid epidemic, the committee advanced major pieces of legislation that became law, including the Comprehensive Addiction and Recovery Act, the 21st Century Cures Act, and the SUPPORT for Patients and Communities Act. These laws expanded critical substance use disorder services and supports for communities across the Nation. But our efforts have not ended there.

And since the beginning of the pandemic, we pushed for the inclusion of funding aimed at the dual public health threats of the virus and rising rates of overdose deaths, substance use and misuse, anxiety, and depression. I look forward to hearing from our panelists about the implementation of these laws, how the pandemic is impacting people suffering from substance use and misuse, and what more can be done to help aid in response to these threats.

On our first panel, we will hear from the Acting Director of the White House Office of National Drug Control Policy (ONDCP), who recently released the Biden administration's first-year drug policy priorities. I commend the administration for taking an evidence-based public health approach to the drug epidemic. I also applaud them for their plans to expand evidence-based treatment, reduce youth substance use, enhance recovery services, and advance racial equity. Their work falls squarely within the jurisdiction of this subcommittee. I look forward to hearing more from ONDCP about how we can work together to eradicate the threat of illicit fentanyl-derived substances.

Our second panel is composed of experienced providers, public health experts, advocates for justice, and Federal law enforcement professionals. This group is on the frontlines of the opioid epidemic, and their insight on the impact of Federal policy is invaluable to our work here. I thank all the witnesses for their selfless dedication to this cause.

Throughout our discussion, it is important to remember that substance use disorder is a complex, but treatable disease. Regardless of a patient's personal history or healthcare coverage, they deserve compassion and help just like any other patient with a diagnosable disease. We must approach the substance use epidemic as a public health crisis and take the lead on destigmatizing effective treatments.

The 11 pieces of legislation we are considering today tackle the epidemic in multiple ways and many of them take a public health approach. This includes proposals to address the need for first responder training and prescriber education, to dismantle barriers to treatment, and to bolster public health and recovery programs in the States.

We have considered some of these policies before and they remain a critical component of a comprehensive response to the crisis. Other policies are a result of the emerging data and rising threat of illicit fentanyl.

We must continue to work in a bipartisan fashion to combat this epidemic as millions of lives depend on it. I commend the sponsors of these bills for their leadership and look forward to our continued work in addressing this devastating epidemic in the months ahead.

Thank you, I yield the remainder of my time.

Mr. PALLONE. Thank you again, Madam Chair. I think this is a very important hearing, and I yield back.

Ms. ESHOO. Thank you, Mr. Chairman.

The Chair now is pleased to recognize the ranking member of the full committee, Representative Cathy McMorris Rodgers, for her 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. CATHY McMORRIS RODGERS,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF
WASHINGTON**

Mrs. RODGERS. Good morning, everyone. Thank you, Chair Eshoo, and thank you to our witnesses.

America remains in the midst of two national emergencies, COVID-19 and the substance use disorder crisis. Experts, including law enforcement, the DEA, and local leaders in my community, are raising the alarm.

We are losing more people to the death of despair. The social isolation, economic shutdowns, stress, fear, loneliness has taken a severe toll. According to the CDC, 88,000 people died of overdose in the last 12 months leading up to August 2020. That is a 26.8 percent increase. And that comes after the CDC released May data that we had the highest number of overdose deaths in the history of our country. This is how one mental health expert in eastern Washington put it to me: "A situation such as 2020 that really stressed even the strongest-willed among us, it can really impact how they are feeling, and it can increase their need for a substance use as a way to protect themselves, as a way to find the comfort they are used to having."

People need hope, hope to overcome fear, change their lives, provide for their families, and thrive, and that is what is on the line as we work to address this epidemic within the pandemic, head on.

While I have some concerns with some of the bills, I am pleased that we are coming together to improve prevention, increase access to treatment, and offer support to those in recovery. All of this will build on our historic bipartisan work on the comprehensive Addiction and Recovery Act, CURES, and the Support for Patients and Communities Act.

Energy and Commerce has a rich history of leading on the most significant efforts against addiction crisis, and today I am hopeful that we can move more of those solutions across the finish line. That includes stopping the scourge of fentanyl coming across our southern border from Mexico and also China. Nearly all States are seeing a spike in synthetic opioid deaths, with 10 western states reporting more than a 98 percent increase.

In Washington State, it is even worse. The fentanyl positivity rate increased by 236 percent. Washington State is the highest in the Nation. Last fall we lost two teenagers in eastern Washington to potential fentanyl exposure. We have had close calls with police officers who barely came in contact with fentanyl, just a few milligrams. What can fit on Lincoln's ear on a penny is lethal. The analogues are oftentimes more potent. If it is reaching our streets in Washington State in deadly quantities from Mexico, I can assure you that the scourge is everywhere.

That is why DEA created a temporary scheduling order for fentanyl analogues, placing these dangerous substances in the schedule I. Previously, drug traffickers could slightly change the chemical structure of fentanyl, so the novel formula was not consid-

ered prohibited. The DEA would then have to individually schedule each variant. Once one analogue was scheduled, a new one would emerge, creating this game of Whac-a-mole for drug control efforts.

With wide class scheduling, any dangerous variant of fentanyl is controlled under schedule I. This allows law enforcement to combat all fentanyl-related substances and protect the public. For example, one recently encountered substance was approximately 8 times more potent than fentanyl. A scheduling order is set to schedule in less than a month.

Given the House schedule, Speaker Pelosi must make this a priority for this week or next. I fear that, like last year, the majority may wait until the last minute. We should work with DEA and other agencies to make this scheduling permanent, like with Mr. Latta's FIGHT Fentanyl Act.

We should also look for reforms that encourage the scientific research. If the majority will not act on a permanent solution, then we must temporarily extend it. Judiciary Republican Leader Jordan and I are leading a one-year extension to buy us time. The clock is ticking. If this is allowed to expire, Customs and Border Protection will lose their authority to seize these substances at ports of entry, and drug traffickers regain the incentive to push deadlier and deadlier drugs on our streets.

There is no excuse to let May 6th come and go without us doing our job to keep people safe, break the cycle of despair, and build a more prosperous future for America.

[The prepared statement of Mrs. Rodgers follows:]

PREPARED STATEMENT OF HON. CATHY MCMORRIS RODGERS

INTRO

Thank you, Chair Eshoo.

And, thank you to the witnesses.

America remains in the midst of two national emergencies—COVID-19 and the substance use disorder crisis.

Experts—including law enforcement, the DEA, and local leaders in my community—are raising the alarm.

We are losing more people to the deaths of despair.

The social isolation ... economic shutdowns ... stress ... fear ... loneliness have taken a severe toll.

According to the CDC, 88,000 people died of an overdose in the 12 months leading up to August 2020.

That's 26.8 percent increase ...

... and comes after the CDC released May data that we had the highest number of overdose deaths in our recorded history.

This is how one mental health expert in Eastern Washington put it:

"A situation such as 2020—that really stressed even the strongest-willed of us—it can really impact how they're feeling, and it can increase their need for a substance use as a way to protect themselves, as a way to find that comfort they're used to having."

People need hope—hope to overcome fear ... change their lives ... provide for their families, and thrive.

That's what is on the line as we work to address this epidemic within the pandemic head on.

SOLUTIONS

While I have some concerns with some of these bills ...

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All of this will build on our historic bipartisan work on the Comprehensive Addiction and Recovery Act ... CURES ... and the SUPPORT for Patients and Communities Act.

Energy and Commerce has a rich history on leading the most significant efforts against the addiction crisis.

Today, I'm hopeful we can move more solutions across the finish line.

FENTANYL AND FENTANYL-RELATED SUBSTANCES

That includes stopping the scourge of fentanyl coming across our southern border from Mexico and also from China.

Nearly all States are seeing a spike in synthetic opioid deaths—with 10 western states reporting a more than 98 percent increase.

In Washington State, it's even worse. The fentanyl positivity rate increased by 236 percent. That's the highest nationwide.

Last fall, we lost two teenagers in Eastern Washington to potential fentanyl exposure.

We've also had close calls with police officers who barely came in contact with fentanyl.

Just a few milligrams—what can fit on Lincoln's ear on a penny—is lethal.

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STOPPING ANALOGUES

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Previously, drug traffickers could slightly change the chemical structure of fentanyl, so the novel formula was not considered prohibited.

The DEA would then have to individually schedule each variant.

Once one analogue was scheduled, a new one would emerge, creating a game of "Whac-a-mole" for drug control efforts.

With class-wide scheduling, any dangerous variant of fentanyl is controlled under schedule I.

This allows law enforcement to combat all "fentanyl-related substances," and protect the public.

For example, one recently encountered substance was approximately 8-times more potent than fentanyl.

The scheduling order is set to expire in less than a month.

Given the House schedule, Speaker Pelosi must make this a priority for this week or next.

I fear that like last year, the majority is waiting until the last minute.

We should work with the DEA and other agencies to make this scheduling permanent—like with Mr. Latta's FIGHT Fentanyl Act.

We should also look for reforms that encourage scientific research.

If the majority won't act on a permanent solution, then we must temporarily extend it immediately.

Judiciary Republican Leader Jordan and I are leading for a one-year extension to buy us time.

The clock is ticking.

If Speaker Pelosi allows this to expire.

Customs and Border Protection will lose the authority to seize these substances at Ports of Entry.

... and drug traffickers regain the incentive to push deadlier and deadlier drugs on our streets.

There is no excuse to let May 6 come and go without us doing our jobs to keep people safe, break this cycle of despair, and build a more prosperous future for America.

Mrs. RODGERS. With that, I yield back.

Ms. ESHOO. The gentlewoman yields back. The Chair would like to remind Members that, pursuant to committee rules, all Members' written opening statements will be made part of the record.

I would now like to introduce our witnesses for our first panel. Regina LaBelle is the Deputy Director of the White House Office of National Drug Control Policy and is currently the Acting Director of the agency, serving as the principal adviser to the Biden-Harris administration on drug policy matters ranging from substance use, prevention, treatment, and recovery to drug interdiction.

Acting Director LaBelle previously served as the Chief of Staff of the ONDCP during the Obama administration, where she oversaw the Federal Government's initial efforts to address the opioid epidemic. And before returning to the agency, she served as a distinguished scholar and program director of the Addiction and Public Policy Initiative at Georgetown University's O'Neill Institute for National and Global Health Law, and was also a director of the graduate school's master of science program in addiction policy and practice.

So we have a seasoned professional representing the agency.

And Acting Director LaBelle, you are recognized for 5 minutes. Please remember to unmute, and I recognize my—I will recognize myself for questions after your testimony.

**STATEMENT OF REGINA M. LABELLE, ACTING DIRECTOR,
WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY**

Ms. LABELLE. Thank you, Chairwoman Eshoo, Ranking Member Guthrie, Chairman Pallone, Ranking Member McMorris Rodgers, members of the subcommittee. Thank you for inviting me to testify today. It is my pleasure to discuss the Biden-Harris administration's drug policy priorities for our first year and the activities of the Office of National Drug Control Policy. Thank you for holding this hearing so early in the 117th Congress. It reflects the urgency of addressing the overdose and addiction epidemic.

ONDCP coordinates Federal drug policy by developing and overseeing 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 work to ensure those efforts complement State, local, and Tribal drug policy activities.

In this role I advocate for people with substance use disorder and their families, for a balanced approach to drug policy that includes public health and public safety, and for greater inclusion and equity in our efforts to tackle the addiction and overdose epidemic. These responsibilities are evident in the work ONDCP has undertaken since President Biden took office.

On April 1st, ONDCP delivered the Biden-Harris administration's Statement of Drug Policy Priorities for the first year to Congress. These seven priorities have two overarching themes: first, immediately getting services to people most at risk for overdose; and second, building the addiction infrastructure necessary to meet the needs of the more than 20 million people in this country who have a substance use disorder.

Our policy priorities include a focus on preventing substance use initiation, including through our Drug-Free Communities Support Program, and expanding access to quality treatment and recovery support services. It also includes supporting harm reduction services. This is especially important during this time when illicitly manufactured fentanyl is present in so many drugs. Harm reduction services include distributing the lock zone and fentanyl test strips, and expanding syringe services programs. These programs build connections, reduce people's chance of overdose, and give them the opportunity to receive services and engage them in healthcare, including treatment.

As the epidemic continues, the shifting dynamics require us to adapt and meet people where they are. I have an example. I recently read about a 60-year-old woman in Miami who had untreated opioid use disorder. After many years she received services finally through a mobile service provider. She engaged in treatment, now has an apartment, and is able to spend time with her children and grandchildren.

Also included in our policy priorities is racial equity in drug policy, both in criminal justice and healthcare. Our priorities include the entire continuum of care and seek to reduce the stigma of addiction.

We also recognize the need to reduce the supply of illicit drugs in the United States. Illicitly manufactured fentanyl, fentanyl analogues, cocaine, methamphetamine, and other drugs enter our country through our ports of entry or through the mail, including express couriers. Our efforts to disrupt drug trafficking networks include working with domestic law enforcement through ONDCP's High Intensity Drug Trafficking Areas Program, and we appreciate Congress's strong support for this program.

We are also working closely with countries such as Colombia, Mexico, and China to disrupt drug-trafficking networks and stem the flow of drugs coming into this country. On this issue Congress is facing a deadline of May 6 to extend the temporary fentanyl class scheduling bill. The administration is asking Congress to extend this law while we work with the Departments of Justice and Health and Human Services to address legitimate concerns regarding mandatory minimums and research provisions involved in class scheduling.

Beyond extending temporary class scheduling, Congress has an important role to play in addressing the overdose and addiction epidemic. Already, Congress has provided needed resources through the American Rescue Plan, and the President's budget request calls for a substantial investment of \$10 billion. This funding will help build the type of infrastructure the Nation needs to reduce overdose deaths in the short term while laying the groundwork for a system of care that is long overdue. These funds will be guided by science and evidence, and we hope this budget request informs your work.

Addressing the addiction and epidemic is an urgent issue, and the Biden-Harris administration's drug policy priorities are intended to bend the curve and save lives. And working with our Members—with Members of Congress, ONDCP will take quick action to implement them.

Thank you for your time, and I look forward to your questions.
[The prepared statement of Ms. LaBelle follows:]



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

**Hearing entitled,
“An Epidemic within a Pandemic:
Understanding Substance Use and Misuse
in America”**

Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

Wednesday, April 14, 2021
10:30 a.m.
via Webex

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

For Release Upon Delivery

Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee, it is my pleasure to discuss the Biden-Harris Administration's drug policy priorities and the activities of the Office of National Drug Control Policy (ONDCP). I am honored to testify as the Acting Director of the agency where I served for eight years under the Obama Administration. I do not take this honor lightly – the issues of addiction and overdose are personal to me. Like many of you, and like millions of your constituents, my family has lived experience with substance use disorders. So in addition to my role as the President's acting chief advisor on drug policy matters, I also understand that my responsibility is to advocate for people with substance use disorders, for balanced approaches to drug policy that include public health and public safety, and for greater inclusion, equity, and civil rights in our efforts to tackle an addiction and overdose epidemic that has been exacerbated by the COVID-19 pandemic.

While the origins of the overdose epidemic began with prescription opioids, it has not remained static. The issues and the drug environment we face today have changed considerably, and so too must the strategies that we pursue to address the addiction epidemic.

Our plan, therefore, does three things. First, it approaches substance use disorders as chronic – not acute – conditions that require long-term solutions. Second, the policy priorities look at the lifecycle of today's addiction epidemic by incorporating actions across the continuum of prevention, treatment and recovery. Beyond preventing substance use disorders, the policy priorities identify how to treat these chronic conditions, reduce the harms associated with illicit substance use and prescription drug misuse, and help people with substance use disorders sustain their recovery. Lastly, we look at disrupting drug trafficking networks that provide the substances that are misused and put our families and communities in harm's way.

The latest provisional data from the Centers for Disease Control and Prevention (CDC) show that an estimated 88,000 people died of an overdose in the 12-month period ending in August 2020, a 26.8 percent increase, from the past 12 months.¹ In the period from 2015 to 2019, drug overdose

¹ Ahmad, F. B., Rossen, L. M., & Sutton P. (2021). Provisional drug overdose death counts. *Centers for Disease Control and Prevention*. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

deaths rose by 35 percent.² This is a greater rate of increase than for any other type of injury death in the United States.³ The CDC data also show us who is the most affected: people 35-44 years old are dying at the highest rate, and people 25-34 are not far behind.⁴ It is also important to note that age-adjusted drug overdose deaths involving synthetic opioids other than methadone (which includes fentanyl analogs) continue to increase.⁵ What's more, data also suggest that recent increases in overdose mortality⁶ have underscored systemic inequities in our Nation's approach to criminal justice and prevention, treatment, and recovery support.

President Biden has made it clear that addressing the overdose and addiction epidemic is an urgent priority for his Administration, and I deeply appreciate the support Congress has already provided on this important priority. The American Rescue Plan Act of 2021, which President Biden signed into law last month, appropriated nearly \$4 billion to the Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration to expand access to vital behavioral health services. This funding is necessary. We need to make sure that the money we are spending is effectively coordinated across the Federal Government and State, local, and Tribal communities, and that it creates more opportunities for people with substance use disorders to access evidence-based services when and where they need them. It is only through building these connections that we can engage people in treatment, and support them through their recovery.

² In 2018, drug overdose death declined (by four percent) for the first time since at least 1999, but resumed their ascent to unprecedented levels in 2019 [Hedegaard, H., Miniño, A.M., Wagner, M. (2020). Drug Overdose Deaths in the United States, 1999-2019. *NCHS Data Brief No. 304*. <https://www.cdc.gov/nchs/products/databriefs/db394.htm>].

³ From 2015 to 2019, the numbers of U.S. injury deaths by firearms increased by ten percent, those by suicide increased by eight percent, those by homicide by eight percent, and those by motor vehicle crash by four percent. Injury death categories are not mutually exclusive. For example, 4,777 suicides in 2019 were by drug overdose [U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. (2020). *Underlying Cause of Death 1999-2019*. CDC WONDER Online Database. <http://wonder.cdc.gov/mcd-icd10.html>].

⁴ Hedegaard, H., Miniño, A. M., & Wagner, M. (2020). Drug Overdose Deaths in the United States, 1999-2019. *NCHS Data Brief, 394*. Figure 2: Drug overdose death rates among those aged 15 and over, by selected age group. Centers for Disease Control and Prevention, National Center for Health Statistics. <https://www.cdc.gov/nchs/products/databriefs/db394.htm>.

⁵ *Ibid.*

⁶ U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. (2020). *Underlying Cause of Death 1999-2019* on CDC WONDER Online Database, released 2020. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on January 22, 2021.

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.

As I mentioned, a lot of this work is done in the formulation and implementation of the Administration's *National Drug Control Strategy*, the blueprint for addressing drug use and its consequences. During an inauguration year, to give a new Administration sufficient time to develop a *National Drug Control Strategy*, ONDCP is required by statute to issue a new Administration's drug policy priorities by April 1, which ONDCP has done, with a complete *Strategy* due February 1 the following year.⁷

Understanding our statutory responsibilities and the critical urgency of the addiction and overdose epidemic, ONDCP issued the Biden-Harris Administration's Statement of Drug Policy Priorities⁸ on April 1. These drug policy priorities represent a focused approach to reducing overdoses, creating more opportunities to engage with people with substance use disorders, and ultimately save lives. The priorities provide guideposts to ensure that the Federal Government promotes evidence-based public health and public safety interventions. They also directly address racial equity in drug policy and the need to embrace a full continuum on interventions, including harm reduction. The priorities are:

- Expanding access to evidence-based treatment;
- Advancing racial equity in our approach to drug policy;

⁷ Section 706(a) of the Office of National Drug Control Policy Authorization Act of 1998, as amended (21 U.S.C. § 1705(a)). See <https://www.law.cornell.edu/uscode/text/21/1705>

⁸ 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>

- Enhancing evidence-based harm reduction efforts;
- Supporting evidence-based prevention efforts to reduce youth substance use;
- Reducing the supply of illicit substances;
- Advancing recovery-ready workplaces and expanding the addiction workforce; and
- Expanding access to recovery support services.

In the first year, the Biden-Harris Administration will work through ONDCP to coordinate with other White House components and its Federal agency partners – as well as with Congress – to begin addressing these priorities.⁹ I will discuss each of them in more detail below.

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. For far too long, people with substance use disorders and those in recovery from them have faced stigma, judgment, and exclusion in healthcare, housing, employment, and other sectors.¹⁰ President Biden has emphasized that ensuring that Americans have access to affordable, high-quality healthcare and achieving universal healthcare is the most crucial step in addressing substance use disorders, and I could not agree more. That’s why our policy priorities emphasize the importance of expanding access to evidence-based treatment through a number of different channels.

In our first year, the Biden-Harris Administration will take steps to ensure that health insurers and group health plans that offer mental health and substance use treatment and services provide the same level of benefits for those services that they do for other medical care. We will evaluate progress made since the 2016 Mental Health and Substance Use Disorder Parity Task Force

⁹ U.S. Government Accountability Office (March 2020). *Drug Misuse: Sustained National Efforts Are Necessary for Prevention, Response, and Recovery*. GAO-20-474. Washington, DC. <https://www.gao.gov/assets/gao-20-474.pdf>

¹⁰ van Bockel, L., Brouwers, E., van Weeghel, J., & Garretsen, H. (2013). Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review. *Drug and Alcohol Dependence*, 131(1), 23–35. <https://doi.org/10.1016/j.drugalcdep.2013.02.018>

issued its recommendations¹¹ and identify additional actions necessary to complete these recommendations. This will include developing and establishing a working group with healthcare insurers and employers to promote full compliance of the Mental Health Parity and Addiction Equity Act to eliminate discriminatory barriers to mental health and substance use disorder services.

There are also several action items the Biden Harris Administration will pursue that address lifting barriers to MOUD and making medications more accessible, including removing unnecessary barriers to prescribing buprenorphine and identifying opportunities to expand low-barrier treatment services; reviewing policies relating to methadone treatment and developing recommendations to modernize it; expanding access to evidence-based treatment for incarcerated individuals; and publishing final rules regarding telemedicine special registration and mobile opioid treatment units that provide methadone.

ONDCP will review evaluations and explore making permanent the actions implemented during the COVID-19 pandemic national emergency, as well as evaluating the continuation of Medicaid and Medicare reimbursements for these telehealth services.

We understand that polysubstance use is common, and overdoses involving stimulants have increased in recent years, escalating the urgency to offer access to treatment for stimulant use disorders. Evidence-based treatments for stimulant use disorders exist – Contingency Management (Motivational Incentives) is the one supported by the best evidence. Our policy priorities include identifying and exploring options to addressing policy and reimbursement barriers to providing evidence-based treatment for stimulant use disorder.

In addition, we will explore the existing landscape, identify barriers, and establish policy to help pregnant women with substance use disorder get the prenatal care and addiction treatment they need, without fearing that they will lose custody of their child or face criminal sanctions.

¹¹ Executive Office of the President of the United States. (2016). *The Mental Health and Substance Use Disorder Parity Task Force Final Report*. Washington, DC. <https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.PDF>

Advancing Racial Equity in our Approach to Drug Policy

Underlying our work on treatment access and other priorities is a clear and discernable need to take steps that advance racial equity¹² in our approach to drug policy. 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 poorer health outcomes. For many people with substance use disorders, access to 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 4-5 years later than White individuals, a disparity that remained even when controlling for socioeconomic status.¹³ In Latino communities, those who need treatment for substance use disorders were less likely to access care than non-Latinos.¹⁴ This discrepancy in treatment access is important to address at a time when overdose rates are increasing for some communities of color.¹⁵

Our first-year actions are focused on, first, acknowledging decades of harms to BIPOC communities, and then taking the steps necessary to begin to correct them. We will focus on establishing a research agenda to meet the needs of historically underserved communities. This will include identifying data gaps related to drug policy to target unmet needs in diverse communities. ONDCP will participate in an interagency working group to agree on specific policy priorities for criminal justice reform, in collaboration with the Domestic Policy Council and other White House components.

¹² 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>

¹³ 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>

¹⁴ 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>

¹⁵ 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>

We will also develop a drug budget that includes an accounting and analysis of how Federal dollars meet the needs of diverse populations. We will shape drug budget recommendations to target resources to address equity issues and direct agencies to develop ways to collect budget data, when presently unavailable, that is disaggregated by demographic categories.

Further, we will identify culturally competent and evidence-based practices for serving BIPOC across the continuum of care that includes prevention, harm reduction, treatment, and recovery services. As part of this, we will promote integration of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Healthcare for providers of substance use disorder prevention, treatment, and recovery support services, starting with a review of CLAS standards by Executive departments and agencies with healthcare roles.¹⁶

Enhancing Evidence-based Harm Reduction Efforts

Harm-reduction organizations provide an opportunity for connections between people who use drugs and healthcare systems, often with peer support workers. Regular engagement between harm reduction staff and people who use drugs builds trust,¹⁷ allowing for an ongoing exchange of information, resources, and contact. Harm reduction staff can build trust over time with patients, making them trusted messengers, and placing them in a position where they can effectively encourage people who use drugs to request services.

As we have mentioned previously, access to quality healthcare, treatment, and recovery support services is essential, but largely inaccessible for many people with substance use disorders. For many people who use drugs, their first point of contact may be outside of the mainstream

¹⁶ Office of Minority Health, U.S. Department of Health and Human Services. (2013). *National standards for culturally and linguistically appropriate services in health and health care: A blueprint for advancing and sustaining CLAS policy and practice*. Washington, DC: Office of Minority Health, U.S. Department of Health and Human Services. <https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf>

¹⁷ 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/>

healthcare system and through harm reduction programs. Services offered at Syringe Services Programs (SSPs) may include providing the overdose reversal drug naloxone, sterile syringes, fentanyl test strips, and testing for human immunodeficiency virus (HIV) and hepatitis C virus. Research has shown that SSPs reduce HIV prevalence.^{18,19,20}

ONDCP will focus on integrating and building linkages between funding streams to support SSPs. This will include identifying state laws that limit access to SSPs, naloxone, and other services. We will also highlight and advance best practices for distribution and use of fentanyl test strip services, standards for fentanyl test strip kits, and the use of fentanyl test strips as part of a strategy to engage individuals into healthcare systems. Further, we will examine naloxone availability in counties that have high rates of overdose and identify opportunities to expand access, awareness, and training in targeted areas among pharmacists, clinicians, peer support workers, family and community members, and people who use drugs.

ONDCP will also support research on the clinical effectiveness of emerging harm reduction practices in real-world settings and test strategies for implementing established evidence-based practices. We will develop and evaluate 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. These approaches will involve a diverse range of community members, including first responders and law enforcement, in evidence-based approaches that address overdose and provide police-assisted access to harm reduction, treatment, recovery support, and other services.

¹⁸ 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](https://doi.org/10.1016/S0140-6736(96)11380-5)

¹⁹ 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/>

²⁰ 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>

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.²¹

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 will use its budget authorities to ensure that prevention programs that receive Federal funding 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 will look at specific areas, including actions to identify opportunities for its DFC program and CDC to enhance culturally competent prevention programming; identify opportunities for prevention programming in communities with high rates of adverse childhood experiences; 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.

²¹ 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>

Reducing the Supply of Illicit Substances

The Biden-Harris Administration will take steps to reduce the supply of illicit substances in the United States. Along with prevention, harm reduction, treatment, and recovery efforts, preventing illicit drug trafficking into the United States is part of a comprehensive approach to reducing overdose deaths. While synthetic opioids, such as illicitly manufactured fentanyl, its analogues, and non-fentanyl synthetic opioids, have driven up overdose deaths since 2015,^{22, 23, 24} the United States is also seeing increased availability and use of methamphetamine and other synthetic drugs. Moreover, the increasing availability and use of cultivated drugs such as heroin and cocaine, often adulterated by synthetic opioids, continue to pose challenges.²⁵

The Nation's ports of entry provide an entry point for illicit substances that harm Americans. These substances can be marketed and sold on the dark web using cryptocurrency, and are delivered to the purchaser through the mail and commercial carriers, or brought across the Nation's geographic borders by multiple conveyances.²⁶ The availability of drugs with historically high purity and low price, along with the increased lethality of synthetic opioids, helps drive the overdose and addiction epidemic.

In this Administration's first year, ONDCP will work with key partners in the Western Hemisphere, such as Mexico and Colombia, to shape a collective and comprehensive response to

²² 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>.

²³ Peterson, A. B., Gladden, R. M., Delcher, C., Spies, E., Garcia-Williams, A., Wang, Y., Halpin, J., Zibbell, J., McCarty, C. L., DeFiore-Hymer, 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>.

²⁴ 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>.

²⁵ 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>.

²⁶ U.S. Department of Justice, Drug Enforcement Administration. (2020). National Drug Threat Assessment. https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf.

illicit drug production and use by deepening bilateral collaboration on public health approaches, expanding effective state presence, and developing infrastructure. This will help ensure that activities to curb the unlawful production and trafficking of drugs nonetheless adhere to the rule of law and respect for human rights.

We will also exercise leadership in regional and multilateral forums such as the North American Drug Dialogue to advance evidence-based public health responses to substance use, and prevent the proliferation of counterfeit medicines and the diversion of licitly produced substances to the illicit market. Additionally, we will use established 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 will work to strengthen the U.S. Government's capacity to disrupt the manufacture, marketing, sale, and shipment of synthetic drugs by addressing illicit Internet drug sales and the continually evolving techniques in illicit financial transactions. This includes engaging commercial carriers to disrupt the movement of synthetic drugs through postal and parcel systems. On the home front, we will support law enforcement efforts through ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program to disrupt and dismantle domestic drug trafficking networks and support initiatives to advance coordinated responses; and support multi-jurisdictional task forces and other law enforcement efforts to disrupt and dismantle transnational drug trafficking and money laundering organizations that provide the funding for the drug trafficking organizations through the use of the U.S. financial system.

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.²⁷ This reluctance is often based on misconceptions and fears, negative attitudes, and

²⁷ 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).

even misplaced beliefs that discrimination against people with substance use disorders (either in recovery or not) is acceptable.²⁸ Our current economic crisis, coupled with the overdose epidemic, requires the public and private sectors to work together to develop a workforce prepared to meet today's challenges.

At the same time, the Nation's addiction workforce is experiencing staffing shortages,²⁹ and we need to address future needs for various behavioral health occupations.³⁰ Hiring diverse practitioners who reflect the communities and cultures they serve is also an important workforce issue.³¹ The United States needs skilled behavioral health providers to provide the array of services necessary to meet the needs of those with behavioral health conditions, especially important 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 will promote 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, and 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 will identify ways in which the Federal Government can remove barriers to employment and expand employment opportunities for people in recovery from addiction, and we will produce guidelines for Federal managers on hiring and working with

²⁸ 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>

²⁹ 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://bhwh.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/state-level-estimates-report-2018.pdf>.

³⁰ U.S. Department of Health and Human Services, Health Resources and Services Administration, Health Workforce. (2020). Behavioral Health Workforce Projections, 2017-2030. <https://bhwh.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf>.

³¹ 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>

people in recovery from a substance use disorder. ONDCP intends to lead by example: several new ONDCP employees are people in long-term recovery who are using their experience to improve our policies and make treatment and recovery easier for those who follow.

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.

In the Administration's first year, 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. In addition, we will develop interagency support for Recovery Month activities in September and engage persons with "lived experience" in the development of drug policy.

CONCLUSION

Addressing the overdose and addiction epidemic is an urgent issue facing the Nation that has only been made worse by the COVID-19 pandemic. We have lost close to one million people since this epidemic began.³² The Biden-Harris Administration's drug policy priorities are designed to bend the curve of this epidemic. The multi-faceted and evidence-based approach

³² 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].

reflected in these priorities will take on this challenge by expanding access to prevention, harm reduction, treatment, and recovery support services, and by reducing the supply of illicit substances. This work will also include long-overdue efforts to address racial equity issues in drug policy and healthcare. Working with our partners, including Members of Congress, ONDCP will take quick action to implement the Administration's drug policy priorities with the aim of turning the tide on an epidemic that has lasted far too long and taken too many lives.

Ms. ESHOO. Thank you very much, Acting Director LaBelle, for being with us.

So how many days have you been on the job?

Ms. LABELLE. So I was sworn in the afternoon of Inauguration Day, so it is 85 days, I guess.

Ms. ESHOO. Well, congratulations to you.

Ms. LABELLE. Thanks.

Ms. ESHOO. You have a weighty portfolio. Now, based on the early data, 2020 is the deadliest year for overdoses, with 88,000 deaths counted so far, 88,000 in 2020.

Now, as Members stated in their opening statements, our subcommittee and the full committee have done a lot of work. We have passed packages of bills. The first big effort, I think, was something like 53 bills. I think every single one of them was bipartisan. We have put money to this.

Something isn't working. Something isn't working. We are not putting a dent in this. And I don't know—I know that you were part of doing a report before you came to head up the agency. What instructions do you have for the subcommittee about what we need to change, what we need to do more of, what is not working, and also the bills, the 11 bills that we have before us? Can you comment on this?

It is very disturbing to me that we all think we have done very important work. And I still think that we have. But 88,000 deaths? I mean, that—we just—it seems to me that we are not making—to put it mildly, I don't think we are making progress.

Ms. LABELLE. Right. So thank you, Chairwoman.

I think the issues are very complex, but I think that we can't see immediate results over a problem that has evolved for decades. You know, we have had overdose deaths increasing since the 1970s. They did go down in 2018, but fentanyl, illicit fentanyl that is getting into the drug stream, it is getting into coke, methamphetamine, heroin, that is really what is driving a lot of these overdose deaths.

So there are things—I mean, there are bright spots. The money has not been wasted. We have seen an increase in the number of providers who are—provide buprenorphine, one of the three forms of medication treatment. We have made efforts. It is not enough yet. And that is why our policy priorities stress what it does—harm reduction, prevention, recovery supports—because this is a chronic disease, and we need the full continuum of care.

Ms. ESHOO. On the soon-to-expire temporary scheduling of the fentanyl-related substances, what is your agency's suggested policy on this?

Ms. LABELLE. So we are going to—we have been having discussions with HHS and the Department of Justice and DEA. We just got the GAO report that had—that was required as part of the Federal scheduling extension from 2 years ago. We are going to be looking closely at what the results have been of that and, you know, come together to make sure we have a whole-of-government approach to this issue.

Ms. ESHOO. And what kind of timeframe are you thinking of here, to get the job done?

Ms. LABELLE. So we are, you know, engaged in continuous conversations about this. We understand the urgency. It is not going to happen before May 6th, but we are going to work as quickly as possible after that.

Ms. ESHOO. And what is your response to the criticisms that classwide scheduling leads to disproportionate incarceration of Black and brown people, many of whom—who don't receive the treatment they need while they are in jail or prison?

But of course, we have an excellent bill that—before us that addresses that. But can you comment on that, please?

Ms. LABELLE. Yes. So the mandatory minimum issues are much broader than this bill. But when we work with Department of Justice, we are going to look exactly at that. What are the effects of this legislation on the fentanyl scheduling on mandatory minimums?

But the—you know, but the mandatory minimum issue is a much broader issue that involves all forms of drug as well as other sentencing.

Ms. ESHOO. Well, thank you very much for agreeing to testify today, and we need to—you know, we need the agency to really operate in top gear, because this number of deaths says to me that we are not making progress, and we have to change that. We have to change that. So thank you very much to you.

And now I will recognize Mr. Guthrie, the wonderful ranking member of our subcommittee, for his 5 minutes of questions.

Mr. GUTHRIE. Thank you very much. And thank you, Director, for being here. I really appreciate it.

One of my prepared questions, by not meeting the May 6 deadline, we have to make, you know, some important decisions—or not having information for us—and I know you have a lot of the experts. I think you said that fentanyl analogues are driving the overdose deaths. And I would—and I said in my opening statement that almost all of my providers are saying that everybody with an overdose death has some fentanyl analogue.

And I would agree it is not just a criminal justice issue, but I think it is a criminal justice issue, but not just. And this committee has responded with the CARES Act, SUPPORT Act, and hopefully we will have a chance to look at all of that and see how it is making a difference. But I think it is both, we have to deal with both. And any disparities in the laws being enforced absolutely need to be dealt with as well. But I would—it would be nice to have information before May 6, or a position from the administration. But I appreciate it.

I know you had—you put out your priorities for the year one report, and I really want to work with you to achieve your seven goals that you set. And specifically, I would like to focus on evidence-based treatment and how you plan to address holistic treatment for those with co-occurring substance use disorders. Are you willing to work with me and the committee on fully evaluating current programs that are authorized or funded for substance use disorders?

Ms. LABELLE. I am sorry, can you repeat the last part of your question? I had a hard time hearing.

Mr. GUTHRIE. OK. Are you willing to work with me and the committee on fully evaluating current programs that are authorized or funded for substance use disorders?

Ms. LABELLE. Yes, absolutely, Congressman Guthrie, thanks for your question. That is—you know, we want to make sure that it is quality treatment that is evidence-based. And so we intend to work across, you know, all the HHS, SAMHSA to make sure that the programs that the Federal Government is funding are effective. And so we have to put those standards into place.

Mr. GUTHRIE. OK, thank you for that.

And then, additionally, I believe we need to ensure that the Office of National Drug Control Policy is addressing polysubstance abuse, not just opioids, but also stimulants and alcohol abuse. Can you please share how you plan to address this, and while also taking a wide lens on what programs we are already funding and how we can make sure they are best serving those with substance use disorders?

Ms. LABELLE. Yes—

Mr. GUTHRIE. So kind of more emphasis on your—

Ms. LABELLE. Sure—

Mr. GUTHRIE. You sort of answered a little bit, but just a little broader on what you just answered.

Ms. LABELLE. Sure, thanks. So polysubstance use is, obviously, as you point out, a huge problem. People are not just using one substance, they are using multiple substances. And we can't kind of have blinders on that we are only going to deal with one drug at a time.

So our policy priorities call for a holistic approach, starting with prevention of all substances—as you mentioned, youth alcohol use—and then treatment, making sure the quality treatment is available where people live, harm reduction, and recovery support services. Those don't have—there are certainly medications that work for certain drugs, but we need to make sure that we are responsive to all forms of substance use disorder.

Mr. GUTHRIE. Great, thank you. And then I will just say again that, when we were looking at all the CARES Act, SUPPORT Act, and all the others that we worked on, I know—and I had to change some of my attitude. Mine was coming from a pure—not pure, but strong emphasis on the criminal justice side, that this is illegal, and people use it illegally. And as you really delve into this, some people commit crimes because of their drug habit. If you could deal with the substance abuse disorder, you could solve the criminal problem.

But some people are criminal, and they are out to—and a lot of them aren't users. That is—if you read some of the books that you read about, that they avoid using because it takes away from their ability to do business. And so my—I would be really concerned if we start descheduling, or not allowing these types of drugs to go forward, particularly that—you have said, and I have witnessed or heard from people who practice in this, that fentanyl analogues are a big driver in the overdose and overdose deaths.

We had a—I mentioned in my opening statement—a little—I have a couple of—few seconds—but a 2-year-old, we felt—they believe touched and handled his mother's fentanyl, and her opioid,

which had fentanyl in it, and that is why the 2-year-old passed away.

And so this is just something that—we need to really look at this as we move forward, and try to work together. So I really appreciate your time, and I will yield back to the Chair.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentleman yields back. The Chair now recognizes the ranking member of the full committee—pardon me?

VOICE. Mr. Pallone.

Ms. ESHOO. Oh, I am sorry. The chairman of the full committee first.

Mr. Pallone?

Mr. PALLONE. Thank you, thank you, Chairwoman. I wanted to ask the Director about this drug policy, first-year drug policy report that you just released.

I know your jurisdiction puts you in a unique position, because you collaborate with public health and public safety agencies to drive the direction of drug policy, not only in the U.S. but around the world. And what we discussed today and what we do in the months to come is really an issue of life and death, so it is very serious.

But your office recently released the Biden administration's first-year drug policy priorities. I want to applaud the bold approach in that to reducing overdose deaths and the urgency in which you intend to act. But I wanted to focus on the first priority, which is expanding access to evidence-based treatment.

Acting Director LaBelle, the statement of drug policy priorities places expanded access to evidence-based treatment at the top of the list. So what actions are you going to take in year one to achieve that specific goal, if you would?

Ms. LABELLE. Sure, thanks. So it is important that we look at the full continuum of care, but also that we look at the types of FDA-approved medications. So it is buprenorphine. We will be looking at how we can reduce barriers to buprenorphine access.

We are also looking at how can we modernize our methadone treatment that is available to people. So there is—there are many steps that we have to take to look for how to update today's treatment approaches and not be stuck in approaches that we had 15 to 20 years ago.

Mr. PALLONE. Well, you know, only a fraction of the patients with substance use disorders have access to these evidence-based treatments. And as part of expanding access for evidence-based treatment, the statement noted that the Biden administration will “remove unnecessary barriers to prescribing BUP, and identify opportunities to expand low-barrier treatment services.”

Just discuss a little further the barriers the administration sees currently to prescribe BUP, and the steps that the administration plans to take to address those barriers, if you will.

Ms. LABELLE. Sure. So the research shows that some of the barriers to people—to prescribers prescribing buprenorphine include—so they don't necessarily feel comfortable treating patients with addiction, so there is stigma attached to that.

There is also a lack of training in many medical schools. We don't do a good job of building out the addiction workforce. That is

a second piece we will be working with medical schools to talk about that.

And then lastly, we have an—interagency working groups going on that are looking at the X-waiver, specifically, which is the eight-hour training for doctors and a 24-hour training for nurse practitioners and physician's assistants. So we are looking specifically at that issue, as well, at how we can remove barriers to the X-waiver, what we can do administratively, what requires legislative action.

Mr. PALLONE. Well, that is great. That is very important, and I appreciate your answer.

Last question: Any other steps that Congress or the Biden administration can take to ensure that providers are equipped with the tools that they need to diagnose or treat patients with substance use disorder?

Ms. LABELLE. Sure. I think—so many of the authors of the appropriations have helped to expand our addiction workforce. We need to look where there have been things authorized and money has not yet been appropriated, because we really need to expand the number of physicians and nurse practitioners and healthcare providers who feel competent to not only treat addiction but to screen for it. Because the earlier we can identify someone who might have an emerging substance use disorder, the easier it will be to treat those people before their condition becomes chronic.

So Congress can help us, you know, expand awareness about the importance of medical training and nurse—nursing training on addiction.

Mr. PALLONE. Well, thank you. You know, I heard Chairwoman Eshoo, you know, repeatedly point out how, you know, this scourge of overdose deaths, and the rising rates, particularly now during the pandemic—so we really look forward to working with ONDCP and the Biden administration to reduce this.

I mean, it is just—I think the ranking member, Mrs. Rodgers, you know, talked about, you know, this essentially double dose of problems between the pandemic and the opioid abuse and misuse. And so we really want to get to the bottom of it. Thank you for being here.

Thank you, Madam Chair.

Ms. LABELLE. Thank you, Congressman.

Ms. ESHOO. Thank you, Mr. Chairman.

Now the Chair recognizes the ranking member of the full committee for her 5 minutes of questions.

Mrs. RODGERS. Thank you. Thank you, Madam Chair and Mr. Chairman. And I too just want to join in saying that we on the Republican side of the aisle look forward to working with you, continuing to work with you. This is a huge issue all across the country. And I think, without a doubt, the last year has been a difficult year, with COVID and everything that it has meant as far as lockdowns, and isolation, and fear, and uncertainty.

But there is this other crisis underway, and the depths of despair has really been on my heart, and I know it is on a lot of people's hearts, with the increased substance abuse, increased suicides. And I absolutely believe that this is an area that we must take action. We must continue to identify what is going to work, what is going

to be most successful in ensuring that individuals and families get the support and the treatment that they need.

But I also think there is more that Congress needs to be doing. And I just wanted to start by asking the Acting Director LaBelle—and I appreciate you being with us today—just—I would like to ask you, do you believe that Congress should extend this—the temporary scheduling order for fentanyl-related substances before it expires on May 6th?

Ms. LABELLE. We are asking Congress to give us more time to—I mean, it can be extended. We need more time to—before it is extended further. So we—as I said, I don’t think we—there is any way we can come to you with new legislation before May 6. So we need—we are asking Congress to extend the time so that we have time to come together and present you with another proposal.

Mrs. RODGERS. So just so I understand, so would you support the temporary extension while we work on a more permanent solution?

Ms. LABELLE. We are looking to Congress to extend this for a period of time. We don’t have a period of time in mind yet, because we have to get our interagency together to talk about this. But we support and we are asking Congress to extend this—the fentanyl scheduling bill for a short period of time.

Mrs. RODGERS. OK, great. I wanted just to highlight to the committee that, when ONDCP Assistant Director Kemp Chester testified before the Senate Judiciary Committee, he stated that codifying the scheduling emergency order and making it permanent is a “critical, most important first step that we have to take.”

And to the Acting Director LaBelle, is it still the position of ONDCP that the scheduling order be made permanent?

And would you just speak if the position is changed?

Ms. LABELLE. Sure. So I think we just got the GAO report. We are working with DEA to see what the results of this fentanyl scheduling act has been so far.

One thing that we know about the drug environment is that it is ever changing. And sometimes legislation that we put in place 2 years ago doesn’t address today’s issue. But the biggest challenges we face are synthetic drugs, and those are morphing over time. We want to make sure that the solutions we put into place and that we ask Congress to put into place address today’s problems, not yesterday’s problems.

Mrs. RODGERS. OK. The chairman of—the chair of the subcommittee highlighted the 88,000 deaths this last year. I would just like to reiterate to the committee that I believe Congress must act, either this week or next, to prevent the spread of deadly fentanyl variants by making it permanent and extending DEA’s classwide scheduling order.

You know, I would just highlight, when you compare the first quarter of 2021—so January to March, 2021, the seizure of fentanyl at the southwestern border by CBP has increased, just in this quarter, by 233 percent from last year, 2020 quarter 1. And so I think what we are seeing is that we do have a crisis on our hands, and we are seeing a huge increase.

If—so if you compare first quarter of 2020 to this quarter, January to March, 2021, seizure of fentanyl at the southwestern border has increased by 233 percent. So we need to make sure that we are

providing the support necessary at the border and throughout the country so that people are protected and that we do not allow the continued negative impacts and destruction of lives and families due to fentanyl in America.

With that, I will yield back. Thank you, Madam Chair.

Ms. ESHOO. I thank the gentlewoman. Yes, there has been the increase coming in from Mexico, but thank God we—the reason we know the figures that you just stated is because it was seized. And—but we need, really, a refreshed plan on this, because we can't gather a year from now and have statistics saying this is what happened in 2021, and it is more lives lost.

The Chair now recognizes the gentleman from North Carolina, Mr. Butterfield, for your 5 minutes of questions.

Good to see you.

Mr. BUTTERFIELD. Thank you so very much, Madam Chair, for convening this hearing—

Ms. ESHOO. I think you are—I can't hear you.

Can everyone else hear Mr. Butterfield?

No, they are shaking their heads no. There is something wrong with your microphone. We can't hear you.

Mr. BUTTERFIELD. Does that work?

Ms. ESHOO. Yes, there you go.

Mr. BUTTERFIELD. OK, I had my earpiece plugged in. That messed it up.

Thank you. Thank you very much, Madam Chair, for convening this very, very important hearing this morning. And thank you for your leadership. It has been nothing less than stellar. Thank you so very much. And thank you for the direction that you are taking this subcommittee. And thank you to the witnesses, the one witness on this panel and the witnesses on the next panel. Thank you for taking the time to join us today.

Director LaBelle, let me just start here. I am hoping that you can help us better understand the ways in which the Federal Government benefits from your office. This is simply a continuation of what Mr. Malone was—Pallone was talking about a few minutes ago.

I understand that your office leads and it coordinates the Nation's drug policy with the goal of improving the health and lives of our constituents. So my question is, your priorities seem to intersect with both public health and public safety. I want to talk about that intersection, if I can. How does your office—what is your office's role, and how does it differ from that of HHS and DEA?

Ms. LABELLE. Sure. Thanks, Congressman. So the Office of National Drug Control Policy is, obviously, a unique office situated in the Executive Office of the President. And the purpose—our purpose of our office is to bridge the gap that often occurs between public health and public safety.

So we bring Drug Enforcement Administration in, the Department of Justice in, as well as with our colleagues from HHS, from all of the various components of HHS, to discuss issues like fentanyl scheduling, because there are different—the X-waiver is a perfect example. Law enforcement has a different perspective and a different goal sometimes. I mean, all of our goals is to reduce overdose deaths. But our charges are different.

So the Office of National Drug Control Policy, we have about 65 full-time staff, about 35 additional staff detailees, and they bring these sides together so we can find solutions that serve both needs. So that is really the unique role that ONDCP plays.

Mr. BUTTERFIELD. Well, in that light, in what way do you coordinate and/or convene the other relevant agencies in your work?

Ms. LABELLE. Sure—

Mr. BUTTERFIELD. Do you coordinate with the other agencies?

Ms. LABELLE. Yes. So we often have convenings. We have—I mean, I think someone gave me data about the number of meetings we have had across the interagency just since the end of January. It has been about 78 meetings, where we work with other White House components. We work with HHS, DOJ, and we talk about these issues that we—our goal is to make things move quicker, and—so that we don't have to—and build those bridges, so that we are not separately talking to Congress, for example, so that we can come together with one approach on an issue.

Mr. BUTTERFIELD. You know, during the presidential campaign, Joe Biden announced a very robust and comprehensive drug policy agenda, and I hope that he will continue to pursue that agenda. How will the administration leverage your office—if you know, how will the administration leverage your office to carry out its drug policy agenda?

Ms. LABELLE. Sure, thanks. So I think the one unique role, again, is that we have public health and public safety experts together in the same agency. That doesn't occur anywhere else.

I am very engaged and aware of all the Biden-Harris campaign pledges that were made. Those are areas that—we are going to take them one by one and look at how we can implement those over the next couple of years and, again, by having our convening authority, which helps to have one voice on these issues.

Mr. BUTTERFIELD. Thank you for those responses, and thank you for your incredible work. I realize that you were just installed the day after the inauguration, whatever date you announced, but it seems like you have hit the ground running. And just thank you so much for what you are doing and what you are going to do. I look forward to working with you as the administration advances its priorities in this space. So thank you, thank you, thank you.

I yield back.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentleman yields back, and I appreciate your very kind comments, Mr. Butterfield.

It is a pleasure to recognize a former chairman of our full committee, the gentleman from Michigan, Mr. Upton, for your 5 minutes of questions.

Mr. UPTON. Well, thank you, Madam Chair. And I just want to share, Ms. LaBelle, this is so personal to all of us. I mean, every one of us on both sides of the aisle have many personal stories on this. We have family members. It is indeed close to our heart, as we try to do our very best to resolve this major issue that continues to plague virtually every one of our communities, families across the country. So I appreciate your leadership.

You and I, of course, both sit as members of the Commission on Preventing Synthetic Opioid Trafficking, as appointed by our re-

spective leaders. And though we had our first meeting just a week or so ago on Zoom, certainly I just want to commit and definitely look forward to working with you and other members of the Commission on ideas to help curb this terrible scourge that plagues our Nation.

Can you briefly share your thoughts on how the Commission could be most impactful on stopping this trafficking?

Ms. LABELLE. Thank you, Congressman. And the Synthetics Commission, we—as you mentioned, we just had our first meeting. We are just organizing it. I think it is charged with a very—with very specific—it has a very specific charge. I think what it—the best part about the Commission is it has external experts, it has a bipartisan approach, including Congressman Trone, yourself, Senator Markey, and Senator Cotton.

So what I think the Commission will be best able to do is to look at these issues, the international synthetics landscape, and come up with some—take the time to come up with some specific approaches that Congress can take up, that we can do by Executive order or administratively. So it is going to be a real focused effort that I think is going to help with this issue.

Mr. UPTON. So I want to—well, thank you. I want to echo our Republican leader, Cathy McMorris Rodgers, in terms of her question on why don't we make this permanent, the classwide scheduling for fentanyl, rather than an extension. I think that makes a lot of sense.

You sensed, as we get—close in on this deadline, again, that perhaps the administration, if Congress fails to act, knowing that we are only in session this week and next, that they might pursue an Executive order to try and extend that?

Ms. LABELLE. So, Congressman, I think I would have to check to see if we have the authority by Executive order. I am not sure that we can do it.

What DEA can do is, you know, ask for—by—analogue by analogue, to schedule it. That they certainly could do. I am not sure the Executive order would—could make it—could extend it, however.

Mr. UPTON. So we know that much of the fentanyl issue is coming from China, right? Tell us what you are doing to try and close that door.

Ms. LABELLE. Sure, thanks. So what we are seeing right now, as I said, these issues are very dynamic, and drug traffickers are, obviously, very crafty. And so what is happening—what Congress did over the last several years is pass several pieces of legislation that allowed our Customs and Border Patrol to identify this—the drugs that were coming through the mail.

Now—and China acted to schedule fentanyl as a class. So now a lot of the drugs are going in through Mexico. We are working with Mexico to make sure that they are working on interdiction, so that it never even comes to the border, that they are working on identifying labs so they can seize these labs. And then lastly, working at their ports of entry to identify and seize these substances. So we have a good working relationship with Mexico on these types of issues, and our law enforcement partners can work together on it.

Mr. UPTON. I don't know—I don't have the clock on my screen. Do I have a lot of time left, Anna?

Wait, I didn't hear you.

VOICE. You have 50 seconds.

Ms. ESHOO. You have a minute.

Mr. UPTON. OK, one of the things that we discovered in the last Congress was that our postal inspectors, frankly, didn't have the resources.

So, as you know, I am from Michigan. Much of our mail in west Michigan actually goes through the Grand Rapids postal facility. You know, we learned that, at the time, they had one postal inspector to really look through all of these different packages coming through. I know Dr. Burgess was up to New York and saw just a number of these facilities. There has been a lot of documentation on that on TV, in terms of the issues there.

What are we doing on more resources to try and stop this from coming in using FedEx, UPS, as well as the Postal Service, things that would seem pretty routine to you and me?

Ms. LABELLE. So I will quickly answer that. So, number one, we saw that there was a decided drop in mail coming from China that had fentanyl in it. So that was a success over the last year.

However, Congress did provide additional resources to the U.S. Postal Service, Inspection Service, to identify these drugs. And there were other pieces of legislation passed to make it easier to identify something that might be coming from a chemical company that could have fentanyl in it.

Mr. UPTON. Thank you, I yield back.

Ms. ESHOO. We thank the gentleman.

It is a pleasure to recognize the gentlewoman from California—and she is a gentlewoman—Congresswoman Matsui.

Ms. MATSUI. Thank you very much, Madam Chair, and thank you for holding this very important hearing.

And Ms. LaBelle, welcome to the committee and thank you for your testimony and the very important work that you are doing.

Now, we know that the lack of access to timely, high-quality behavioral health treatment continues to be a significant challenge. And that is why I have long supported the expansion of Certified Community Behavioral Health Clinics, CCBHCs, which provide a comprehensive range of mental health and substance use disorder services to vulnerable individuals, including 24/7 crisis response and care coordination.

Addiction treatment is a core component of CCBHCs' required service offerings. And as a result, all 340 clinics across 40 States, DC, and Guam have either launched new addiction treatment services or expanded the scope of their addiction care. And well over half of CCBHCs provide same-day access to medication-assisted treatment for patients with opioid use disorder. This model is really well placed to respond to the pandemic's expected long-term impact on behavioral health needs, and Congress has recognized its value by extending support to the program in recent COVID relief bills.

Ms. LaBelle, how does the Biden administration plan to leverage existing treatment networks like CCBHCs expand access to recovery support services?

Ms. LABELLE. Sure, thank you, Congresswoman. You raise a really important point about recovery services.

As we recognize that addiction is a chronic condition, we need to have recovery support so that we can sustain people's recovery over a period of time. CCBHCs received about \$420 million in the American Rescue Plan, and that includes—they are required to have recovery support services within them.

Peer support services are incredibly important, as you point out. They have to be provided throughout communities. As some Member of Congress mentioned, one of our highest rates of overdose death are among people—the reentry population, people leaving jails and prisons. It is important that recovery services reach them to help them sustain their recovery so that they don't overdose and that they can go on to live full lives.

So we look forward to working with you further to determine how to integrate recovery services throughout all of our treatment programs.

Ms. MATSUI. Well, I look forward to that, thank you very much.

You know, in 2018 Congress included in the SUPPORT Act a provision requiring DEA to issue regulations around a special registration process to expand remote prescribing of controlled substances. While in the past year the public health emergency has eased historic barriers to certain telehealth services, including allowing providers to initiate treatment for opioid use disorder over the phone and via video chat, the DEA has still not completed its statutory requirement to stand up the special registration process for remote prescribing.

Ms. LaBelle, can you expand a bit on the framework ONDCP is using to evaluate whether to make permanent the emergency telehealth provisions related to MAT prescribing?

Ms. LABELLE. Thanks for asking that. So we—you know, we have this included in our policy priorities. There are researchers at NIDA who are funded by the National Institute on Drug Abuse who are looking at exactly how effective the regulatory changes that were made during COVID have been. We are going to be looking at that and determining if it is administrative changes that need to be made, are there legislative changes, and how can we—what we have heard is a lot of anecdotal information that is really positive about how telehealth has helped people who are already in treatment be retained in treatment.

So we want to be guided by science and evidence, and we are working with our colleagues at the National Institute on Drug Abuse to inform those policies.

Ms. MATSUI. Well, thank you very much, because I have been working with many providers in my community, and—whether it is at the hospital or the community health centers, they have had an increase in the telehealth with their patients and found very much that it was almost immediate, as far as the prescriptions and all of this and the sense of being able to, in fact, walk people through some of these crises as they have occurred.

So I really do encourage that you really look at this, and I would be happy to work with you as we do this too. So thank you very much, very much for being here today.

Ms. LABELLE. Thanks.

Ms. MATSUI. I yield back.

Ms. ESHOO. The gentlewoman yields back. It is a pleasure to recognize the gentleman from Texas, Dr. Burgess, for his 5 minutes of questions.

Mr. BURGESS. I thank the Chair. I thank our witness for being here.

Ms. LaBelle, it is great to make your acquaintance. I have worked with your predecessor, James Carroll, while we—in two Congresses ago, when we worked on the SUPPORT Act. So this ongoing work is critically important.

Just to pick up on one of your answers to Ms. Matsui's question about telehealth, do you sort of foresee telehealth, you know—that was a big deal in getting people to continue doing their treatment, because they lost the in-person care that they were at one point receiving during the pandemic. So how do you see this working, as we come on the other side of the pandemic?

Will telehealth continue to be complementary to the treatment available?

Ms. LABELLE. Yes, thank you, Congressman. I think that telehealth will always be an essential piece going forward.

I don't think it is going to replace in-person care, but it certainly makes it a lot easier for people who may be some distance from a treatment provider. What we want to do is increase interventions at every single point. And so, if we can remove the barrier that people face—it might be transportation, it might be child care—telehealth can help remove those types of barriers to get people to be retained in treatment.

Mr. BURGESS. Yes, and I was interested in your testimony, because it actually talked a little bit about the methadone treatment programs. Obviously, that is—by definition, that is in person, because the methadone is administered and has to be taken on site, literally.

I actually worked in a methadone clinic when I was a senior medical student on an elective, but this was back in 1975, so it has been some time. But methadone—you are right, I don't think the methadone availability or methadone clinics have quite kept pace with what is available technologically. And I do think that is an important part that we need to include.

Ms. LABELLE. Yes, sure. And that is—I think that is one thing we found, again, anecdotally—the research will follow soon, hopefully—is that, particularly for patients early in their methadone treatment, I mean, that is a long haul for many people to get to a methadone clinic, as you know. And so allowing them to have take-home doses and be able to have telehealth is a really—a great way to remove a barrier for someone who might otherwise not be able to continue in treatment and might be subject to overdose.

Mr. BURGESS. Right. But the risk for diversion is significant with methadone, and that has to be borne in mind.

Let me just ask you—and I appreciate you providing the Biden-Harris administration policy priorities. One of those listed is reducing the supply of illicit substances. And clearly, that is absolutely critical. And many of us have spent some recent time down on the—I represent a district in Texas. I am not on the Texas border with Mexico, but there is a lot of activity, and a lot of illicit activ-

ity, a lot of contraband, of course, as well as people that are coming across the border.

So how do you see what your task in preventing that is, in disrupting the supply of illicit substances? How do you see that working?

Ms. LABELLE. Sure. So we have ongoing conversations with the Government of Mexico, and with our law enforcement partners through something called North American Drug Dialogue. We are working with Mexico on interdiction in their own country to prevent those drugs from even getting to the border, identifying and disrupting their labs, lab production, which is how the fentanyl is produced, or heroin, and then also their ports, which is where the precursor chemicals come. So that is kind of what—you know, some of the steps we are taking to make sure that it never even gets to the border. And that is a partnership that we have had, a long partnership with Mexico.

Mr. BURGESS. Well, good luck. But, I mean, if you have ever been down to the Texas-Mexico border, particularly that sector in the lower Rio Grande Valley, it is very, very difficult to provide those—that interdiction. And, of course, you couple that with the human toll that is coming across the border, and our Customs and Border Protection are tied up having to administer to them, it creates a diversion where additional supply can pretty much come across uninterrupted. So please don't take your eye off of that. That is absolutely critical, that we bring that under control. And that is certainly part of the Biden-Harris agenda that I would support, is interdicting that illicit supply coming into the country.

Ms. LABELLE. Right—

Mr. BURGESS. Thank you, Madam Chair, I will yield back.

Ms. ESHOO. The gentleman yields back. Those are excellent points.

And now it is a pleasure to yield to the gentleman from Maryland, Mr. Sarbanes.

[Pause.]

Ms. ESHOO. I saw Mr. Sarbanes.

There you are. Are you—Mr. Sarbanes? Can you hear us?

Mr. Sarbanes, you need to unmute.

Mr. SARBANES. Sorry, Madam Chair.

Ms. ESHOO. You looked like you were studying something very hard there.

Mr. SARBANES. Yes, I appreciate—

Ms. ESHOO. You are recognized.

Mr. SARBANES. Yes, thank you very much for the hearing.

Many of us, it is clear from our comments already, are focused on the impact of this opioid crisis on our particular States, the districts that we represent. I am no different from my colleagues in that respect.

In Maryland, since 2017 we have seen over 2,000 opioid-related deaths each year, and the numbers have gotten worse, as we have been discussing today, during the coronavirus pandemic. In the first three quarters of 2020 there were more opioid-related deaths in Maryland than in the same time period in prior years. So we are seeing that acceleration. I think that goes to the heart of your

opening comments about what do we need to do to really get our arms around this.

I had the opportunity to serve on Energy and Commerce back in 2018, when we were crafting a legislative package to address the crisis that resulted, as you will recall, in H.R. 6, the SUPPORT for Patients and Communities Act, which included bills addressing a wide range of substance use disorder issues.

Workforce issues are a very important part of the conversation, in terms of reversing this opioid epidemic. And the package back in 2018 included a bill which I had worked on, the Substance Use Disorder Workforce Loan Repayment Act, which would help increase the number of healthcare professionals working in addiction treatment and substance use disorder programs. It would provide loan repayment for individuals who provide direct patient care at opioid treatment programs in high-need areas.

Director LaBelle, in your testimony you discuss staffing shortages in the behavioral health occupations. Could you describe some of the challenges that you are seeing in this area in particular and how it relates to our ability to address this crisis?

Ms. LABELLE. Sure. Thank you, Congressman. And the loan repayment program is a good example of a solution.

You know, we know how much colleges—medical school costs for people. And it might be—there are many communities around this country where they don't have access to any type of addiction treatment. Buprenorphine-waived doctors are not available. Methadone clinics are not available. Doctors don't know how to treat addiction or screen for it.

So the workforce piece is something we are looking at very closely, and actually have had conversations with Johns Hopkins about how we work to encourage more medical schools, more healthcare providers, healthcare professional schools to include addiction in their curriculum, so that when people come out they are prepared to screen and identify folks for substance use disorder. The workforce issue is so important because, as we—Congress has been very generous in giving a lot of money to the States, but unless we address those workforce shortages, we are not going to be able to put that money to good use across the country.

Mr. SARBANES. Can you be a little more specific about some of the actions you plan to take in this space in the coming months?

I mean, do you have a kind of prioritized list when it comes to boosting the workforce?

And then, how can we help? I mean, how can Congress help support those efforts in concrete ways?

Ms. LABELLE. Sure, thanks. So a couple of things.

One is that there are fellowships that are available that have been funded by—in HRSA by HHS that are not filled yet. So we are going—we plan first to just make sure that people know that these fellowships, addiction fellowships, are available that can help build the addiction treatment workforce.

Secondly, we plan to talk once again with our colleagues in medical school—medical schools, nursing schools—about what they can do to make sure that, for example, all of their residents are DATA-waived. That is one step they can take.

So those are two things that we plan to take on right away. And again, we are going to work closely with Johns Hopkins on several of these issues.

Mr. SARBANES. Thank you very much.

Madam Chair, I yield back my time.

Ms. ESHOO. The gentleman yields back. It is a pleasure to recognize the gentleman from Virginia, Mr. Griffith, for your 5 minutes of questions.

Mr. GRIFFITH. Thank you very much, Madam Chair.

Director LaBelle, I first want to say that I greatly appreciate the work that the Office of National Drug Control Policy does and the role it plays in combating abuse of controlled substances.

In fact, you mentioned one of the programs that was very helpful in my district—in fact, they would like it expanded—and that is the HIDA program.

Former Director Jim Carroll traveled to the district a little over a year ago, and we visited with the folks in a far southwest corner of Virginia where the opioid epidemic has hit particularly hard, although it is spread across the district. And prescription opioid abuse has been a major problem, as it has been in many districts. But for many years, the Nation's highest per-capita prescribing rates for opioid pain pills occurred in two of the localities in my district. One, it was 306 pills per person, and in another it was 242. So obviously, we can do better, and we are doing better, and I appreciate your work on this as well.

And we have more than our share of illegal drugs trafficked in from China and Mexico.

But the question is, how does the ONDCP approach to data collection and recommendations differ between schedule I and schedule II substances?

Ms. LABELLE. So I think—I am sorry, can you repeat the last part of the question?

Mr. GRIFFITH. Sure. What is—what are the differences between schedule I and schedule II when it comes to your data collection and then the recommendations you make?

Ms. LABELLE. So the National Survey on Drug Use and Health is one of our tools that the Health and Human Services Department uses to collect data on drug use. And it has—it asks questions about lifetime drug use, substance use. It includes alcohol, it includes schedule I and schedule II drugs. And they added a lot about schedule II—I am sorry?

They added quite a few questions about schedule II drugs in the last couple of years because, as you said, we can't keep our eye off the ball of other types of substance misuse.

What we are trying to do in our strategy, in our policy priorities, is look at this from a holistic standpoint, that it is not just about one drug, it is about all drugs. It is about polysubstance use. And that can include alcohol use, as well, because we know that that is a substance that young people first start with, including alcohol and marijuana.

So those are our issues. We work closely with HHS through their National Survey on Drug Use and Health to inform our policies.

Mr. GRIFFITH. And I appreciate that. And I appreciate recognizing that all substances may have a problem. I come from a fam-

ily with some history of substance abuse, and so I have chosen throughout my life not to use any of the substances, including alcohol and marijuana.

All right, new subject, Director LaBelle. In 2019 a Federal inter-agency work group led by ONDCP recommended the use of permanent classified scheduling for fentanyl-related substances, along with legislative modifications to allow for easier rescheduling of any fentanyl-related substances with low or no abuse potential. This would allow rescheduling to happen in a more timely manner, and it would make it easier to conduct research on schedule I substances. And I am big on research.

I understand that ONDCP is reevaluating permanent scheduling, but does ONDCP still stand by these recommendations to make conducting research for medical purposes easier?

Ms. LABELLE. So we are talking to HHS about exactly what the barriers are to research with the fentanyl scheduling legislation as it currently stands. We will be engaging with them in the future. We can build off of what was done and have that inform our work, but we need to make sure we are talking to them about the issues they are facing today.

Mr. GRIFFITH. Because, I mean, I think this is an important issue, and I think we need to do research because, while some of this stuff is the nastiest stuff out there and has no benefit whatsoever, sometimes things have medical capabilities that we are just not aware of. And if we don't allow our research facilities and our medical teams to experiment and try to figure out how to—how do you solve these problems, then we will still be in the dark 20 years from now.

Ms. LABELLE. Right.

Mr. GRIFFITH. So I would hope that you all would allow more research, even on schedule I, and figure out ways to make it so that it is practical and effective and efficient.

And I have got a little bill that will help you do that, but—that Dan Crenshaw and I are carrying. But I am encouraged by your comments, and I yield back.

Thank you, Madam Chair.

Ms. LABELLE. Thank you.

Ms. ESHOO. I thank the gentleman, and especially for being willing to express what your family and extended family have dealt with. That is to your credit. And I think it is important for not only Members but the American people hear you express that, Mr. Griffith.

Now I would like to recognize the gentleman from Oregon, Mr. Schrader, for your 5 minutes of questions.

Mr. SCHRADER. Thank you very much, Madam Chair.

And Director LaBelle, thanks for being here. I appreciate it very, very much. I am encouraged by the interest shown by ONDCP in pursuing mental health parity. We try and do that in Oregon. It is a huge benefit at minimal cost, and I would argue it saves millions of lives and a lot of money in the long run.

Just like we have been talking about here, access to treatment is a huge issue. And while payers can't create more providers, ensuring that, you know, they cover the ones that exist is one piece of the puzzle.

And so, in that regard, what policies is ONDCP considering to encourage the growth of substance use disorder providers?

Ms. LABELLE. So what we are doing is making sure, obviously, that there is quality treatment. As you mentioned, the parity work, we did quite a bit of that when I was here at ONDCP last. We need to catch up to see where the barriers still exist to parity. We need to work with Department of Labor as the agency that administers and enforces the Parity Act. So we will be working with them to determine what the gaps—where the gaps continue to be.

Mr. SCHRADER. Very good, very good, excellent.

And others have spoken about this too, but, you know, the—last March, millions of Americans that were getting treatment for alcohol, cocaine, methamphetamine, marijuana, fentanyl, heroin addictions basically lost access. There have been some creative opportunities through telehealth to help in that regard.

And so, given the constraints that we have encountered with the in-person care, has ONDCP given any consideration—the field—the FDA cleared and regulated products called Prescription Digital Therapeutics that use software to treat serious unmet medical health needs? And if so, how so?

Ms. LABELLE. Sure. Thank you for asking that. So clearly, there are lots of innovations that have come out across the country to address this need.

I mean, there are—technological innovations kind of abound, which is great because, as I said before, our policy priority is about increasing interventions at every single point and removing barriers. And technological advances such as the one you identified, that is something I need to look into a little bit further, and I would be happy to talk to you about that more.

Mr. SCHRADER. Well, that would be great. I would like to have you work with the committee on the opportunities that are there.

My understanding is that the products actually have accountability and support features built into them, which are both very, very important in terms of followthrough. So I want to make sure that, while these apps and opportunities are there, they are actually doing what we want them to do and can register improvement from our patients. So if you will work with us, I would appreciate it.

Ms. LABELLE. Sure, thank you.

Mr. SCHRADER. Thank you.

And Madam Chair, I yield back.

Ms. ESHOO. Thank you. The gentleman yields back.

It is a pleasure to recognize the wonderful Mr. Bilirakis—

Mr. BILIRAKIS. Thank you very much. I appreciate it, Madam Chair—

Ms. ESHOO [continuing]. Members on our committee.

Mr. BILIRAKIS. Thank you so much, it is appreciated.

Madam Chair, the United States remains in an overdose epidemic. I know you know that. Sadly, according to the CDC, drug overdose deaths rose from 2018 to 2019; 70,630 lives lost in 2019, sadly. And with deaths involving synthetic opioids, primarily fentanyl, there was a continued increase with more than 36,359 lives lost in 2019. It is just terrible.

DEA temporarily scheduled fentanyl analogues as controlled substances 3 years ago. Last year Congress passed a temporary extension that continued to criminalize fentanyl analogues until May 6, 2021. Locally, we have seen that fentanyl has been a major problem even with the schedule being in place. Madam Chair.

For example, Pasco County in my district has already had 48 people die from overdoses since January of this year. And Pasco is not alone, as you know. Many communities throughout the country are experiencing the same overdose increases as the pandemic has only exacerbated the mental health and addiction crisis in our country. If this scheduling ban expires, we expect far more fentanyl to flood our streets and many more lives to be tragically lost. We cannot allow that to happen.

While we have made meaningful bipartisan strides to address this scourge, we are certainly far from being out of the woods. It is critical that we remain engaged in the fight to save the communities we are charged to represent, and the lives of our neighbors too often cut short.

Director LaBelle, thank you for being here. Thank you for your testimony. Can you discuss our working relationship with China to prevent the entry and sale of fentanyl and its analogues?

And then, given the dynamics of the current U.S.-China relationship, what is the level of transparency and information sharing with law enforcement agencies, please? Thank you.

Ms. LABELLE. Sure, thank you, Congressman. I will start with your first question first.

So our office, the Office of National Drug Control Policy, has a regular conversation with our embassy in Beijing, where we discuss these very issues that you raised. China has a very large chemical industry, much of it which is unregulated. So we are discussing with them on a regular basis about just the issues that we have discussed, how to control the chemical industry so the precursor chemicals that are used in the manufacturing of fentanyl and fentanyl analogue are more controlled.

And then the second—your second question concerned, you know, what—going forward, what we can do. Again, you know, it is making sure that—there were several pieces of legislation put into place that—so we could have our Customs and Border Protection and the U.S. Postal Service make sure they are getting the chemicals that are coming in, the fentanyl analogues that are coming in through the mail or express couriers, so they can seize those.

And then also, I think it was good in—a couple of years ago when China—working with China to make sure they were—they scheduled all of their fentanyl. So that did reduce the amount of fentanyl coming in directly to the United States from China.

Unfortunately, a lot of that—the chemicals are now going to Mexico, where we are working with Mexico on the problem.

Mr. BILIRAKIS. Thank you.

You know, Madam Chair, while China's step to designate fentanyl and all its related analogues as controlled substances is certainly helpful, if COVID-19 has taught us anything, it is that we ought to remain skeptical and not rely on the goodwill of the Chinese Communist Party.

A permanent American solution is necessary, as you know, and I encourage my colleagues to review and consider a permanent ban for these deadly analogues under H.R. 1910, the FIGHT Fentanyl Act, or continuing the temporary ban under H.R. 2430, the Temporary Reauthorization of the Emergency Scheduling Fentanyl Analogues Act.

Thank you very much for holding this very important hearing, Madam Chair, and I will yield back. Thank you.

Ms. ESHOO. I thank the gentleman, and he yields back.

I don't see Dr. Ruiz, so I am going to go to the gentlewoman from Michigan, Mrs. Dingell.

You are recognized.

[Pause.]

Ms. ESHOO. Unmute.

Mrs. DINGELL. I know—

Ms. ESHOO. Now we can hear your voice.

Mrs. DINGELL. I am sorry. Thank you, Chairwoman Eshoo and Ranking Member Guthrie, for convening this important hearing on the opioid crisis, which, as we have all talked about this morning, remains one of the defining public health challenges of our time. And thank you, Acting Director LaBelle, for the leadership you and your team have already put forward at the Office of National Drug Control Policy.

As we know, substance abuse disorders are complex, but they are treatable diseases. And it is good to be part of a committee that has recognized that and sees this as a public health problem.

Despite all of our work over the years, the Nation is still experiencing a significant treatment gap, and I would like to ask you to expand on how we can work together to reduce barriers to treatment, particularly for patients who receive methadone. By law, only certain treatment programs can dispense methadone for the treatment of opioid use disorder. Patients who receive methadone as part of their treatment must also receive the medication under the supervision of a practitioner.

Could you—Director LaBelle, could you—the administration's drug policy priority states that you plan to review policies relating to the methadone treatment and develop recommendations to modernize them. When will this review begin, and when do you expect to develop recommendations?

Ms. LABELLE. Thank you for your question. And methadone is, obviously, a proven medication for opioid use disorder, as you have recognized. We are—we have not yet begun that review. I can't give you a timeline. We do know how urgent it is.

Methadone regulations and rules haven't been reviewed in some—for some time. So we need to—you know, our policy priorities were issued on April 1st. We are now looking for what the best venue is to review that. So as soon as we know that, I will make sure our office stays in touch with your staff about it.

Mrs. DINGELL. Thank you. During the pandemic SAMHSA and other agencies have made exceptions to rules around treatment for opioid use disorder. But some restrictions around methadone remain in place, such as requiring new patients that are treated with methadone to complete an in-person medical exam. Does that in-

person requirement exist for other forms of opioid use disorder treatment?

Can this requirement be a barrier for patients seeking treatment?

Ms. LABELLE. So the methadone—the way—and again, I am a lawyer, not a doctor, so I don't want to step into clinical recommendations. But as I understand it, one of the issues with methadone is making sure you get the right dose, which is why it is so important to have the in-person piece.

Those are issues that we need to make sure are reviewed and that we have clinicians who can discuss that very issue, because we know methadone works and we want to remove those barriers.

Mrs. DINGELL. One way to—thank you for that. One way to reduce barriers to treatment is to find ways to meet patients where they are. Your priorities include finalizing a rule related to methadone treatment vans. Can you talk to—talk us through how these would work and why they might be important for both rural and urban communities?

Ms. LABELLE. Great, thank you. So methadone treatment vans have been—we haven't had new ones for almost a decade now, and so that is why it is so important to get these methadone rules out. The mobile methadone vans can be useful. I feel very strongly they can be useful in—across the country in jails that may not have their own opioid treatment program. A methadone van could provide those services to those individuals.

I also think that it is important—and I talked about the, you know, the mobile treatment availability. It is—that is important for rural areas, but it is also important in urban areas as well, where you might have the same type of—or similar issues with transportation. So I am a strong proponent of mobile methadone vans, and we are working diligently to make sure that those get out as soon as possible.

Mrs. DINGELL. Thank you, Director LaBelle. As we have heard today, the trend in drug overdose death statistics is really alarming, and we know that increasing the availability of treatment will ultimately save lives.

I lost my sister to this, so it is an issue that remains very personal. My father was an addict too. So thank you for all the work you are doing, and we also have to remove this stigma attached to it so we can get out there and really treat the problems. Thank you.

I yield back, Madam Chair.

Ms. ESHOO. The gentlewoman yields back. And I would also add to Mr. Griffith's personal testimony, I think that it is really rather courageous of Members coming forward, as Mrs. Dingell has, to let the American people know that we are all just as human as the rest of the people in our country and that these terrible, terrible drugs have impacted so many Members in—obviously, in a very personal way. So thank you to you.

The Chair now recognizes the gentleman from Missouri, the one, the only Congressman Long.

Mr. LONG. Thank you, Madam Chair, and I appreciate it very much. And I remember being on a trip to Turkey with you a few years ago, right around the start of the Syrian War. And we had

some refugees from Syria in our roundtable discussion, so we were there a week and really trying to drill down. And at one point you leaned back and you said, "What a mess." And that, I think, is what we are faced with here again today. What a mess.

I never came home growing up and had my parents tell me that one of their friend's children had deceased from drugs. And just within the last month I have had the fourth child that is the same age as my children and grew up with them, that deceased from opioid abuse, I guess you would call it. And all four of those cases, all four, are personal friends of mine that have lost children. They had had them—they were all middle—upper- or middle-class and above. They had all done everything humanly possible for their children, had them in rehab facility, rehab facility, after rehab facility. One died, they found him in the bushes of the rehab facility with a needle still stuck in his arm.

So thank you very much, Madam Chair, for holding this very important hearing today. It is titled, "An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America." And I hope we can understand how to break the addiction for these kids, because in all four cases in our—you knew what was going to happen, you knew how the book was going to end, how the story was going to end. And it did. And I don't know what the breakthrough will be, with a drug company or with someone to come up with something to break this horrendous addiction, and—that brings so much death to families across America.

I was in Kansas City a couple of years ago visiting a drug facility where, when the cops pick you up, instead of taking you to jail, they take you to this facility. And the first thing that they do is they test you for drugs. And they have got this guy in there, the cops brought him in, and instead of taking him to jail, bringing him to the rehab facility, brought him in, and they said, "What are you on?"

And he said that he was on opioids, and they tested him and they said, "You don't have one opioid in your system. You have fentanyl."

He said, "What is fentanyl?"

So, again, I, you know, just want to thank you for holding the hearing.

And Ms. LaBelle, for years Missouri had one of the worst problems in the country with meth labs. And that trend has, thankfully, gone down. But, unfortunately, these bigger manufacturing operations are filling the void.

We tend to think of meth as the small lab's business. And when I was an auctioneer, I would go out to book a farm, a real estate auction, and there would be a black trash bag on the ground with, like, smoke coming up. It wasn't smoke. I don't know exactly what it was, but somehow I guess you can put meth in a black plastic trash bag. But—so we tend to think of it as small labs in basements or out in the fields, I guess. But it is clear that the meth production has turned into a highly industrialized operation.

And last week a Missouri State Highway Patrol trooper found 88 pounds of meth in a car during a traffic stop. And this was following a similar traffic stop in Missouri the week before, where they discovered 75 pounds in a cooler in the back of a car.

Last year, in March, we had a hearing on substance use disorder, and I asked Admiral Brett Giroir, the Assistant Secretary of HHS at the time, about methamphetamine. He noted the cartels were manufacturing and then distributing hundreds of thousand pounds of pure methamphetamine. And he characterized methamphetamine as the fourth wave of substance abuse.

Director LaBelle, last year's hearing was right before the COVID pandemic and everything that came with it. Fast forward a year. What are you now seeing, in terms of availability, manufacture, and distribution, and use of methamphetamine?

Ms. LABELLE. Thank you, Congressman. So I think, as you said, it is not yesterday's meth. Meth that is being—now it is manufactured in Mexico, and it is coming in to the United States across the border. So—and we are seeing it where—I grew up in New England, but lived in Washington State for a long time. Never heard of it in New England. Washington State had a lot of meth labs. Now we are seeing more meth availability in the Northeast and across the country.

And so I think that that is getting much more attention. We know there are treatment programs that work, and will be working with HHS on making sure that, again, the barrier to effective treatment for meth use disorder is something that we take up.

Mr. LONG. OK, I only have 47 more questions, but I am out of time. So, Madam Chair, I yield back.

Ms. ESHOO. The gentleman yields back. I think that it is worth noting that when—with a sweeping schedule I designation, it is very difficult for there to be the development of new drugs to be administered to people that would benefit from them, because in that sweeping schedule I it eliminates the possibility of some of these substances to be used to the—for the benefit of individuals. So I think we need to keep that in mind.

Let me recognize the gentleman from California, Dr. Ruiz, for his 5 minutes of questions.

Mr. RUIZ. Thank you, Madam Chair, and thank you, Acting Director LaBelle, for providing an update on the administration's drug policy priorities.

One issue I would like to address today is access to treatment, and how that is directly related to the amount of education and training of providers. In other words, also the physician shortage that we see, not only in all aspects and all specialties, but specifically with addiction medicine.

As an emergency physician myself, I have cared for countless individuals in the emergency department who were actively overdosing and have resuscitated many and intubated them, et cetera, given them the appropriate medications when appropriate, and saved their lives. And there is an obvious opportunity in the emergency department to help an individual get help by seeking long-term treatment.

However, many patients with substance use disorders also come to the emergency department for completely different reasons. And being able to identify the more subtle signs of substance use disorders can be a critical tool to help more individuals get access to the treatment they need. In other words, identify those at risk, give them the treatment before they come in blue and not breathing.

And this is not just for emergency physicians. The more providers in all specialties that can help identify the signs, the more opportunity we have to open doors for our patients to seek care and improve their lives. A National Academies paper issued last April found that, “despite the impact and pervasiveness of the opioid epidemic, most clinicians cannot confidently diagnose and treat patients with substance use disorder.”

So Acting Director LaBelle, just talk to me about whether or not additional education and training around substance use disorders improve provider confidence in diagnosing and treating substance use disorders and, therefore, increase access to treatments for individuals with substance use disorders.

Ms. LABELLE. Thank you, Doctor. I couldn’t agree more about the importance of all providers, all healthcare providers, being able to identify early stages of a substance use disorder before it becomes chronic, when it is much harder to treat, as you know.

So we are working with the National Academies. We will continue to work with the National Academies, the American Medical Association, pediatricians. These are all important parts of the answer to this, is to make sure that they get the training that they need in medical school but also, you know, during residency, so that they understand how to identify and refer people to treatment. That is a key element of our strategy.

Mr. RUIZ. Thank you. And you also note in your testimony that the Nation’s addiction workforce is experiencing staffing shortages. In what way does the Biden-Harris administration plan to support, diversify, and expand the addiction workforce?

Ms. LABELLE. Thank you, an important point about diversifying the addiction workforce.

There are fellowship programs, minority fellowship programs in particular, that would help diversify the workforce. I don’t think we are there yet. And I want to work with your office to identify how better to address those issues, because I think there have been workforce approaches that have been authorized but not appropriated. We need to work with HHS to identify what those are and expand them, and particularly in areas where there is a high need.

Mr. RUIZ. Director LaBelle, I helped start a medical school in one of the—California’s most underresourced areas that faced high health disparities, our senior—founding senior associate dean at the UC Riverside School of Medicine. And one of our missions was to develop a workforce that comes from the underserved communities. In other words, it is—diversity was very important.

The best way to do so is to create pipelines from those communities into those specific targeted specialties that you need for that region. And so I am more—and I developed pipelines, not only through my pre-med mentorship programs from those underserved communities but also developing residency, because the best predictors of where a person will practice is where they are from and where they last train. So you need to develop pipelines and create residencies in addiction medicine in those under-served communities.

And so with that, I want to thank you. I want to make myself available to you as we address this pandemic the right way.

And I yield back my time.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentleman yields back. It is a pleasure now—

Mr. GUTHRIE. Excuse me, Madam Chair?

Ms. ESHOO. Yes?

Mr. GUTHRIE. Hey, it is Brett Guthrie. Hey, you made a comment between the last two questioners about research and fentanyl. And I am not speaking for every single Republican, I think, but for our side is that we just want to say we want to do research, but we don't think they are mutually exclusive, that you can have scheduling—and there is a bill that I think Mr. Griffith and Mr. Crenshaw have allows for research to go forward too.

So I just wanted to—I know we don't have a chance to respond to that comment, I just wanted to respond to what you said between the last two.

Ms. ESHOO. Yes, it is not a hit on anyone. I think there is bipartisanship on the—always on the development of new drugs to—

Mr. GUTHRIE. Absolutely.

Ms. ESHOO [continuing]. Suppress whatever it is that is serious out there.

Mr. GUTHRIE. Right.

Ms. ESHOO. I thought it was, you know, important just to mention, and thank you for raising it.

Mr. GUTHRIE. Thank you, I appreciate that.

Ms. ESHOO. We can be for—we can certainly be for both, and I believe that we are, and bills address it.

I now would like to recognize the gentleman from Indiana, Dr. Bucshon, for his 5 minutes of questions.

Great to see you. Look at that big smile. You make me happy, just looking at my screen.

Mr. BUCSHON. Yes, well, thank you, Madam Chairwoman. I very much appreciate it. And thank you to the panel.

I was a cardiovascular and thoracic surgeon before, so I have been in healthcare for over 30 years, and this is really a critical subject.

But before I get to my questions, I would like to share my concerns regarding one of the bills being considered today. Buprenorphine can be effectively administered by properly educated and trained providers who counsel and educate patients. However, the vast majority of individuals currently receive little or no counseling.

I have been working in Congress to implement prescribing limits and increased prescriber education for buprenorphine and other medication-assisted treatment to mitigate the practice of only treating people with medication-assisted treatment but not continuing on with a more comprehensive treatment plan.

However, not everyone agrees with this, and some of my friends continue to work on expanding the scope of practice to allow almost anyone, regardless of their qualifications and/or training, to prescribe buprenorphine. In my opinion, that is exactly what H.R. 1384, the Mainstreaming Addiction Treatment Act, does. It removes education requirements and limits, making it easier to prescribe the medication known to be one of the most highly diverted drugs in the country.

This bill will only expand access to medication, not real and effective treatment for individuals with substance use disorder. Everyone who is legitimately involved in the medication-assisted treatment space to treat people who are addicted recognize the importance of a comprehensive treatment plan. The last thing Congress should do is relax the requirements for prescribing and dispensing narcotic drugs such as buprenorphine because, as I mentioned before, expanding the use of medication-assisted treatment is not going to be effective unless we have a comprehensive treatment plan in place. So I would like to voice my opposition to this legislation.

Pivoting now to another topic, pain management is real, and people have chronic pain, and we must look—all of us—to finding non-opioid alternatives to use to help individuals that suffer from pain daily. Director LaBelle, recently eight States have passed non-opioid directives that ensure non-opioid options are considered for the treatment of pain management. These directives are voluntary and are intended to spur discussions between patients and providers around alternative ways to alleviate pain.

Does the White House support establishing a Federal—my question is, does the White House support establishing a Federal non-opioid directive to further empower patients and providers across the country to engage in important conversations around the need for non-opioid alternatives?

And are we—also I would request that the White House consider reimbursement as an issue, as opioids are cheap and new medicines are expensive. And what advice might you have to Congress in addressing that particular issue?

Ms. LABELLE. Thank you, Congressman. So, on the first one, I think we could—we would be happy to work with your office to get more information on that issue, on the directives.

On the second issue, the reimbursement rates certainly, you know, are something that we would have to speak with CMS about. And as we go forward in our national drug control strategy, which we will issue next year, we can certainly take a look at that.

Mr. BUCSHON. Yes, because that is one of the most important barriers for hospital systems or clinics, is, again, opioids are very cheap, potentially new non-opioid alternatives are expensive. And when you look at, you know, bundled payments that—based on diagnostic-related groups and other ways providers are reimbursed, it doesn't make a lot of economic sense, in many cases, to use non-opioid alternatives, and we need to fix that, because, whether we like it or not, in healthcare financial incentives drive the ship many times.

Ms. LABELLE. Right, right.

Mr. BUCSHON. And so we need to address that. So I appreciate that.

You can also not properly combat the opioid misuse epidemic without addressing one of its root causes: again, as I just mentioned, inadequate pain management. HHS has included improving pain management as one of their pillars of the opioid strategy. What is ONDCP's position on improving pain management, provider education, and patient access to non-opioid therapies?

And that is just an extension of what I just mentioned.

Ms. LABELLE. Sure. I think it is really important that we make sure that people who are—have pain are treated properly, whether that is—and what the alternatives are, that is an important issue that I know that the National Institutes on Drug Abuse have looked at, as well as the rest of HHS and CDC. So it is a very important issue that we will look at, going forward.

Mr. BUCSHON. Thank you. I can—I had a personal experience with my father, who has now passed away, had substantial back issues that, really, there was nothing they could do for him—he was in his late 70s, early 80s—other than opioids, unfortunately. And all of us are fighting the opioid epidemic. But what happened to him is—in his home State—is it became more and more difficult to acquire his medication, even through his primary care provider, because of things put in place at the State level.

So I just want to mention the pain—chronic pain management is an issue. We need good opioid alternatives.

With that, Madam Chairwoman, I yield back. Thank you.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentleman yields back. It is a pleasure to recognize the gentlewoman from New Hampshire, certainly not a newcomer to this issue, offered really important insights and leadership on the whole issue of opioids, Ms. Kuster.

You are recognized.

Ms. KUSTER. Thank you so much, Chairwoman Eshoo, and thank you to Director LaBelle for joining us today. I am pleased to see that this administration's priorities focus on evidence-based approaches that holistically address prevention, support, and treatment for those battling with substance use disorder. And I think you can appreciate today, for many of us, this is a personal issue in our families as well.

My legislation, the Emergency Support for Substance Use Disorder, was included in the American Rescue Plan to ensure smaller organizations on the front lines of the addiction crisis would receive support for their harm reduction services during COVID-19. I look forward to working with you.

I want to commend Representative Tonko's bill today about treatment at the end of incarceration, and I would like to meet with you about treatment during incarceration so that we can break this terrible recidivism cycle that we are engaged in.

This is deeply personal. And New Hampshire has consistently had one of the highest rates of overdose deaths in the country. In 2019 my State ranked third for the most overdose deaths per 100,000 people. And we had the highest rate of fentanyl overdose deaths per capita in the United States for many years. In 2020 about 65 percent of the overdoses in New Hampshire were caused by fentanyl, or a combination of fentanyl and other drugs, as we have heard today.

But we know this is not just happening in my State. My colleagues all have similar stories about how the opioid crisis has evolved into an overdose crisis at the hands of synthetic opioids.

Now, at the same time, the Drug Enforcement Agency has had the ability to go after the proliferation of fentanyl-related substances through emergency classwide scheduling. Despite this tool, we have seen the continued upward trend of overdose deaths re-

lated to fentanyl and its analogues. And that is why I have introduced, with my good friend and colleague Congresswoman Blunt Rochester, the STOP Fentanyl Act to provide a comprehensive, balanced public health approach.

Director LaBelle. You have said the administration is supportive of this short-term extension, but could you explain, as specifically as you can, how another temporary extension is necessary to explore a more comprehensive and effective approach to fentanyl-related substances?

Ms. LABELLE. Sure. Thank you, Congresswoman, and thank you for your work on this issue.

I think that we need the extension because we need a little bit more time to—you know, we have only been in this position for about 85 days. There are many people who aren't even in place yet. This is a critically important issue, and we want to do it right. So we need the time to look at the mandatory minimum implications of this legislation as well as the research implications that have come up several times on both sides of the aisle. So that is why we need the extension of time.

Ms. KUSTER. And if I could press you a bit further, what is the plan to use that time effectively, so we won't be back in this same situation if we grant a seven-month extension?

Ms. LABELLE. Sure. I mean, so the plan is that, you know, it is a process plan, which is we get our colleagues together from the Department of Justice, we get our colleagues together from HHS, and we hash this out. We have had a couple of meetings already. We are going to have more, and we are going to come together and have a resolution of the issues.

Ms. KUSTER. And how can we work with you to make sure that we address the issue of racial equality?

I am very concerned, as many of us are on both sides of the aisle, about the disparate impact on race with these mandatory minimums. How can we do a better job with a public health approach, rather than being so focused on mandatory minimums, when we know we are not getting the treatment into the jails and prisons across this country?

Ms. LABELLE. Yes, so we know that incarceration rates are higher for poor Black Americans, and the work that has to be done in jails across the country, we are getting there. Certainly, New Hampshire has medication, most of the New England States do. There is a lot more work that needs to be done.

I am encouraged by the Congress's help, though, to provide funds through the Department of Justice to expand access to treatment in jails.

Ms. KUSTER. Well, we would love to meet with you. I will set that up. We have game-changer legislation that would eliminate the exclusion of Medicaid during incarceration. And I think it would really change the scope. We would be talking about treatment, we would be talking about support services, and we would help people get back on their feet and lead much more productive lives.

So with that, I yield back, and thank you.

Ms. ESHOO. The gentlewoman yields back. I would like to recognize the gentleman from Georgia, Mr. Carter, our favorite pharmacist.

Mr. CARTER. Thank you, Madam Chair. I appreciate that very much. And thank you for being here. We appreciate this very much, this is extremely important.

I wanted to mention, first of all, that I understand we don't have jurisdiction over the border in this committee. But I do want to bring up the border crisis, as it is impacting this epidemic. And I know that because I was there last week. I was there last Friday.

The GAO has reported that Customs and Border Patrol data at U.S. ports of entry at the southern border show seizures of fentanyl and its analogues have gone up more than 200 percent in the last couple of years.

Ms. LaBelle, is it correct the majority of fentanyl and its analogues come through the southern border from Mexico?

Ms. LABELLE. Most—well, much of fentanyl certainly is seized at the border. We are getting some that comes through couriers. So mail systems, that is much reduced, but much of it comes—is seized at the southern border.

Mr. CARTER. Well, from my investigation of it, my studies of it, what I have seen is there is enough fentanyl coming across the southern border to kill every American several times over. So I think it is really a stunning problem.

Again, I want to allude back to my visit this past Friday to the border, and what I witnessed there, because, listen, these cartels, they are not dumb. In fact, they are very smart. And what they are doing is flooding the border in one area so that it takes the attention of Customs and Border Patrol agents, and then they are just bringing drugs across at another point. It is causing us to have even more of a problem.

Obviously, we have got a humanitarian crisis down at the border with what is going on with the illegal immigrants. But we have also got another problem, and that is a national security problem with our—with all of these drugs that are coming across this border. We have got to get this under control.

You know, it would be easy for all of us just to sit back and think, oh, what is happening down there is just a problem at the border, and those poor people down there. But it is much more than that, because when we talk about fentanyl, when we talk about illegal drugs, those drugs that are coming across that border, they are going to be in your community next. Whether you are in Georgia, whether you are in the northern United States, or the northeast, or the northwest, it is going to be impacting you.

And that is why it is such a big problem. It is killing people in our communities. Just this past week in Georgia we had two incidents of fentanyl overdoses, one in Richmond County near Augusta, one in Chatham County near Savannah, where my district is. And that is a problem that we have got to deal with, and it is a problem that is being exacerbated by the fentanyl that is coming across the southern border and coming across from Mexico.

I wanted to ask you, Ms. LaBelle, would you agree that you have an obligation to advise the President, as he must get the border under control, because the epidemic that we are discussing today has gotten much, much worse—have you discussed with the Vice President or the President the harm an open border is having on the opioid epidemic, specifically the trafficking of fentanyl?

Ms. LABELLE. So we are working very closely with all of our White House colleagues on this issue. We are separating the migrant issue from the drug issue. And that is where we have ongoing conversations on a monthly basis with the Government of Mexico and with our law enforcement partners, to make sure that they are doing everything they can to interdict the synthetic drugs that are coming from China into Mexico. So certainly these are ongoing conversations, and particularly with the National Security Council.

Mr. CARTER. So I want to make sure I heard you right. You said these are monthly conversations, that you only discuss them once a month?

Ms. LABELLE. With Mexico.

Mr. CARTER. With Mexico. But in the administration, with the Vice President—

Ms. LABELLE. Oh, no, we have—

Mr. CARTER. That was—

Ms. LABELLE. I am sorry, sir. We have ongoing conversations with our colleagues throughout the White House on this issue on a daily basis.

Mr. CARTER. We were told last week when we were down there that over \$400 million of illegal drugs crossed that border last month, that we know of. That, to me, is substantial. And I think to everyone in America it would be substantial. Don't you feel like this deserves more immediate attention than what it is getting at the White House right now?

Ms. LABELLE. I think that everyone is paying very close attention to the issue. Certainly, the issue of how many drugs are coming through can be a matter of enforcement, because that is what we are seizing. That is not necessarily—it is hard to tell what it is when—

Mr. CARTER. And that is why I mentioned \$400 million of what we know of, because what is happening is the Customs and Border Patrol agents, as you know, are having to be in the processing facility, and they are not able to monitor the borders. Therefore, we are not catching as much as what is coming across. So we don't really know the true number, but we know it is more than 400 million.

OK, well, listen, this deserves immediate attention, Ms. LaBelle.

Ms. LABELLE. Yes, sir.

Mr. CARTER. I hope you will go back to the White House immediately. And listen, we have got to get this stopped.

Thank you, Madam Chair, and I yield back.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentleman yields back. It is a pleasure to recognize the gentlewoman from Illinois, Ms. Kelly.

Ms. KELLY. Thank you, Madam Chair. The Biden-Harris administration's statement of drug policy priorities for year one published by the Office of National Drug Control Policy stated, and I quote, "Black individuals generally entered addiction treatment 4 to 5 years later than White individuals. And this effect remains when controlling for socioeconomic status."

Have plans been identified on how to ensure that Black people have more timely access to evidence-based care that includes prevention, harm reduction, treatment, and recovery services?

Ms. LABELLE. Thank you, Congresswoman. So we included that in there in order to make sure that we can work with HHS to look at the data, to look at the research, just what we identified in our policy priorities, and then put in place specific programs that can handle—that can tackle those issues.

We want to do more than just a program that sounds good or looks nice. We want to put in programs and policies that are really going to make a difference once and for all on this issue. And it is not going to happen overnight.

I mean, one of the first steps is making sure that we acknowledge this is an issue, and then we are going to work with HHS to put plans in place that are going to make a difference on it.

Ms. KELLY. Thank you. In the HHS OIG report titled “Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder,” 40 percent of counties in the United States did not have a single waived provider, and waived providers were not necessarily found in areas where the need for the treatment is most critical.

How can we ensure equity of access for geographic locations, and is telehealth a tool that we can use to ensure provider equity?

Ms. LABELLE. Thank you. So this raises the issue that we talked about before with methadone clinics, that—you know, so you can go to an office and get your buprenorphine, a doctor’s office. If you are going to a methadone clinic, you are probably standing out in the street corner, waiting to get in. So much less private, much less personal care.

Certainly, there are a lot of great opioid treatment programs around the country that provide methadone, but it is a different form of care.

So how we tackle this is, number one, removing barriers to buprenorphine treatment to expand the number of providers—not just physicians, but nurse practitioners and physicians’ assistants—so that we can reduce those barriers to care that occur around the country.

Ms. KELLY. And can you give more insight on why providers must receive a waiver to provide medication to treat opioid use disorders but not to prescribe the medications that have gotten us to where we are today? This seems counterproductive.

Ms. LABELLE. Sure, thank you. So I think the issue is that we have—as we have spoken about, we really have minimal training and education in addiction in the healthcare services. And so, in order—and so, you know, people who are prescribing buprenorphine are required to go through that training, the eight-hour training, because they may not have ever really encountered or have a lot of knowledge about the treatment of addiction.

So I think what we really need to do is expand the number of people in our healthcare system who understand how to screen and treat and help people recover from addiction, as opposed to hinging it all on this one medication.

Ms. KELLY. OK, thank you so much. And Madam Chair, believe it or not, I will yield back.

Ms. ESHOO. The gentlewoman yields back, and now I have the pleasure of recognizing the gentleman from Florida, Mr. Dunn, for your 5 minutes of questions.

Mr. DUNN. Thank you very much, Madam Chair. You know, the increase in fentanyl throughout the United States, including Florida, is deeply troubling. Sadly, this has been a growing problem in my district too.

Just last month the Panama City Police Department arrested a man with 90 grams of fentanyl. That is more than 43,000 lethal doses of this drug. And for perspective, that is enough to kill over half of the population of Panama City.

On the other end of my district, the Ocala Police Department seized 177 grams of fentanyl in a single bust just last fall, and the police chief there said that that was enough fentanyl to kill, with overdose, every person in Polk County, man, woman, or child.

When using fentanyl for medical purposes, a typical dose would be 25 micrograms. That is 25 millionths of a gram. Doctors always use this drug very, very cautiously, with extreme care, because even the medical formulation of fentanyl is extremely potent and potentially hazardous.

Florida law enforcement is doing a heroic job getting it off the streets, putting traffickers behind bars. However, they need help. Fighting fentanyl requires a team effort among the trade and shipping industries, law enforcement, healthcare professionals, community leaders, and lawmakers.

And I want to associate myself with the comments made by my colleague Dr. Bucshon regarding the dangers of making access to buprenorphine and Suboxone too easy. Because honestly, these are drugs that are used—buprenorphine is the single most common cause of opioid overdose in northern Europe. So we have to be careful. We have to get this in the hands of skilled people who know how to use it safely.

And I do have some questions, but I will be submitting those to the second panel of witnesses. So with that, Madam Chair, I yield back. Thanks so very much.

Ms. ESHOO. The gentleman yields back, and I thank him for his questioning, and it is a pleasure to recognize the gentlewoman from Delaware, Ms. Rochester Blunt—Blunt Rochester, I am sorry. You need to unmute.

[Pause.]

Ms. ESHOO. You need to unmute. Lisa?

[Pause.]

Ms. ESHOO. We will get this one of these days, right?

VOICE. I don't think she can hear you.

Ms. ESHOO. I don't think she hears us, so I think I will go to—Angie Craig?

VOICE. Angie Craig.

Ms. ESHOO. We will go to the gentlewoman from Minnesota, Angie Craig, for her 5 minutes of questions, and then circle back with—I hope Ms. Blunt Rochester's staff is listening, but we will—Ms. Craig is—Representative Craig is recognized for her 5 minutes of questions.

Are you with us?

No?

VOICE. Schrier.

Ms. ESHOO. All right, then we are going to go to another doctor, the gentlewoman from Washington, Dr. Schrier.

It is great to see you.

Ms. SCHRIER. Well, great to see you, and I am now unmuted. I was just texting Lisa to see if I could let her know. Thank you, Madam Chair, and thank you to Ms. LaBelle for sharing how the White House is going to be focusing on these issues.

You have already heard that Washington State has been hit hard by this opioid epidemic. For over a decade, our State has lost about 700 people per year from overdoses, mostly from opioids. And sadly, we saw a 40 percent increase in mortality due to opioid use in 2020.

So we know fentanyl in particular has become an increasingly dangerous threat in my State and, as we have heard, across the country. In 2019, three students in my district died because the oxycodone that they thought they were taking, which is bad enough already, was laced with fentanyl. And two were students in the high school just down the street from my house.

Then, 2 days ago, in a conversation with another parent, I heard about a bring-your-own-pill party, where a group of high school seniors in my town all brought whatever pills they had to a party: Ritalin, Adderall, oxycodone, Vicodin, whatever. They dumped it in a bowl like M&Ms and then helped themselves without even knowing what they were taking. And this is barely 1 year after the two deaths that I just mentioned.

So, Ms. LaBelle, you mentioned in your testimony that one of your strategies to mitigate drug abuse and death is support evidence-based prevention efforts to reduce youth substance abuse. And as a pediatrician I know how important it is for pediatricians to talk with their patients, and parents to talk with their children. I wonder if you could just talk briefly about the most effective ways to prevent these risky behaviors from starting, and then these tragedies.

Ms. LABELLE. Thank you very much, Congresswoman, for asking that important question. I want to raise one issue about the pressed pill issue that you raised. I think all of us need to be aware that this is a trend. CDC has sent alerts about these pressed pills. That is a lot of what we are seeing. This is pure fentanyl, and people have no idea what they are getting. And this is why the administration has put out the fentanyl test strips, so people who—can test what it is that they are getting. I am not talking about that for youth use, but that is important for—to prevent overdose deaths.

So for youth use, the National Institute on Drug Abuse has some great tools. SAMHSA—I am a parent myself. I probably drive my son crazy by talking to him about these issues so much, because he has a genetic predisposition to this. So I—you know, you have to—there is a—SAMHSA has a “you talk, they listen,” which is a great tool. And actually, the University of Washington has some great prevention programs, and one of the preeminent prevention researchers in the country is there.

So there—we can’t—we think that kids won’t listen. Certainly, they are going to roll their eyes, but they will listen to you when you talk to them.

The other piece that we want to do on prevention is preventing adverse childhood experiences that lead to risky behavior, and that

includes substance use. So that is an area that we will be working more with the Centers for Disease Control and Prevention on, particularly with our drug-free community coalitions.

Ms. SCHRIER. I really appreciate you bringing all those things up. Can I ask just a quick followup question on the fentanyl test strips?

Are those—are the pills—do they contain fentanyl only on the outside, or throughout?

I mean, is this something we have to crush a pill to test strip it, or can you just rub it on the outside of a pill?

Ms. LABELLE. You could—you wet the test strip, and you can rub it on the outside of the pill.

Again, these are—you know, these are—there are various forms of this, but in many cases it is pure fentanyl.

Ms. SCHRIER. OK. It is devastating. Thank you.

Also, with the limited time I have left, you know, one of the barriers to care that we have all talked about is simply not having enough access to providers who are trained and confident in treating substance abuse disorder. In particular, most pediatricians have no experience with medically assisted treatment. And I was wondering what ONDCP's role is in ensuring that there is a broad provider network that is adequately trained, and where pediatricians might fall in that plan.

Ms. LABELLE. So the pediatrician association actually encourages, as you are probably aware, screening for all of their patients. So we want to work with them again on expanding that work.

Ms. SCHRIER. And screening is standard. Treatment, not so much—

Ms. LABELLE. Right—

Ms. SCHRIER [continuing]. Pretty intensive appointments. Do pediatricians generally get the special training?

Ms. LABELLE. No, they don't. So we need to—we will be happy to work with you on that issue.

Ms. SCHRIER. Thank you, I yield back.

Ms. ESHOO. The gentle doctor yields back, and it is a pleasure to recognize the gentleman from Pennsylvania, Mr. Joyce, for your 5 minutes of questions.

Mr. JOYCE. Thank you, Chairman Eshoo, and thank you, Ranking Member Guthrie. This is an important discussion that we have, specifically discussing the epidemic that we face within the pandemic.

In Pennsylvania, where I represent, the availability of illicit drugs, and specifically fentanyl, is a crushing blow to our local communities. In joining this COVID-19 pandemic, this epidemic has spiraled further out of control. In 2020, Blair County, my home county, we have seen an 80 percent increase in overdose deaths. Eighty percent.

Coroner Patty Ross, she can rattle off these statistics in a breath, and she will tell you that fentanyl can be 100 times more potent than morphine. Coroner Patty Ross knows how many families have been torn apart, how many children have suffered from drug-related circumstances. She has witnesses—she has been a witness to tragedies firsthand. She talks about addressing families, talking to

them as she relays the tragedy of the death of a loved one, talking to them about these loved ones who have just come out of rehab.

In Pennsylvania and around the country, Coroner Ross and other local leaders, they are desperate for Congress to get serious about combating fentanyl and illicit drugs, providing support to the brave Americans in recovery, and advocating for communities with the widespread ramifications of substance abuse and addiction, and addressing what we need to address: the stigma of drug abuse. We need to be taking action right now to keep our communities safe. But also we need to expand lifesaving treatments for those who have substance abuse disorders.

Director LaBelle, shortly before leaving office, the previous Director of ONDCP, James Carroll, announced new practice guidelines for the administration of buprenorphine for treating opioid use disorder. And these guidelines were intended to make it easier for practitioners to prescribe buprenorphine. As I understand it, on January 14th the Biden administration made a statement saying that those guidelines were issued prematurely and could not be sustained.

Director, could you please tell us why these guidelines were pulled?

Ms. LABELLE. Sure, thank you, Dr. Joyce. These are important issues that you just raised. We all want to expand access to evidence-based care. The practice guideline that was rescinded by the administration, or that is being reconsidered, and making sure—what we don't want to do is to issue a practice guideline that would not be upheld, or would not withstand legal scrutiny.

So we are taking a look at it to make sure that anything else that is issued can withstand any kind of legal challenge to it. So that is where we are at right now.

Mr. JOYCE. And what is the current status of your evaluation for renewing these guidelines?

Ms. LABELLE. We are taking a look with our lawyers on it to make sure that it gets issued. So we are working on it. I can't give you a precise timeline right now.

Mr. JOYCE. The previous administration came up with rural guidelines addressing substance abuse. In the rural communities throughout America, as you pointed out, as well as in the metropolitan areas, these substance abuses still exist. And we are looking forward to having the answers to when these guidelines will be reissued.

Can you assure us, so I can take back to the coroners, to the leaders who are facing these issues, that this is of utmost concern to you, as the acting director of the ONDCP, as it was to your predecessor?

Ms. LABELLE. Absolutely, sir.

Mr. JOYCE. Can you provide for us additional guidance of what we should be doing from a legislative point of view to aid you in making this decision?

Ms. LABELLE. So I think that what we want to make sure is that, when it is released, that it is lifted up.

But we can't stop there. We have a lot more work to do. Our policy priorities lay out our expansive approach to this, because it can't—we can't just look at one tool. We have to look at all the tools

available to address every form of addiction, not just opioid use disorder. So we are looking forward to working with you on the totality of the addiction epidemic.

Mr. JOYCE. I thank you for your hard work, and I look forward to seeing the guidelines on the administration of buprenorphine for treating opioid disorders. Thank you for being here today.

And again, thank you, Chair Eshoo and Ranking Member Guthrie.

Ms. ESHOO. The gentleman yields back.

And I apologize to you, Dr. Joyce. I think it is very important, when recognizing our physician Members, that it—that that always be stated. So apologies to you.

Mr. JOYCE. Not necessary, Chair. Thank you, though. I appreciate that.

Ms. ESHOO. We are very happy to have you as a member of our subcommittee.

Mr. JOYCE. It is an honor, thank you.

Ms. ESHOO. Oh, you are very nice. You are such a gentleman.

And now I recognize with pleasure, from Delaware, Congresswoman Lisa Blunt Rochester.

I am sorry that you didn't hear us earlier.

Ms. BLUNT ROCHESTER. Thank you so much, Madam Chairwoman. And forgive me, I am on two screens at the same time, so please—

Ms. ESHOO. Not to worry, not to worry. We see you and hear you now.

Ms. BLUNT ROCHESTER. Thank you so much. And I want to thank you, Ms. LaBelle, for joining us as well, and for your work and dedication.

Under the previous administration, the approach towards fentanyl-related substances was handled through policies that more promoted decriminalization and not public health. And evidence shows us that that isn't the most effective approach.

The U.S. Sentencing Commission's January 2021 report on fentanyl and fentanyl analogues found that in fiscal year 2019 a greater proportion of fentanyl and fentanyl analogue offenders were Black, and over half of the total offenders were convicted of an offense with a mandatory minimum penalty. But less than 10 percent of offenders knowingly sold fentanyl and fentanyl analogues as another substance.

I am seriously concerned that our efforts are targeting minimally involved individuals instead of the higher-up traffickers and cartels. What is the administration's plan to stop illicit fentanyl from coming into the country, so we are targeting the drug traffickers that are manufacturing fentanyl and placing it into the drug supply?

Ms. LABELLE. Thank you, Congresswoman, for that important question.

So, you know, when—the Office of National Drug Control Policy works a lot on international issues. I would say it is probably half of the time in our office. And so we are working with China to look at their regulatory controls over their vast chemical industry. We are also working closely with Mexico on their interdiction efforts inside Mexico, as well as destroying and using evidence from their

labs, their lab takedowns, and then—as well as working with them on how to identify some of the precursor chemicals that are coming from China into their ports.

So those are numerous—a number of issues that we are dealing with with China and Mexico right now to stop it from ever coming into the country.

MS. BLUNT ROCHESTER. And can you be more specific about the length of time that you would need to come up with the permanent solution of—because I know a couple of people have asked this, and because time is of the essence, it would be really good if we could get a clearer picture of the specific length of time that you would need.

MS. LABELLE. Yes, thank you for asking that. It is urgent. We know it is urgent. I can't give a timeline. As I said, you know, we have been here about 85 days, and there are plenty of people at DOJ who aren't in place yet. So I can't give a timeline, but know that we are working diligently on this issue.

MS. BLUNT ROCHESTER. And thank you. I know that you are aware that overdose deaths involving synthetic opioids like fentanyl continue to rise, and from 2017 to 2018 rose as high as 10 percent. If we don't pursue a public health approach as part of the solution for addressing fentanyl-related substances, as Representative Kuster and I are suggesting, what would be the impact on people with substance use disorder, and how will their access to evidence-based treatment change?

MS. LABELLE. So the public health approach that we have laid out in our policy priorities identifies the specific actions we can take, as—such as harm reduction programs that can prevent people from overdosing.

I am very concerned that, if we don't expand access to evidence-based treatment throughout the country, especially in areas of high risk for overdose, that these rates are just going to continue to climb. And I have been working on this issue since 2009, when it first started. And it is—and the steps that we are taking are—every day counts at this point.

MS. BLUNT ROCHESTER. Yes. Will ONDCP commit to working with Congresswoman Kuster and I on a comprehensive public health approach to addressing the overdose epidemic?

MS. LABELLE. Yes, we look forward to working with you, absolutely.

MS. BLUNT ROCHESTER. Thank you so much, and I yield back my time.

MS. ESHOO. The gentlewoman yields back. It is a pleasure to recognize the gentleman from Utah, Mr. Curtis, for your 5 minutes of questions.

MR. CURTIS. Thank you, Madam Chair. I enjoyed the interchange between you and Dr. Joyce. I am wondering if there is a title that we should use for those of us that have put children through medical school. Maybe we could work on that. And you are on mute, so I am just going to keep going, Madam Chair.

Director, 4 in 10 adults—and this is as reported by the Huntsman Institute of Mental Health—have reported new symptoms of anxiety and depression disorder, which is a fourfold increase since

last year. And so, to state the obvious, this hearing couldn't be more important, couldn't be more timely, and the work that you do.

I am grateful for Representative Scott Peters of San Diego. He and I recently reintroduced a bill, H.R. 2051, which would declare meth an emerging drug threat. And I want to thank Congressman Peters for his leadership on this issue. It is an important issue to both of us in our districts, and we view it as the first of many steps in continuing to fight substance abuse.

The legislation would require the Office of National Drug Control Policy—you—to develop a strategy to prevent the sale and use of this drug. We have touched on meth a little bit in this hearing. Can you just share, from your perspective, where this fits in with the larger picture of what you are seeing across—with meth across the United States?

And specifically what can Congress be doing to help you?

Ms. LABELLE. Sure. Thank you. So our policy priorities include contingency management and looking at the barriers to expanding access to contingency management therapy, which is an effective tool to use for people with meth use disorder.

Our policy priorities also include an emphasis on prevention. So that is another tool that we need to use to reduce meth use.

And then also our policy priorities include disrupting the drug supply coming in from Mexico, which is where much of our methamphetamine is sourced. So all of that is part of our priorities for us that we will be looking at in the first year.

As far as what Congress can do, I think that we may be coming back to on contingency management, to see if there are legislative barriers to expanding that. I think the most important thing that Congress can do is making sure that we have sustainable funding for a lot of these programs, particularly for prevention and treatment, so that the States are not reliant and local communities are not reliant on one-time grants that may not help them address the totality of the issue.

Mr. CURTIS. Thank you, a very good answer.

I have listened as my colleagues have all expressed—many have expressed close loved ones and people they know who have been impacted by this tragic problem. It came home to me and my wife with not only some of our loved ones, but this summer, when we purchased a home, we kind of randomly did a meth test that—we were purchasing a home from a couple that had passed away in old age, and we were surprised to find out the home had been used as a meth lab. And I think that is just a small indication of what is going on across the United States.

Quickly, I represent a very rural community with very limited resources, particularly for law enforcement, a vast geography, very, very difficult for law enforcement to cover it, which poses a challenge to crack down on this. Are there ways that we can leverage machine learning?

Have you spent any time on this, by using data collected by law enforcement agencies and public health agencies on drug overdose in certain communities to help augment the local authorities in rural areas?

Ms. LABELLE. So ONDCP funds ODMAP, which gets information from local law enforcement that helps kind of identify trends. That is in all 50 States, but it is not universal. That is one tool.

We also should be working with our partners at the Bureau of Justice Assistance and the COPS program to look at exactly those issues that you just raised, because we know law enforcement in rural areas is stretched thin.

Our High Intensity Drug Trafficking Areas Program works with a lot of law enforcement in rural areas, and that is a force multiplier for a lot of rural efforts.

Mr. CURTIS. Yes, thank you for appreciating the special needs in rural.

It has been touched on a lot today, so I am only just going to mention—not ask the question, but just—I want to reemphasize the conversations we have had today about telehealth, how important it is in these rural parts of my district.

And with that, Madam Chair, I yield my time.

Ms. LABELLE. Thank you.

Ms. ESHOO. I agree with you on telehealth. I think that—and I think other Members believe that it should be made permanent. So we have our work to do on that.

I don't think there are any other Republicans that need to be recognized. I see Mr. Latta, but I know that you are interested in panel two, is that correct?

OK, so we have two Democrats, and then we are going to go to—or we might have another one, I don't know, but I have two lined up right now.

And then, Members, we do have a second panel with five witnesses that are waiting in the wings for us. So I will recognize the gentlewoman from Minnesota, Ms. Craig, for her 5 minutes.

Ms. CRAIG. Well, thank you so much, Madam Chair.

Acting Director LaBelle, thank you very much for your testimony today. Your experience and your expertise is greatly appreciated.

As many of you are aware, over 20 million Americans struggle with substance use disorder. A significant portion of them have an opioid use disorder. Moreover, many overdose deaths involve opioids such as illicit fentanyl and fentanyl-mixed substances. The DEA recently cited fentanyl-mixed cocaine and meth as an accelerant of overdose deaths, due to its widespread availability. This trend is reflected in my home State of Minnesota, where an overwhelming majority of opioid overdose deaths involve synthetic opioids. Unfortunately, it is likely we are going to see a record increase in those deaths from 2020.

I recently hosted a roundtable in my district that addressed veterans' access to mental health services and the disproportionate rate of substance use disorder among veterans. One of the barriers to care raised by stakeholders is the stigma that often surrounds substance use disorders, an issue I know is not limited just to this Nation's veterans.

It is critical to remember that substance use disorder is a treatable disease. People with substance use disorder deserve compassion and adequate access to affordable, quality care. The problem won't be solved in jails and emergency rooms. It will take a shift in attitudes by many of the stakeholders involved.

So Acting Director LaBelle, how does ONDCP hope to reduce stigma associated with substance use disorders through its drug policy priorities in year one?

Ms. LABELLE. Thank you for asking that important question, Congresswoman.

So the first step we took, and that happened during the transition, was hiring people, bringing people on who are in recovery. Our chief policy adviser is a person in long-term recovery. Our outreach director is a person in long-term recovery.

And we are expanding a lot of our work on talking about recovery and making—because really, when you look at our policy priorities, all of these barriers really go back to stigma, the stigma that is attached to addiction. Why don't people want to treat addiction? There is stigma attached to it. Why don't people want to seek out help? Because there is stigma attached to it.

So the first step we can take, as ONDCP, is setting an example and involving people who are in recovery in the policymaking process.

Ms. CRAIG. Thank you so much. And I know stigma is one part of this that you are focused on, but also folks face barriers due to lack of access to coverage. So what levers is your office using, can you use, to address the access to care in the long term?

Ms. LABELLE. So there are lots of pieces to this. One is we are going to focus on parity to make sure that coverage, insurance coverage, is—that people are complying with parity.

The other access-to-care pieces are—involve workforce. How do we improve the workforce access throughout this country, and then also identifying, you know, the barriers to treatment with buprenorphine, methadone treatment, and contingency management services.

Ms. CRAIG. Let me ask you what you think Congress can do to build on the previous legislation that we put forward, particularly around reduction of stigma. What are the most important couple of things that we could be focused on that helps you reduce stigma when it comes to this particular disease?

Ms. LABELLE. Thanks. So I think one thing we can do is to make sure that Congress, by looking at this as an ongoing issue—this is not a—these are chronic conditions, not acute conditions, that require sustainable funding over the long term. So if we—by having Congress make sure that we are recognizing that these are not acute conditions, that people don't go into treatment and then 20 days later they are cured, that recovery services are part of the continuum of care, and continuing to emphasize recovery services is important.

Ms. CRAIG. Well, thank you so much, Director LaBelle, and I look forward to working with you and the Biden-Harris administration.

Madam Chair, with that I will yield back.

Ms. ESHOO. The gentlewoman yields back, and we thank her, and we now will go to the gentlewoman from Massachusetts, Mrs. Trahan, for your 5 minutes.

And thank you for your patience. You have been with us from the very—as most Members—from the very beginning of today's hearing.

Mrs. TRAHAN. Well, thank you—

Ms. ESHOO. And it is now afternoon.

Mrs. TRAHAN. Yes. But it is such a critically important hearing, and I thank you for convening us on this topic. Certainly my thanks to Director LaBelle for being here today. And we all look forward to working closely with you and ONDCP in the months and years ahead to push policies that take a multipronged approach to curb overdoses.

You know, the substance use disorder epidemic has claimed too many lives in all of our districts, red and blue alike. And over the last 20 years our Nation has lost more than 750,000 lives due to drug overdoses. The latest CDC data suggests that the coronavirus pandemic has triggered an acceleration in lives lost to overdoses.

Now, anyone with a loved one who has suffered from this terrible disease knows how powerful addiction can be. It can appear to have an unbreakable hold on those in its grip. My heart certainly goes out to those suffering from substance use disorder. You know, I have met with too many moms who have lost a child—the worst thing a parent can even imagine—and they and their families deserve our compassion and acceptance, free from judgment.

But we also owe it to all of our constituents, particularly our young people, to do more to defeat SUD through greater attention to preventative measures and safer, effective treatment options. The Medication Access and Training Extension Act, legislation I have introduced with Representatives Kuster, Carter, Trone, and McKinley, would ensure that most DEA-licensed prescribers, at a minimum, have the baseline knowledge to treat and manage their patients with substance use disorder.

So Director LaBelle, in your written testimony you say that the origins of the overdose epidemic began with prescription opioids. Current CDC data shows that overdose deaths involving prescription opioids more than quadrupled from 1999 to 2019. How does prescription drug misuse continue to contribute to the overdose and overdose death epidemic in our Nation today?

Ms. LABELLE. Thank you, Congresswoman, for asking that. So it continues to be part of the issue. As I said, our policy priorities focus on the addiction epidemic. And so there are certainly specific prevention tools that we can use for each substance. So in that regard, prescription opioids as a driver is—of later substance use disorders is important.

But we are really taking the entirety of the addiction epidemic and looking at it from how do we prevent, treat—have quality treatment, provide harm reduction services, and help people recover. So that is really our—the extent of our continuum of care that we are looking at implementing.

Mrs. TRAHAN. So many prescribers must take some sort of, say, prescribing education, but few take substantial education on how to identify, treat, and manage their patients with opioid and substance use disorder. You know, Dr. Ruiz said it himself, that many patients with SUD enter medical offices and emergency rooms for separate medical reasons. And so the ability of physicians to identify the more subtle signs of SUD is critically important.

Does the Biden-Harris administration believe that it is the responsibility of all prescribers with a DEA license to know how to

identify, treat, and manage their patients with opioid and substance use disorder?

And would this education increase access to care?

Ms. LABELLE. Yes, if we recognize that addiction is a chronic disease, then it is up to the healthcare community providers, healthcare providers, to be able to recognize it, screen for it, and treat it, or at least refer people to treatment. But if they can't identify it, they are not going to screen it or treat it.

So I think that that is something that we have long emphasized, is the importance of addiction training in medical schools for DEA-licensed providers. And I think it is something we need to look at.

Mrs. TRAHAN. And certainly one of the best things that we could do to, as Congresswoman Craig said, accelerate the end of stigma associated with addiction.

Thank you, I yield back the remainder of my time.

Ms. LABELLE. Thank you.

Ms. ESHOO. The gentlewoman yields back. It is a pleasure to recognize the gentlewoman from Florida, Ms. Castor, for your 5 minutes of questions.

Ms. CASTOR. Well, thank you, Madam Chair, and thank you so much for your leadership on this very important issue. I know you have seen today that all of the Members, we are really interested and concerned about substance use and misuse.

And thank you, Acting Director LaBelle, for spending some very—a lot of quality time with the committee today. And thank you for your leadership. I want to—I have two real quick questions. One is going back to Dr. Schrier's attention to prevention, especially among young people.

And one of the bills that is on our list today is the Drug-Free Communities Pandemic Relief Act. You identified in the—in your—the national drug control strategy that this is an essential element to prevent and reduce drug addiction misuse among young people. That bill would waive the local matching requirement during the pandemic, because many of these local community groups simply haven't been able to make that local match.

Can you share with me why that is important at this time, and what you are hearing from drug-free communities across the country?

Ms. LABELLE. Sure. Thank you, Congresswoman. So the Drug-Free Community Coalition is—one of the great things about them is that they are community-based, and—but they rely upon in-kind contributions. In-kind contributions that we found in the last year during COVID have been—there have been shortfalls in that. And so helping Drug-Free Community Coalitions in that regard is very important. They—we know that Drug-Free Community Coalitions reduce youth substance use, and that is an important tool that we can use to reduce addiction overall.

Ms. CASTOR. Thank you very much. And that is what I hear from folks back home, as well. The issues that are so complex these days—but there has been a dropoff on community support, and I think this would go a long way to helping keep all of those coalitions moving forward and focused on youth drug use prevention.

So my second question is a much broader one on the American Rescue Plan. We are so proud of the depth and breadth of the

American Rescue Plan recently signed into law by President Biden. It provides, just in this area, \$4 billion to SAMHSA and HRSA for a lot of the issues that your office will oversee.

Give us a good thumbnail sketch on what you are working on right now, in coordination with those agencies and our local partners, to ensure that those dollars get to communities and families that need them. Will—we—are you coordinating the guidance that will be issued from the agencies, and what can we expect?

Ms. LABELLE. Thank you. So the—HHS, SAMHSA, the Substance Abuse Mental Health Services Administration, we are working closely with them on what this is going to look like, because, I mean, the good thing is that this funding can be spent over a period of time so that States aren't going to get this huge influx of money that they have to spend in a year. So there will be a more sustainable funding source for them.

So we are talking to SAMHSA about, you know, what are the gaps, what is missing, who are the vulnerable groups. That is—so because this money is going through the block grant, it will be easier to facilitate that funding. So it is a great opportunity to really make a difference on this issue.

Ms. LABELLE. I agree. We are all so proud of what we have been able to do in the American Rescue Plan. And a lot of folks are focused, of course, on vaccinations and the stimulus payments, and kids in school safely. But there are very significant dollars for our local communities when it comes to behavioral health. So thank you so much, and we will look forward to working with you in future months.

Mrs. TRAHAN. I yield back.

Ms. ESHOO. The gentlewoman yields back. It is a pleasure to recognize a fellow Californian, Mr. Cárdenas, for his 5 minutes of questions.

Mr. CÁRDENAS. Hello, can you hear me?

Ms. ESHOO. Yes, very well.

Mr. CÁRDENAS. OK, can you see me?

Ms. ESHOO. I can see you, and you look very well too.

Mr. CÁRDENAS. OK, thank you so much, because earlier today during gavel I was not recognized as being seen, so I had to wait and—

Ms. ESHOO. Oh, I am sorry.

Mr. CÁRDENAS [continuing]. My questions, so—

Ms. ESHOO. Sorry. How does that happen?

Mr. CÁRDENAS. Sorry about that.

Ms. ESHOO. Oh, my.

Mr. CÁRDENAS. We will hopefully get a better system within the committee to make sure that that doesn't happen again to any of us as we all try to be here at gavel—

Ms. ESHOO. Is that the technological difficulty with the committee's technology, Tony?

Mr. CÁRDENAS. Well—

Ms. ESHOO. No?

Mr. CÁRDENAS. I don't know what happened, because I saw myself on the screen, I heard you clearly, I saw you, I saw a bunch of my colleagues and the witnesses, or what have you. But anyway, that is housekeeping. We can take care of that later.

Ms. ESHOO. OK, good.

Mr. CÁRDENAS. But thank you so much—

Ms. ESHOO. I apologize.

Mr. CÁRDENAS [continuing]. Madam Chair. No, that is OK.

Ms. ESHOO. What happened?

Mr. CÁRDENAS. I want to talk a bit about health disparities. And when it comes to pandemics, when it comes to addiction, when it comes to incarceration, all of these kinds of things are issues. So I would like to know, how does that fit into what the dynamic of the administration's efforts are on the topic we are talking about today when it comes to opioid—the opioid pandemic and—epidemic, excuse me, it is a pandemic, sort of—and when it comes to assisting with making sure that we treat it more as an illness, not as something that is just—we treat it as a punitive matter.

Ms. LABELLE. Right. Thank you, Congressman. So the disparities in treatment, we have identified some of them in our policy priorities. They include kind of a two-track system that we have seen. Certainly, some people get healthcare, treated through the healthcare system, and others are incarcerated. And what the President has committed to is reducing rates of incarceration, and having—not having it so that people are incarcerated for drug possession alone, because we know that often people who have low amounts of drugs in their possession are—often have a substance use disorder themselves. So there is a couple of things that we want to do.

Number one, we need to make sure that we have better data sources on this. And I know that sounds like it is not an immediate issue, but it is not something that we have a great deal of granularity on, you know, where the disparities exist and how exactly are we going to address those disparities. So that is one step that we have to take.

The second thing that we need to do, we talked a little bit about before, is make sure that our workforce reflects the people that are served. And that is something we will work closely with HHS on.

And then also—so we also will be looking at, you know, criminal justice reform, writ large. The drug piece is a part of that, so we will be looking at that, as well.

Mr. CÁRDENAS. Thank you. And you mentioned something that—my question is how are the departments going to work together?

Because when there is this presumption that in poor communities—White communities, as well, poor White communities, poor Black and brown communities, Native American reservations, et cetera, where all of a sudden policing seems to be the fortified method of trying to address the issue of drug addiction and drug abuse in those communities. I think it is important that the departments understand that the amount of resources that we allocate at the Federal level, local level, et cetera, needs to be proportional to how we are going to—be honest with ourselves about how it should be addressed.

Are you working with other departments to make sure that we are all on the same page?

Ms. LABELLE. Yes, we work closely with our law enforcement partners as well as our health department partners.

And I think what you raised is an important piece. I think that some of this is because—that is why we talked about harm reduction programs in our policy priorities, because that is—provides an alternative intervention point for people who may not otherwise be able to get treatment and may end up in law enforcement's hands in the criminal justice system. So that provides an alternative intervention point.

Mr. CÁRDENAS. Yes, because I would venture to say—I am in Los Angeles, and in my community where I grew up in Pacoima, law enforcement seemed to be the answer to treating people with addictions or addressing the issue of people with the addictions.

But yet, just a few miles away in Beverly Hills, I would contend that there is just as much drug use going on with teenagers and adults and seniors in those households as it is in households in Pacoima, in a different ZIP code, only the difference is, in those other communities like Beverly Hills, “Oh, my gosh,” you know, “little Johnny is addicted. We got to get Johnny some help. We got to put him in a program,” et cetera, which I believe is the proper, humane way to deal with these issues.

But yet, just a few miles away on the other side of town, book him and book him, send the cops in, get the DEA to do a crash unit or something, and all of a sudden you have people on one side of town who are behind bars, not addressing the issue of addiction. But on the other side of town, the other person is actually getting support.

Do you believe that that has been going on in America far too much?

Ms. LABELLE. I think we have two bifurcated systems of how we treat addiction. And I think that has been with us for a very long time, and we are going to work on that.

Mr. CÁRDENAS. OK. Well, I look forward to speaking to you in the future, and—

Ms. LABELLE. Yes.

Mr. CÁRDENAS [continuing]. And also working with you—

Ms. LABELLE. Yes.

Mr. CÁRDENAS [continuing]. Both as a legislator and as two Americans, to make sure that we get a system that is much more appropriate for addressing issues for all of us.

Thank you so much, I yield back.

Ms. LABELLE. Thank you, sir.

Ms. ESHOO. The gentleman yields back. We now have two Members that have waived on to our subcommittee, and we welcome you. It is always a pleasure to have our colleagues from the full committee be a part of our subcommittee.

So the Chair will recognize the gentleman—and he is a gentleman—from New York, Mr. Tonko, for his 5 minutes of questions. And he has been very active on the issue of opioids, especially, as I recall, fighting for more beds so that patients would really get the care that they need.

You are recognized.

Mr. TONKO. Thank you, Madam Chair. Can you hear me?

Ms. ESHOO. I can. Talk a little louder, though.

Mr. TONKO. OK, thank you, Madam Chair, and thank you for allowing me to waive on.

I am indeed thankful to hear about the leadership already put forward by the Biden-Harris administration and want to express gratitude to you, Acting Director LaBelle, for agreeing to testify today, and thank you for your leadership.

I am a proud sponsor of two pieces of legislation being considered today, including the Medicaid Reentry Act and the Mainstreaming Addiction Treatment, or MAT, Act. These two bipartisan bills are considered some of the most effective policy actions that we can take at reducing opioid overdoses.

The Medicaid Reentry Act would empower States to restore Medicaid eligibility for incarcerated individuals up to 30 days before their release to ensure those transitioning will have immediate access to critical services, including mental health support, addiction treatment, and COVID testing. Granting States the ability to jumpstart Medicaid coverage for these individuals will mean they are not only able to receive lifesaving treatment for mental health, substance use disorders, and other conditions; it will also help them stay out of our already-overburdened hospitals and on the path to recovery and rebuilding their lives.

As ONDCP identifies ways to reduce the increasing number of overdose deaths and to strengthen access to evidence-based substance use disorder treatment services and medications, would passage into law of the Medicaid Reentry Act help to achieve these important goals?

Ms. LABELLE. Thank you, Congressman, for your leadership on these important issues.

So I am a strong believer that we need to make sure that people, regardless of their circumstances, have access to evidence-based treatment. And providing incarcerated populations access to treatment before they leave is one way to do that.

We also need to make sure that we follow up, that there are reentry tools available to help people with their recovery. And actually, upstate New York has a lot of great examples. Buffalo MATTERS is one good example.

So this is a high-risk population that we need to get services to.

Mr. TONKO. Thank you so much. And I heard your earlier comments about giving your undivided attention to some of the issues concerning the X-waiver. So I also ask for your commitment to prioritize the elimination of the X-waiver in order to deliver on President Biden's promise to expand access to medication-assisted treatment. I ask that you examine all actions you can take on this—support passage of our Mainstreaming Addiction Treatment Act, the MAT Act, in order to accomplish this goal.

So a couple of questions. Are you aware that, after France took similar action to make buprenorphine available without a specialized waiver, opioid overdose deaths declined by some 79 percent over, I believe it was, a 4-year period?

Ms. LABELLE. Yes, I am familiar with the research, thanks. Yes.

Mr. TONKO. Yes. And again, I thank you for your attention to this matter.

Are you aware that in 2020 the number of waived physicians accounted for only 5.9 percent of the total active physicians?

Ms. LABELLE. Yes, sir.

Mr. TONKO. And are you aware that, in 2018, 40 percent of counties in the U.S. did not have a single waived provider?

Ms. LABELLE. Yes.

Mr. TONKO. And are you aware that providers can already prescribe buprenorphine without additional training, but only when treating pain?

The X-waiver training to prescribe buprenorphine only applies to providers treating patients with opioid use disorder.

Ms. LABELLE. Yes.

Mr. TONKO. OK, so today I would like to submit a letter for the record signed by a number of groups, including the Association for Behavioral Health and Wellness of the Kennedy Forum, Shatterproof, Mental Health America, National Association of Attorneys General, the National Alliance on Mental Illness, the National Council for Behavioral Health, and many other groups.

And I would indicate that they write—and I quote—“The existence of the X-waiver sends a terrible message to practitioners and the public alike, that treating OUD with buprenorphine requires separate, stigmatizing rules, and that buprenorphine is inherently more dangerous than the powerful opioids that have fueled this crisis.”

So I fully agree that the X-waiver reflects a longstanding stigma around substance use treatment and sends a message to the medical community that they lack the knowledge or ability to effectively treat individuals with substance use disorder. So do you agree that the X-waiver sends a terrible message to practitioners and the public alike, and increases stigma?

Ms. LABELLE. I think there is a great deal of stigma in every aspect of our addiction system, and this—you know, the buprenorphine waiver is just one element.

Mr. TONKO. OK. Well, again, I thank you for your devotion to this issue and, again, for your open-mindedness as you approach it.

Ms. LABELLE. Certainly, thank—

Mr. TONKO. With that, Madam Chair, I yield back, and thank you again.

Ms. ESHOO. The Chair thanks the gentleman, and the letters will be placed in the record at the end of the hearing.

[The information appears at the conclusion of the hearing.]

Mr. TONKO. Thank you.

Ms. ESHOO. So thank you for joining us.

And now we are going to switch back to a member of the subcommittee before we go to Mr. O'Halleran, who is waiving on.

To Mrs. Fletcher from Texas, you are recognized for your 5 minutes of questions. Great to see you.

Mrs. FLETCHER. Thank you so much, Madam Chairwoman. It is great to see you, and I am so grateful that you are holding this important hearing today.

It is clear from the data and the testimony today that substance abuse disorders are an epidemic in this country. And my hometown of Houston is not immune. The pandemic has also exacerbated this crisis. Tragically, first responders in Houston reported a 17 percent increase in overdoses in the second quarter of 2020 compared to that same time period in 2019. So I really appreciate that the committee is holding this hearing today.

The alarming drug use overdose statistics are staggering. They are deeply concerning. However, I want to acknowledge that substance use disorder is a diagnosable and treatable disease. We have FDA-approved medications and evidence-based treatment that work. Patients with substance use disorder can and do recover, and they go on to lead meaningful lives in our society.

In fact, the Biden-Harris Cabinet includes department heads like Secretaries Marty Walsh and Deb Haaland, who are both open about their long-term recovery from substance use disorders. They exemplify the fact that recovery is possible.

My first question for you, Acting Director LaBelle: In your experience talking to communities across the country, what benefits do you hear about when it comes to efforts like recovery housing, college and high school recovery programs, and other peer support services?

Ms. LABELLE. Thank you, Congresswoman, for asking that question. Recovery is something that is a relatively new area of research. But we know—I mean, I think all of us know people who have benefited from recovery facilities. Recovery high schools, I mean, literally, save lives. And so I think recovery supports—having people, peer support workers, working with folks in early recovery is a really important part. It is in our—included in our policy priorities, and something that we look forward to working—

Mrs. FLETCHER. Thank you so much. And I just want to follow up with that. Can you talk a little bit about the ways the Federal Government supports Americans in long-term recovery and how your office plans to build on or improve upon those efforts?

Ms. LABELLE. Sure. So in a couple of ways. One is, as I mentioned, we have hired people who are in long-term recovery in our office. We engage people in recovery in all of our work. We will continue to engage people in recovery, and not just to tell their stories but to engage them in the policy development process and implementation process. Those are two ways.

Also, we intend to work with the—with HHS on expanding recovery support services and—as well as research on what works best with different communities, and making sure we have culturally competent recovery services across the country.

Mrs. FLETCHER. Well, thank you for that explanation and thank you for all the recovery-related efforts that you and the administration are working on and plan to put forward. I appreciate your testimony here today.

And again, I appreciate you, Madam Chairwoman, holding this hearing. And with that I will yield back the balance of my time.

Ms. ESHOO. The gentlewoman yields back, and now it is a pleasure to welcome back to our subcommittee the gentleman from Arizona who is waiving on, Mr. O'Halleran.

You have 5 minutes for your questions, and thank you for—

Mr. O'HALLERAN. Thank you, Madam Chair—I appreciate it—and Ranking Member, for putting on this meeting in a group that historically has been very bipartisan in addressing these types of issues. And I am looking forward to that occurring throughout this process and these bills.

You know, I have—this is a different time, different place, different drugs, but here we are—all are again, sitting here. I was ad-

dressings it as a police officer back in the 1970s: drug overdoses, drug crime. As far as how it was dealt with then, a lot of things have changed, but we still have a problem that is a continuing problem, day in and day out. And our families are being devastated by this, and we need to address it. And I know this group feels that way.

But it is a comprehensive approach. It is not just one piece or another piece. It has to be comprehensive, taking into account the disparities within our society, taking into account the real elements of what causes this, and how do we get the therapists necessary to address this issue.

And that is especially true in areas like rural America. We are short of doctors, anyway. We are short of therapists to a high degree. We have distances for patients to travel that are unreasonable. I know telemedicine is going to be coming around at a higher level later on, but not immediately, and we have to do something now. Two people die in Arizona every day.

In August of this year—last year, I should say—507 people died from overdoses. And anybody that hasn't been around somebody that has died from an overdose, and watched them die, I can guarantee you—I am glad the families don't have to see it as much as the rest of society sees it when it happens in the public arena. But everybody should know that this is a tragic example of how America treats people with this type of health problem.

And so, Ms. LaBelle, thank you for being here, obviously, but how is the administration planning on addressing the opioid—in rural America?

Now, I want to—I don't see a healthcare issue, whether it is the VA or anything else dealing with healthcare, where there are specialists, where there are therapists, and our patients sometimes have to drive 10 hours round trip to get there. If you are calling from—for an overdose, you have to have people that—it might take an hour for people to get—even get to the house. And that is just something that has to be addressed immediately. So I am interested in how to address that.

And by the way, hospitals are declining in rural America, they are not increasing.

Ms. LABELLE. Thank you, Congressman. So I think in a couple of ways. One is you mentioned how long it takes for—it might take a first responder to get to a rural area to resuscitate someone who has experienced an overdose. So the first thing we want to do is make sure that we expand naloxone availability across the country, particularly in rural areas, to people who are at risk.

The second piece of what you talk about—and this is going to take a little longer—is the workforce issue. As identified before, we have shortages. You just said, you know, you have healthcare shortages that are already predominant in rural areas. So we need to get—and specifically in targeted areas, with high rates of overdose, or high rates of substance use disorder generally—get the addiction workforce, the trained addiction workforce available and encourage them to stay there through loan repayment programs. So we will be working with our colleagues at HHS on those workforce issues that are important in rural America.

Mr. O'HALLERAN. And I know that you have just started on this, so I appreciate the need for some time to get this going. But I think the people of America, and the people of rural America especially, would appreciate the ability to see a plan of action, not a plan that is going to take 2 years, 3 years to get it——

Ms. LABELLE. Right.

Mr. O'HALLERAN [continuing]. Addressed, and then the workforce issue is imperative. It is just imperative.

And the realization, again, that this is not just one piece, it is not waking up in the morning and saying, "I have an addiction to opioids." It is a process of lifestyle, it is a process of being—not being able to get jobs, or—alcoholism is part of it. It is a vast issue for this huge country of ours, and it hasn't been addressed in the appropriate way for decades.

And I thank you, and I yield back.

Ms. LABELLE. Thank you.

Ms. ESHOO. All right. Well, the gentleman yields back.

And I want to thank you, Doctor. I don't know when you—you probably didn't realize, when you signed on and said yes to us that you were going—would be willing to come and testify today, that you would be with us for, let's see, 10:30, 1:30—3 hours and 10 minutes.

What it demonstrates is what a deep and broad interest and concern every single member of the subcommittee has. And you heard firsthand what they see and have experienced in their districts, in their own families and extended families, and their knowledge of the various policies that have been proposed, legislation that we have put on the books, more—you know, bipartisan bills that are being voted on in the House today.

So we look forward to working with you to put more than a dent in this. We have a lot of work to do. But you have a subcommittee that wants to work hand-in-hand with you.

Ms. LABELLE. Right.

Ms. ESHOO. And to the extent that your agency succeeds, then the—it will be the betterment of our country from this scourge that is taking place in people's lives. So we thank you. We thank you for being with us and the time that you gave to us. And we will keep working together.

Now it is a pleasure for me to welcome our second panel of witnesses. Let me introduce them to you:

Mr. Geoffrey Laredo, a principal at Santa Cruz Strategies, LLC.

Ms. Patricia Richman, National Sentencing and Resource Counsel for the Federal Public and Community Defenders.

Mr. Mark Vargo is the Pennington County State's Attorney and the legislative committee chairman for the National District Attorneys Association.

Dr. Timothy Westlake is the emergency department medical director at the ProHealth Care Oconomowoc—let me do this again, Oconomowoc Memorial Hospital. I got it done, I did it.

And last but not least, Dr. Deanna Wilson, who is the assistant professor of medicine and pediatrics at the University of Pittsburgh School of Medicine.

Welcome to each one of you, and thank you for your patience, for waiting in the wings. I am sure that you found it highly instruc-

tive, whenever you joined us in the testimony of the new acting director and, very importantly, the excellent questions of members of the subcommittee.

So I am going to go to you, Mr. Laredo, for your 5 minutes of testimony.

And thank you again to each one of you, a panel of just superb experts who—you should each know will be highly instructive to each one of us.

So, Mr. Laredo, you are recognized for your 5 minutes of testimony. Remember to unmute, please.

Mr. LAREDO. Thank you so much, and I hope that you can see and hear me OK this afternoon.

Ms. ESHOO. I can, thank you.

STATEMENTS OF GEOFFREY LAREDO, PRINCIPAL, SANTA CRUZ STRATEGIES, LLC; PATRICIA L. RICHMAN, NATIONAL SENTENCING RESOURCE COUNSEL, FEDERAL PUBLIC AND COMMUNITY DEFENDERS; MARK VARGO, PENNINGTON COUNTY, S.D., STATE'S ATTORNEY, AND CHAIR, LEGISLATIVE COMMITTEE, NATIONAL DISTRICT ATTORNEYS ASSOCIATION; TIMOTHY WESTLAKE, M.D., EMERGENCY DEPARTMENT MEDICAL DIRECTOR, PROHEALTH CARE OCONOMOWOC MEMORIAL HOSPITAL; AND DEANNA WILSON, M.D., ASSISTANT PROFESSOR OF MEDICINE AND PEDIATRICS, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

STATEMENT OF GEOFFREY LAREDO

Mr. LAREDO. Chairwoman Eshoo, Ranking Member Guthrie, members of the subcommittee, thank you so much for inviting me here today. My name is Geoffrey Laredo. I am a substance use and addiction policy expert who retired from the Federal civil service in 2018 after serving for 30 years in a variety of policy positions, mostly within the U.S. Department of Health and Human Services. Twenty-two of those years were at the National Institutes of Health, where I advocated, as appropriate, for science and scientists, research and researchers. I continue that work now as a consultant.

VOICE. See, I have never had to do that before.

Mr. LAREDO. Thanks also for continuing your focus on the addiction crisis in the United States.

This committee has for several years written in advance legislation aimed at a broad array of addiction research, prevention, treatment, and recovery issues. And it was my honor to work with you and your staffs on those bills.

You are considering a range of legislative proposals addressing the addiction crisis. One of those is the potential classwide scheduling of fentanyl-like compounds. And because of that issue's timeliness and my experience working on it as a legislative and policy staff at the National Institute on Drug Abuse, that is where I have focused my testimony.

It is absolutely crucial to define what we care about. As a public policy professional especially focused on public health, what I care about is morbidity and mortality. Every aspect of our Nation's drug policy must be laser-focused on decreasing disease and death.

How do we decrease both, and how do we advance evidence-based practices to achieve both?

Classwide scheduling is not the road to success. Despite alternative claims, to my knowledge there just isn't any credible evidence to show where the classwide scheduling of any compound actually reduces morbidity and mortality. Conversely, there is ample evidence that properly funded and scaled research programs and evidence-based services can dramatically reduce morbidity and mortality.

Further, proposals to increase the use of classwide scheduling minimize or eliminate the role of health agencies in this process. This is just unacceptable. Health agencies should have the primary, if not the sole, responsibility for deciding how or whether to schedule compounds. I don't support including the Drug Enforcement Administration in this decision process, and I would strongly support removing the agency from the process as it currently stands. Let health and medical authorities do the work of health and medicine, and let's provide them appropriate resources to do that work.

I think you are familiar with the arguments around the difficulties of conducting schedule I research. You have talked about that a bit today. Since our time here is limited right now, I won't delve into those details. We tried hard when I was at NIDA to work with the DEA and the FDA to streamline that process. We reached some agreement, but it was unclear to me, frankly, whether any of those steps have actually really been taken. And I have to say this was not a pleasant process, and I will come back to that in a moment.

Researchers have clearly shown that similarities in the chemistry of certain compounds do not necessarily equate to similar abuse liability. This is really important when discussing requirements for a schedule I designation, and I refer you to Dr. Sandra Comer and colleagues' work, as I mentioned in my written statement.

So we find ourselves in a situation where placing an entire class of compounds into schedule I would clearly delay and deter research on exactly what you have been begging for: additional and improved solutions for opioid addiction, overdose reversal medications, and other medications' development results that we perhaps haven't even thought about. Why would we take a classwide scheduling action at exactly the time that we need to be increasing and accelerating potentially lifesaving work?

In my written statement, I also describe steps we took in an effort to improve the overall situation. I hope you will read those details. They are pretty unpleasant. Not only did we not succeed, but senior DEA staff actually told me that I personally—and NIDA as an agency—were “aiding and abetting drug dealers.” That is pretty outrageous.

That said, I am not naive, and I do understand the difficult position that the subcommittee and the full committee is in. I understand the politics. I understand the optics and the possible need for compromise. I also understand that you might choose to implement classwide scheduling. Such implementation without addressing crucial research issues would be a setback for our field. If you move in that direction, I strongly recommend that you include in your

decision provisions that, for research purposes, treat all schedule I compounds as if they were in schedule II, truly streamline the process for obtaining a schedule I license, don't create separate licensing and process requirements for different classes of compounds, and finally, facilitate the de- or rescheduling of compounds when scientists verify that that would be justified.

Members of the subcommittee, you focused a lot of time and effort on these issues over the past several years. So have other committees. If we are all really serious about this health issue, then I think you deserve to take and have the lead on legislation guiding those efforts.

We should listen to science and scientists, and help them do their jobs. We should be thoughtful, especially in the face of significant disease and death. We should make the wise choice and avoid the knee-jerk reaction of just trying to "ban" substances that might or might not be helpful.

And they might or might not—excuse me, they might or might not be harmful, and they might or might not be helpful. By doing so, we will help find answers that will improve conditions in the field.

Ms. ESHOO. Thank you, Mr.—

Mr. LAREDO. Thank you so much for the honor of sharing my views with you, and I will be glad to discuss these issues further.

[The prepared statement of Mr. Laredo follows:]

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

**An Epidemic Within a Pandemic: Understanding Substance
Use and Misuse in America**

April 14, 2021

Testimony Submitted by:

Geoffrey Laredo
Principal
Santa Cruz Strategies, LLC

Chairwoman Eshoo, Ranking Member Guthrie, Chairman Pallone, Ranking Member McMorris Rodgers, and all members of the subcommittee -- thank you very much for inviting me here today. My name is Geoffrey Laredo. I am a substance use and addiction policy expert who retired from the federal civil service in 2018 after serving for 30 years in a variety of policy positions, mostly within the U.S. Department of Health and Human Services. Twenty-two of those years were at the National Institutes of Health, where I advocated as appropriate for science and scientists, research and researchers. I now have a small consulting practice where I continue to focus on those and related public health issues.

Thank you also for continuing your focus on the addiction crisis in the United States. Not just the “opioids crisis,” or “stimulant crisis,” or “overdose crisis,” but the broad addiction and health crisis. This committee has for several years written and advanced legislation aimed at a broad array of addiction research, prevention, treatment and recovery issues, and it was my honor to work with you and your staffs on those bills. I’m proud to have played a small role in helping you to help the nation, and am honored to be here today to continue our work together.

The addiction crisis, as you well know, is not new. We faced it for years prior to the COVID-19 pandemic, but things have only deteriorated over the past year. I know you have seen the data, especially the alarming increases in overdoses - most due to illicit fentanyl.

In this session of Congress, and at this hearing today, you are rightly considering a range of legislative proposals addressing the addiction crisis. As part of this very broad topic area, I know you are considering the issue of “classwide fentanyl scheduling.” Because of that issue’s timeliness and my experience working on it as legislative and policy staff at the National Institute on Drug Abuse (NIDA), that is where I choose to focus my testimony. I don’t want to get lost in too many details, but I do want to make clear the basis for my opinions.

How should we focus our work?

I think it is absolutely crucial to define what we care about -- what are our goals, and to the degree possible, how do we measure our success in attaining them? As a public policy professional especially focused on public health, what I care about is morbidity and mortality. I believe that every aspect of our nation’s drug policy must be laser-focused on decreasing disease and death. How do we decrease both, and how do we advance evidence-based practices to achieve both?

Is class-wide scheduling the answer?

To my knowledge, there isn't any evidence to show that class-wide scheduling of ANY compound reduces morbidity and mortality. Conversely, we can find ample evidence that properly funded and scaled research programs and evidence-based services will dramatically reduce morbidity and mortality.

Further, to my knowledge, proposals to increase the use of class-wide scheduling either completely or greatly eliminate the role of the health agencies -- most especially the FDA as a regulatory agency -- in this process. This is unacceptable. In my opinion, it should be the health agencies that have the primary, if not SOLE responsibility for deciding how or whether to schedule chemical compounds. I do not support including the DEA in this decision process, and would strongly support removing the agency from the process as it currently stands. Let health and medical authorities do the work of health and medicine - and let's provide them appropriate resources to do that work.

Let's back up and consider conducting research on any schedule 1 substance.

There is an argument in the substance use and addiction field around the difficulties many claim they face (or would face if they did this kind of work) in conducting research using schedule 1 substances. This issue dominated many policy discussions over the last several years of my federal career. The scientific community generally decries an overly burdensome system, and the regulators - the Drug Enforcement Administration (DEA) within the U.S. Department of Justice - generally rejects many of those claims. This argument is NOT focused on fentanyl or "fentanyl-like compounds;" it applies to ALL schedule 1 substances.

In brief: To obtain, handle and conduct research on schedule 1 substances, DEA requires a long list of security measures of any researcher and the institution to which they are attached. Strict researcher and institution licensing is required. They also require certain research protocol reviews to be conducted and approved by the Food and Drug Administration (FDA) before even the smallest addition or change to a research project is initiated. The scientific community has bristled at many of the restrictions and has cited numerous instances of licenses taking significant time and effort to obtain, research being slowed or thwarted, and many researchers choosing not to do this work at all, to avoid these difficulties.

In fact, NIDA Director Dr. Nora Volkow echoed these views in testimony to this very committee in January of last year. She testified: "Obtaining or modifying a schedule 1 registration involves significant administrative challenges, and researchers report that obtaining a new registration can take more than a year. Adding new substances to an

existing registration can also be time consuming.”

When I worked at NIDA, I also received these complaints on a regular basis. We reached out to DEA in an effort to help our field identify some common ground to streamline the process as much as possible. NIDA worked with DEA and FDA colleagues in an attempt to reach some level of compromise. We of course involved senior officials at NIH, HHS and DOJ, and did reach an agreement on ways to try to streamline the process. To my knowledge, these steps have not yet been implemented, and you have seen many of them articulated in documents such as Admiral Brett Giroir’s testimony to the House Judiciary Committee in January of last year (attached).

I am sorry to say that, despite the importance of the issue, my experience working on it was not at all positive. I will elaborate on this point later in my testimony.

How does this specifically relate to opioids?

From everything I have read and experienced, I am unaware of evidence showing us that class-wide scheduling of any schedule 1 substances reduced morbidity or mortality. Given that lack of evidence, I reject these proposals as possible avenues for success in addressing the addiction and overdose crisis in the United States.

Regarding opioids, researchers have clearly shown that similarities in the chemistry of certain compounds does not necessarily equate to similar abuse liability. This is a key point when discussing requirements for a schedule 1 designation, and I refer you to Dr. Sandra Comer and colleagues’ work - they describe things in stark detail (attached). Thus, we find ourselves in a situation where placing an entire class of compounds into schedule 1 would clearly delay and deter research on exactly what the Congress and all concerned with these issues have been begging for: additional and improved solutions for opioid addiction, overdose reversal medications, and other medications development results that we perhaps have not yet even considered. Why would we take a class-wide scheduling action at exactly the time that we need to be increasing and accelerating potentially life-saving work?

My negative experience working on this policy and why it matters.

As the opioid addiction and overdose crisis worsened several years ago, many fentanyl and “fentanyl-like” compounds were in fact placed into schedule 1. This action did not decrease morbidity or mortality. What it did do, as I understand it, was succeed in incentivizing “rogue chemists” to continually create new molecules that might or might not have been dangerous when added to fentanyl or other compounds known to be harmful to human health.

Legislation was also introduced by former congressman Charles Dent of Pennsylvania to administratively place into schedule 1 well over 300 compounds, the identifying information of which was provided to him by the DEA. This move concerned NIDA and FDA for the reasons I've outlined in this statement, and we hoped we could work with the DEA to look more closely at what the compounds actually were, what their abuse liability might be, and generally try to figure out if they were all truly harmful, held promise for some sort of therapeutic development, etc.

After significant discussion, we devised a process whereby scientific staff from NIDA, FDA and DEA spent some months developing a review protocol and actually worked through every substance Mr. Dent listed in his bill. It was difficult, detailed work, and those staff deserved and still deserve our thanks for their tenacity. At the end of the process, only two dozen of these identified compounds were "cleared" for scheduling action. The proposal in its initial form was an incredibly blunt instrument that had little if no chance of success; that is, of reducing morbidity and mortality. Scientific staff struggled to even identify what many of them actually were. This does not mean that over time we might have discovered some that should have been scheduled. However, this is exactly my point: identify what you think is a problem and rigorously do the work to figure out if it is or is not.

This episode was and remains personal for me. On one conference call involving all three agencies, the then Director of DEA's Diversion Control Division told me that I personally, and NIDA as an agency, was "aiding and abetting drug dealers." To say that I took affront to this charge would be a gross understatement. I was working with a large team of dedicated public servants, not to mention the entire scientific research community, trying to figure out what to do to alleviate a public health crisis. Then, as now, I was convinced that health and medicine experts should be making health and medicine policy. Period.

What Should We Do?

I am not naive, and I understand the difficult position the Committee is in as you consider policy and program issues aimed at addressing the nation's addiction crisis. Yes - that includes complicated political issues. I fully recognize that the "optics" of opposing class-wide scheduling of "fentanyls," at a time of high and increasing levels of disease and death, are difficult. I recognize that it is likely that compromises might be necessary. So, despite my strongly-held beliefs outlined in this statement, what might you focus on to make a notable difference right now?

I understand that there is a chance that you will choose to implement class-wide scheduling. Such implementation without addressing crucial research issues would be a setback for our field. IF you move in this direction, and understanding the strong disagreements among interested parties, I strongly recommend that you include in your decision provisions that:

1. For research purposes, treat all schedule 1 compounds as if they were in schedule 2. That change alone should help the research community a great deal;
2. More generally, streamline the process for obtaining a schedule 1 license. This could include, for example, mandated, relatively short approval times; eliminating or greatly reducing the “protocol change” review requirements; elimination of certain requirements within review teams or institutions regarding who has to hold what kind of license, etc;
3. Do not create separate licensing and process requirements for different classes of compounds. As I said, this is a schedule 1 issue broadly, NOT just a fentanyl issue. Through this process you can and should make changes that will facilitate research on ALL schedule 1 compounds; and
4. Facilitate the de- or rescheduling of compounds when scientists verify that this is justified.

Members of the Committee and Subcommittee, you have focused much time and effort on these issues over the past several years. So have other congressional committees. If we are serious about this HEALTH issue, then I think you deserve to take and have the lead on legislation guiding those efforts.

As I outlined earlier, I spent my entire federal career working in substance use and addiction policy. Twenty-two of those years were at the National Institutes of Health.

I believe in science.

I believe in evidence.

I believe our goal in advancing evidence-based drug policy is to reduce morbidity and mortality. We should measure everything we do through this lens.

We should listen to science and scientists, and help them do their jobs. We should be thoughtful, especially in the face of significant disease and death. We should make the wise choice and avoid the knee-jerk reaction of just trying to “ban” substances that might or might not be harmful, and might or might not be helpful. By doing so, we will help find answers that will improve conditions in the field.

Thank you so much for the honor of sharing my views with you. I would be glad to discuss any of these issues and answer any questions you have.

Attachments for the record:

1. Comer et al article: *Potential Unintended Consequences of Class-Wide Scheduling Based on Chemical Structure: A Cautionary Tale for Fentanyl-Related Compounds*
2. Dr. Charles France letter of 29 November 2019
3. Dr. Patrick Beardsley letter of 27 November, 2019
4. Testimony of Admiral Brett Giroir, January 2020

Ms. ESHOO. Thank you very much, Mr. Laredo. We appreciate your being with us, your willingness to testify, and the content of your testimony.

Next the Chair would like to recognize Ms. Richman for 5 minutes for your testimony.

And thank you for being a witness, and for your patience, and for your willingness to be instructive to us. We are all ears, so you may proceed.

STATEMENT OF PATRICIA L. RICHMAN

Ms. RICHMAN. Thank you, Chairwoman Eshoo, Ranking Member Guthrie, members of the subcommittee for inviting me to this hearing today and the opportunity to share my perspective. I, too, will focus my remarks today on why this committee should reject the permanent or continued classwide scheduling of fentanyl analogues.

Yesterday Senators Booker, Markey, Hirono, Warren, and Whitehouse wrote President Biden to caution against “adopting a policy explicitly designed to expedite drug prosecutions and increase penalties.” I urge you to follow their advice.

We are in the midst of a national reckoning over police officers’ use of force against communities of color. Last Sunday, Dante Wright was killed just 10 miles from where a police officer is on trial for the killing of George Floyd. Incidents like these are, in part, the product of a tough-on-crime culture focused on punishment instead of preventative community and health solutions.

As a former Federal public defender in Baltimore, Maryland, I witnessed the impact of these punitive practices. My clients faced harsh sentences for drug offenses. In recent years, nearly 80 percent—80 percent—of people who received drug mandatory minimums in Maryland’s Federal courts are Black, even though they make up only 42 percent of the State’s population.

And there is no bright line between user and seller. The vast majority of my clients grappled with substance use disorder, and many had lost friends and family members to the overdose crisis. This crisis is a complicated problem.

Today I ask this committee not to repeat past mistakes. Over the past decade, bipartisan efforts such as the Fair Sentencing Act of 2010 and the First Step Act moved in the right direction. And President Biden has pledged to end mandatory minimums, reduce racial disparities in the criminal legal system, and shift drug policy towards public health solutions.

Today fear and misinformation are being used to support classwide scheduling of fentanyl analogues, and I ask you to look to the evidence. To be clear, harmful fentanyl analogues are illegal with or without classwide scheduling. If the classwide expires on May 6, no harmful fentanyl analogue will become legal.

During the 3 years that the ban has been in place, many experts have examined whether the classwide approach works. They have asked two core questions: first, does classwide scheduling actually reduce overdose deaths; second, does classwide scheduling reduce the supply of harmful substances in our country? The answer to both questions is no.

These are the facts, according to the CDC and the GAO. The CDC has reported that, during the 3 years the ban has been in place, the number of overdose deaths attributed to fentanyl and fentanyl analogues has continued to rise, and fentanyl and fentanyl analogues have continued to enter the country in large quantities. The recent GAO study found that “seizures of fentanyl and its analogues entering the U.S. ports increased substantially from 2017 to 2020.”

And a chorus of voices, public health experts, scientists, and impacted people in the criminal justice community, have also identified ways that classwide scheduling is counterproductive and unnecessary.

Public health experts warn that, even if there is a shift away from novel fentanyl analogues, it will be to something even more potent and harmful.

Scientists warn that blanket bans of substances impede scientific research and may delay or eliminate the discovery of badly needed antidotes and treatments. They have identified specific substances that have been improperly scheduled by the ban and have therapeutic promise.

And the criminal justice community cautions that classwide scheduling would expand mandatory minimums, exacerbate racial disparities, and eliminate crucial checks against DEA overreach.

Federal sentences for fentanyl analogues increased nearly 6,000 percent between 2015 and 2019, and people of color made up 68 percent of those cases in 2019. That year, mandatory minimums were imposed in more than half of those cases. Meanwhile, classwide scheduling has not been used to prosecute kingpins but to continue the failed practice of prosecuting low-level players. This practice does not disrupt supply or the real driver here, demand.

Classwide scheduling is not regulatory. It is punitive. We cannot incarcerate our way out of this problem. It is time to do the work to heal our communities and country by finding and building evidence-based, science-first solutions that are proven to reduce demand and harm associated with these substances.

And in addition to this work, the most important step Congress can take to fix America’s broken drug policy is to end mandatory minimums and to apply those changes retroactively.

Thank you so much for the opportunity to testify today.

[The prepared statement of Ms. Richman follows:]

**Testimony of Patricia L. Richman
National Sentencing Resource Counsel,
Federal Public and Community Defenders**

April 14, 2021

**U.S. House of Representatives Committee on Energy and Commerce
Health Subcommittee Hearing**

*Hearing on “An Epidemic within a Pandemic: Understanding Substance
Use and Misuse in America”*

Chairwoman Eshoo, Ranking Member Guthrie, members of the Subcommittee, thank you for inviting me to participate in this important hearing. My name is Patricia Richman and I am National Sentencing Resource Counsel for the Federal Public and Community Defenders, based in the Office of the Federal Public Defender for the District of Arizona. At any given time, Federal Public and Community Defenders and other appointed counsel under the Criminal Justice Act represent 80 to 90 percent of all individuals in the federal criminal system because they cannot afford counsel.

I. Introduction

I focus my remarks today on one proposed response to soaring overdose deaths: the permanent or continued classwide scheduling of fentanyl analogues.¹ But first, I want to speak a little bit about where my perspective comes from.

I began my career as an Assistant Federal Public Defender in Baltimore, Maryland, where the scars of the war on drugs run deep.

For decades, Baltimore officials and law enforcement agencies have prioritized criminalization over a public health response to drugs. That approach has failed:

¹ The Federal Public and Community Defenders have previously addressed the House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security on the fentanyl analogue classwide scheduling proposal; that testimony is still relevant to this issue and is incorporated into this statement. *Fentanyl Analogues: Perspectives on Classwide Scheduling*: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 n.18 (Jan. 2020) (Testimony of Kevin L. Butler, Fed. Pub. Defender for the Northern District of Alabama.) (“Butler Test.”), <https://bit.ly/3dPgEYm>.

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Overdose deaths in the city are still sky high,² as is the racially disparate enforcement of drug laws. In 2016, the Department of Justice (“Department”) found that police in Baltimore have been arresting Black individuals at rates five times higher than for others and that the racial disparity “*is not attributable to any legitimate law enforcement objective.*”³

As a public defender in Baltimore, many of my clients were the casualties of harsh war-on-drugs enforcement policies as well as centuries of racial discrimination. As children, many of my clients grew up in communities where generations of excessive punishment for drug crimes had perpetuated an unbroken cycle of trauma and socioeconomic marginalization.⁴ Despite facing these challenges, few of my clients received appropriate medical, mental health, or educational interventions during their childhood or adolescence. Instead, their first and only opportunities for treatment for psychiatric and substance use disorders was in the criminal legal system, and that treatment was often inconsistent and inadequate.⁵ Today, many parts of Baltimore remain a “treatment desert,”⁶ where huge economic and health

² See Maryland Opioid Operational Command Center: 2020 Second Quarter Report, Apr. 1, 2020–Jun. 30, 2020, at 3 (Sept. 22, 2020) (“Maryland Second Quarter Report”) <https://bit.ly/3d5xeLm> (“According to preliminary data provided by the Vital Statistics Administration (VSA) of the Maryland Department of Health (MDH), there were significant increases in unintentional intoxication fatalities related to nearly all major drug categories in Maryland through the second calendar quarter of 2020.”).

³ See United States Department of Justice Civil Rights Division, *Investigation of the Baltimore City Police Department* (Aug. 10, 2016) (“DOJ Report”), <https://bit.ly/3d6zzW4>. In 2019, Black people and people who identify as Hispanic made up 42 percent of Maryland’s population, but represented more than 83 percent of people sentenced in Maryland’s federal court. See Premal Dharia & C. Justin Brown, *Opinion: Maryland’s Senators Must Ensure Biden’s Judicial Nominees Embrace Reform*, Wash. Post (Feb. 9, 2021), <https://wapo.st/2Q5dFeR>.

⁴ Many Baltimore neighborhoods have shorter life expectancies and experience poorer health conditions than “economically distressed cities in Nigeria, India, China and South Africa” and in 2015, Baltimore ranked in the top three cities with teens seeing the “highest prevalence of sexual violence, substance abuse, depression, and PTSD.” See Edwin Rios, *7 Charts Explaining Baltimore’s Economic and Racial Struggles*, Mother Jones (Mar. 20, 2017), <https://bit.ly/3t8yh6m>.

⁵ See Meredith Cohn, *Maryland Made a Plan to Help People Leaving Prison get Drug Treatment—But it Never Used it*, Wash. Post (Mar. 11, 2019), <https://wapo.st/2PO7g4M>.

⁶ See Brian Mann, *Drug Overdose Deaths Surge Among Black Americans During Pandemic*, NPR (Mar. 3, 2021), <https://n.pr/3s5h169>.

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disparities⁷ leave substance use treatment often inaccessible to the city's poor⁸—who are often Black and Brown residents—as overdose deaths remain high.⁹

The harmful policies first adopted in the war on drugs have failed not just in Baltimore, but across America. Tens of millions of Americans continue to struggle with substance-use disorder and its consequences.¹⁰ Near-daily headlines reporting large scale seizures of a variety of drugs prove that our Nation's choice to address drug dependence through sweeping law enforcement efforts, rather than public health responses, has failed to reduce demand.¹¹ Overdose deaths have surged during COVID-19, including new spikes in deaths involving cocaine, methamphetamine, and other psychostimulants.¹² The overdose crisis, which has run parallel to the war on drugs for the past three decades¹³ is “the clearest indictment so far of the failure of prohibition to curb drug use.”¹⁴

⁷ See Jay A. Perman, MD, *The Greatest Gap: Health Inequity in Baltimore*, University of Maryland, Balt. (June 2016), <https://bit.ly/3wHplDw>.

⁸ See German Lopez, *The Opioid Epidemic is Increasingly Killing Black Americans. Baltimore is Ground Zero*, Vox (Apr. 1, 2019), <https://bit.ly/3uFWAYx>.

⁹ See *Maryland Second Quarter Report* at 3.

¹⁰ Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health*, at 2 (2020), <https://bit.ly/2RvoZQp> (In 2019, approximately 20.4 million people aged 12 or older had a substance use disorder (SUD) related to their use of alcohol or illicit drugs in the past year).

¹¹ See, e.g., U.S. Customs and Border Control, *CBP Air and Marine Operations and Partners Seize Combined 4 Tons of Cocaine in Eastern Pacific* (Apr. 7, 2021), <https://bit.ly/327YXo6>; News Release, *Law Enforcement Seizures of Methamphetamine, Marijuana Rose During Pandemic*, National Institute on Drug Abuse (Mar. 2, 2021), <https://bit.ly/3wOCLxg>; U.S. Customs and Border Control, *Border Patrol Agents Seize Over 800 Pounds of Marijuana* (Apr. 6, 2021), <https://bit.ly/3dabduG>; Stella Chan & Amanda Jackson, *DEA Announces Biggest Domestic Seizure of Meth in Agency History*, CNN (Oct. 14, 2020), <https://cnn.it/3uFeSGQ>.

¹² See Joan Stephenson, *CDC Warns of Surge in Drug Overdose Deaths During COVID-19*, JAMA Health Forum (Jan. 5, 2021), <https://bit.ly/3t6agt2>.

¹³ See Hawre Jalal, et al., *Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 through 2016*, Science (Sept. 21, 2018), <https://bit.ly/3sani7l>.

¹⁴ See *Controlled Substances: Federal Policies and Enforcement*: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 117th Cong. 2 (Mar. 2021) (Testimony of Katherine Neill Harris, Ph.D., Rice University's Baker Institute for Public Policy), <https://bit.ly/3uGwx0F>.

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II. Classwide Scheduling of Fentanyl Analogues

I now turn to the principal topic of my testimony today: the permanent or continued classwide scheduling of fentanyl analogues is not the answer to the overdose crisis. Instead, it takes us backward by returning to the failed and unjust strategies of the drug war.

President Trump's Department of Justice ("Department") and Drug Enforcement Agency (DEA) administratively implemented classwide scheduling of fentanyl analogues in February 2018,¹⁵ and in 2020, Congress extended that control until May 6, 2021.¹⁶ There are many proposals to make this control permanent, including H.R. 1910, the "Federal Initiative to Guarantee Health by Targeting Fentanyl Act."¹⁷ H.R. 1920 would amend the Controlled Substances Act by permanently placing an unknown number of "fentanyl-related substances" in Schedule I of the list of federally controlled substances, if their chemical structure has been modified in one (or more) of the five specific ways set forth in the bill.

Since 2015, fentanyl, fentanyl analogues, and other synthetic opioids have replaced heroin and crack as the face of drug misuse in our country.¹⁸ Fentanyl is a potent, fast-acting, synthetic opioid. Fentanyl analogues are substances with chemical structures and effects substantially similar to fentanyl. Fentanyl and its analogues have increasingly emerged in the illegal drug market, most often added to heroin or sold in counterfeit opioid prescription pills.¹⁹

Classwide scheduling of fentanyl-related substances would "give the DEA broad and unilateral authority to place any existing or future substance it deems to have a certain chemical structure on Schedule I, the highest restriction, with no further

¹⁵ See, e.g., Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188, n.4 (Feb. 6, 2018) (*2018 Scheduling Order*).

¹⁶ *Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act*, Pub. L. No. 116-114 (2020). The Trump Administration referred to fentanyl analogues as "fentanyl-related substances," and the terms have been used interchangeably.

¹⁷ H.R. 1910, 117th Cong. (2021).

¹⁸ See Daniel Ciccarone, *The Triple Wave Epidemic: Supply and Demand Drivers of the US Opioid Overdose Crisis*, Int'l J. Drug Policy, at 2 (Sep. 2020), <https://bit.ly/3s13hQI> (*The Triple Wave Epidemic*); Drug Policy Alliance, *Criminal Justice Reform in the Fentanyl Era: One Step Forward, Two Steps Back*, at 6 (2020), <https://bit.ly/3g24L11> (*One Step Forward*).

¹⁹ *The Triple Wave Epidemic*, at 2; see also Centers for Disease Control and Prevention, *Synthetic Opioid Overdose Data*, (Mar. 19, 2020) <https://bit.ly/32e13Tn>.

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health or scientific justification required.”²⁰ This abdication of public health and science is unprecedented, and would harm public health, impede scientific research, and disproportionately harm communities of color. It would also set a dangerous precedent for our country’s approach to drug control.

Since the DEA administratively implemented the temporary classwide scheduling of fentanyl analogues in 2018:

- Overdose deaths related to synthetic opioids have continued to skyrocket: “deaths from synthetic opioids—the biggest killer—were up by 52% year-on-year in the 12 months to August [2020], the last month for which data are available.”²¹ Fentanyl is now present in most heroin in the Midwest and Northeast and its prevalence is worsening in the Western part of the country.²²
- Fentanyl analogue prosecutions have increased exponentially, despite little use of either the classwide control or the Controlled Substances Analogue Act by federal prosecutors. Between 2015 and 2019, prosecutions for federal fentanyl offenses increased by 3,592% and fentanyl-analogue prosecutions increased by 5,725%.²³
- There are significant racial disparities in these prosecutions, with people of color comprising almost 75% of those sentenced in fentanyl cases in 2019.²⁴ This holds true for fentanyl analogues, for which 68% of those sentenced were people of color.²⁵

²⁰ See *Butler Test*, at 4.

²¹ See The Economist, Daily Chart, *Opioid Deaths in America Reached New Highs in the Pandemic: Once a Problem Confined to the Eastern Part of the Country, Fentanyl has Spread West* (Mar. 30, 2021), <https://econ.st/32gJmmx>.

²² See *id.*

²³ U.S. Sent. Comm’n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* (Jan. 2021), at 20 (“USSC Fentanyl Report”), <https://bit.ly/3daUMhI>.

²⁴ *Id.*

²⁵ *Id.*

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- The Department has targeted minimally involved individuals and street level dealers in its fentanyl-analogue enforcement efforts, rather than kingpins, importers, or manufacturers.²⁶
- Scientists and researchers have confirmed that the classwide scheduling would improperly criminalize helpful and harmless substances and negatively impact public health.²⁷

Classwide scheduling removes public health and science from drug control. The unprecedented and radical nature of the DEA's placement of an entire class of drugs onto Schedule I bears emphasis,²⁸ particularly considering warnings from scientists that "class-wide banning based on chemical structure is likely to have unintended consequences including severely limiting biomedical research and, in the long term, adversely impacting public health."²⁹

Customarily, the Attorney General consults with the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA),³⁰ to confirm a substance's potential for abuse—and lack of therapeutic potential—before it is permanently placed in Schedule I.³¹ But, in the case of the 2018 temporary scheduling order on fentanyl-related substances, rather than allow for the completion of scientifically and medically-based proceedings, the DEA and the Trump administration persuaded Congress to create an exception to the ordinary rule by enacting a bill to extend the temporary scheduling of fentanyl-related substances until May 6, 2021.³²

This approach to drug classification is not supported by science. "[T]he main problem with class-wide bans is that potentially thousands of compounds are defined solely by their chemical structures without regard for their pharmacological

²⁶ See *id.* at 28. More than half of all federal fentanyl-analogue prosecutions in 2019 involved a street-level seller or other minor role; only 10.3% of these cases involved the most serious functions. *Id.*

²⁷ See, e.g., Dr. Sandra D. Comer et. al., *Potential Unintended Consequences of Classwide Drug Scheduling Based on Chemical Structure: A Cautionary tale for Fentanyl-Related compounds*, Drug and Alcohol Dependence, 3 (2021), <https://bit.ly/2OF8no9> (*Unintended Consequences*).

²⁸ See Butler Test. at 15.

²⁹ *Unintended Consequences* at 3.

³⁰ See 21 U.S.C. § 811(b).

³¹ See 21 U.S.C. § 811(h).

³² See Pub. L. No. 116-114, 134 Stat. 103 (2020).

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activity.”³³ As a result, classwide scheduling preemptively classifies an unknown number of similar substances with unknown effects, including harmless and therapeutic substances.³⁴ This is a flawed approach because knowledge of a drug’s chemical structure alone cannot predict how it will affect the human brain.³⁵ For example—loperamide (Imodium®) is an over-the-counter anti-diarrheal medication. Although it does not fall under the classwide scheduling order, Imodium® has a structure similar to fentanyl, and like fentanyl, *is* an agonist of the mu-opioid receptor. But unlike fentanyl, Imodium® does not get into the brain when it is taken as directed and would be misclassified if placed onto Schedule I.³⁶

The relative potency of fentanyl and fentanyl analogues varies widely: “[s]ome analogues, like acetyl fentanyl, are less potent than fentanyl; others, like carfentanil, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive.”³⁷ There are already examples of the classwide control’s overbreadth: scientific research has identified specific substances that meet the criteria for classwide control that have little to no pharmacological potential for abuse.³⁸ Under classwide control these would be controlled substances and criminal defendants could face draconian sentences if found in possession of such substances.

Classwide Scheduling Results in Overcriminalization. Under the classwide control, any offense involving a fentanyl-related substance is subject to federal criminal prosecution, even if the substance in question has no potential for abuse. This approach would result in convictions for substances that may not even have a psychoactive effect similar to fentanyl. Data in a recent Sentencing Commission Report shows that these type of prosecutions are already occurring: after 2018, the

³³ *Unintended Consequences* at 3.

³⁴ *Id.*

³⁵ See *Fentanyl Analogues: Perspectives on Classwide Scheduling*: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 (Testimony of Dr. Sandra D. Comer, Professor of Neurobiology (in Psychiatry), Columbia University Irving Medical Center, New York State Psychiatric Institute) (Jan. 28, 2020), <https://bit.ly/3rkKd1r>.

³⁶ *Id.* at 16.

³⁷ Kemp Chester, Assoc. Dir., Nat’l Heroin Coordination Grp., Off. of Nat’l Drug Control Pol’y, *Response to Questions for the Record Following Hearing Entitled, The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary* (June 4, 2019) at 3, <https://bit.ly/3s7BFcy>.

³⁸ *Unintended Consequences*, at 3.

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government prosecuted cases involving benzyl fentanyl,³⁹ a substance the DEA has known to have no potential for abuse since at least 2010.⁴⁰ If classwide scheduling becomes permanent, prosecutors would have no obligation—and thus no incentive—to determine whether a substance has abuse potential. Nor would prosecutors be equipped to make such assessments, particularly for substances under classwide control, which would be scheduled without relevant scientific evidence. Moreover, because such substances are automatically in Schedule I, criminal defendants would have no ability to present evidence at trial showing that the substance has no potential for abuse; this evidence would be, in fact, irrelevant at trial.

Classwide Scheduling is Unnecessary: Harmful Fentanyl Analogues are Illegal with or without Classwide Scheduling. The campaign in support of classwide scheduling has rested on the repeated—and false—claim that failure to enact classwide scheduling would *legalize* harmful fentanyl analogues. A recent press release from House Minority Leader Jim Jordan, and House Energy and Commerce Committee Ranking Member Cathy McMorris Rodgers (R-WA) claimed that “[i]f Congress doesn’t extend the fentanyl analogues ban by May 6, these extremely lethal drugs coming from China and also across our southern border will *essentially become street legal*.”⁴¹ In 2020, while facing the possible expiration of the first temporary classwide scheduling of fentanyl analogues, former Attorney General William Barr wrote: “[T]he legal prohibitions on the various forms of fentanyl expire next month unless Congress reauthorizes them,” and that, without classwide scheduling, fentanyl analogues would become “newly legalized.”⁴²

³⁹ See USSC Fentanyl Report at 23.

⁴⁰ In 1985, the DEA temporarily placed benzyl fentanyl on Schedule I based on its structure, but later removed it from control after “further research found no evidence of abuse potential.” Drug Enf’t Admin. Correction of Code of Federal Regulations: *Removal of Temporary Listing of Benzylfentanyl and Thénylfentanyl as Controlled Substances*, 21 C.F.R. § 1308 (2010). In 2019, DEA classified benzyl fentanyl as a “List I” chemical, meaning that it is an ingredient that can be used to create fentanyl analogues. See Drug Enf’t Admin., *Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 Federal Register 73 at 20822-20829, (April 15, 2020), <https://bit.ly/3d9m1cD>. In contrast to Schedule I fentanyl analogues, the potential sentences for distribution of List I chemicals are largely capped at five years. See 21 U.S.C. § 841(f)(1) (“Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall, except to the extent that paragraph (12), (13), or (14) of section 842(a) of this title applies, be fined under title 18 or imprisoned not more than 5 years, or both.”)

⁴¹ See Press Release: *Leaders Rodgers and Jordan Call for Extension of Emergency Scheduling of Fentanyl Analogues*, House Energy and Commerce Committee (Apr. 8, 2021), <https://bit.ly/2OFB17f>.

⁴² Barr, *supra* note 18; see also Drug Enforcement Administration (@DEAHQ), Twitter (Jan. 11, 2020, 3:28 PM), <https://twitter.com/DEAHQ/status/1216094432648409090> (“Without the emergency

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These claims are not true.

With or without classwide scheduling, the Department is armed with powerful tools to successfully and aggressively prosecute cases involving fentanyl and its analogues. First, the Department can use its broad authorities under the Controlled Substances Act (CSA) to temporarily schedule—and then prosecute—fentanyl analogues on a substance-by-substance basis.⁴³ Second, the Department can use the Analogue Act to immediately prosecute new substances that have not been scheduled.⁴⁴ Crucially, and in contrast to classwide scheduling, both of these existing authorities include essential checks to confirm the accuracy of DEA's designation of a substance as harmful.

First, the CSA. Many fentanyl analogues, such as carfentanil and acetyl fentanyl have already been scheduled on a substance-by-substance basis.⁴⁵ Fentanyl analogues that are scheduled controlled substances can be prosecuted as any other controlled substance would be prosecuted. The CSA also equips the DEA to swiftly add new substances to the schedule by providing it with temporary scheduling authority. Temporary designation can become permanent if the AG asks the Secretary of Health and Human Services ("Secretary") to confirm the accuracy of the designation and the Secretary so confirms. From 2019 to 2020, most prosecutions for fentanyl analogues involved analogues that had been individually scheduled prior to class-wide scheduling.⁴⁶

The second avenue that has been available to the Department since 1986 for the prosecution of unscheduled analogues—of fentanyl or any other Schedule I or II drug—is the Analogue Act. Congress passed the Analogue Act to criminalize the harmful unscheduled chemical variants of controlled substances "that otherwise would escape the reach of the drug laws."⁴⁷ Under the Act, a "controlled substance

scheduling of the entire class of fentanyl-related substances, all non-scheduled fentanyl substances will no longer be illegal. This scheduling expires in 26 days.").

⁴³ See, e.g., 21 U.S.C. § 811.

⁴⁴ See 21 U.S.C. § 813.

⁴⁵ 21 C.F.R. § 1308.12 Schedule II (2019) (carfentanil); 21 C.F.R. § 1308.11 Schedule I (2019) (acetyl fentanyl).

⁴⁶ USSC Fentanyl Report at 23.

⁴⁷ *United States v. Hodge*, 321 F.3d 429, 437 (3d Cir. 2003) (quoting 131 Cong. Rec. 19114 (1985) (statement of Sen. Thurmond) ("This proposal will prevent underground chemists from producing dangerous designer drugs by slightly changing the chemical composition of existing illegal drugs."); 131 Cong. Rec. 27311 (1985) (statement of Sen. D'Amato) (stating that the Analogue Act "closes the loophole in present law that allows the creation and distribution of deadly new drugs without

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analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in Schedule I.”⁴⁸ Congress listened to and relied on evidence from experts when it properly defined a “controlled substance analogue” to require two things: first, a chemical structure which is substantially similar to a schedule I or II controlled substance, and second, a physiological effect on the central nervous system that is substantially similar to or greater than the effect of a schedule I or II controlled substance.⁴⁹

It is this second prong—the proof of a substantially similar *effect*—that classwide scheduling erases. And requiring proof of this effect was something that Congress carefully considered when it enacted the Analogue Act. At that time, the Department argued for an approach that have required proof of only the first prong—a chemical structure similar to a Schedule I or II controlled substance. But Congress ultimately (and wisely) accepted the views of the American Chemical Society. The Society testified before the Senate Judiciary Committee that it “believe[d] it necessary to require that designer drugs meet both of these tests” – that the definition of controlled substance analogue must “be specifically designed to have . . . a chemical structure substantially similar to that of a controlled substance” and “a biological effect substantially similar to that of a controlled substance” – “in order to protect the legitimate production of drugs that are intended for human consumption and that have similar chemical structures to those of designed drugs, but that are designed to have the opposite or dissimilar biological effects,” such as naloxone and other analogs designed with the purpose of countering drug abuse.⁵⁰ So long as an unscheduled substance is proven to be a “controlled substance analogue,” it can be treated and prosecuted as if it was a schedule I controlled substance.

violating Federal law”); 131 Cong. Rec. 32950 (1985) (statement of Rep. Lungren) (“The focus of this proposal is clearly to impact on the designer drug phenomena by making it illegal for the clandestine chemists to manufacture and distribute these substances.”).

⁴⁸ 21 U.S.C. § 813(a).

⁴⁹ 21 U.S.C. § 802(32)(A)(i)-(ii). Alternatively, the second requirement can be met “with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance that is in schedule I or II.” *Id.* at 21 U.S.C. § 802(32)(A)(iii)

⁵⁰ *Controlled Substance Analogs Enforcement Act of 1985*: Hearing on S. 1437 before the S. Comm. on the Judiciary, 996th Cong. 79 (1985) (American Chemical Society Responses to Questions from Senator Biden); *see also United States v. Roberts*, No. 01 CR 410 RWS, 2001 WL 1646732, *5 (S.D.N.Y. Dec. 17, 2001).

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The Department's Criticisms of the Controlled Substance Analogue Act are Not Backed by Evidence. The Department has long complained that Analogue Act prosecutions for fentanyl analogues are unwieldy and unnecessarily resource-intensive, but these concerns lack factual support. The Department has not provided specific examples of fentanyl analogue cases where this has been borne out, and information provided by the Sentencing Commission identifies only five Analogue Act prosecutions involving fentanyl analogues in the past five years.⁵¹ After repeated inquiries to the nationwide field of federal public and community defenders, I have been unable to identify any cases involving a resource-intensive “battle of the experts” over the identity of a purported fentanyl-related substance, nor have I identified examples where juries or courts reached different conclusions about whether a fentanyl-related substance was or was not an analogue.

A recent law enforcement letter⁵² in support of classwide scheduling cites two Analogue Act cases—*U.S. v. Bays*⁵³ and *U.S. v. Gas Pipe, Inc.*⁵⁴—for the proposition that the Analogue Act can improperly “produc[e] inconsistent jury verdicts, even for the same substance.” In *Bays* the jury convicted; in *Gas Pipe* it acquitted. Both cases involved a synthetic cannabinoid called XLR-11. But XLR-11 seems to have been a somewhat unique analogue: an entire division of DEA, the Office of Forensic Sciences, did not believe that XLR-11 was “substantially similar” to a Schedule I substance or the proper target of federal criminal prosecution. The jury in *Gas Pipe* heard this evidence, including testimony by two DEA employees from the Office of Forensic Science, and acquitted. It is not clear whether the *Bays* jury even heard this information, or if DEA’s internal disagreement was ever disclosed to the defense.⁵⁵ Importantly, in the end all drug trafficking charges were dropped in

⁵¹ See Email from [REDACTED] United States Sentencing Commission to Christine Leonard, Senior Counsel, United States House of Representatives, Committee on the Judiciary, *Re: Follow up data* (Feb. 10, 2021) (on file with author).

⁵² See Letter to The Hon. Dick Durbin & The Hon Chuck Grassley (Mar. 17, 2021), <https://bit.ly/3s8WN2k>.

⁵³ *U.S. v. Bays, et al.*, 3:13-CR-357-B (N.D. Tx.)

⁵⁴ *U.S. v. Gas Pipe, Inc.*, 3:14-cr-298-M (N.D. Tex.-Dallas)

⁵⁵ The government inconsistently disclosed the disagreement among DEA chemists to individuals facing criminal prosecution for XLR-11. For example, in *United States v. Fedida*, Case No., 6:12-cr-00209-RBD-DAB (M.D. Fla. Jul. 11, 2013), the government did not disclose the conflicting opinions about XLR-11 to the defense before or at an evidentiary hearing. See Statement of Kevin L. Butler Before the U.S. Sentencing Comm’n, Washington, D.C., at 15-17 (Mar. 14, 2018), <https://bit.ly/3mFcSvf>. Nor did the DEA Section Chief of the Diversion Control Division (Terry Boos) disclose the dissenting opinion of the Office of Forensic Sciences when he testified that XLR-11 should be treated as a controlled substance analogue. *Id.*

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Bays; it does not appear that the jury was ever asked to decide whether XLR-11 was a controlled substance analogue.⁵⁶

Overcoming an individual's presumption of innocence is not intended to be convenient for the government. Congress carefully designed the elements of the Analogue Act to secure convictions for dangerous novel substances while shielding harmless conduct from criminal sanctions. The government's own scientists disagreed about whether the substance in *Bays* and *Gas Pipe* was illegal. Rather than implicate the reasonableness of the Analogue Act, these cases demonstrate why Congress should not grant the Department and DEA unchecked discretion to determine the legality of substances.

Classwide Scheduling Repeats the Mistakes of the Past. The political rhetoric that we hear today about fentanyl is familiar to anyone who has studied the history of the war on drugs. Nearly fifty years ago, President Nixon declared drug abuse as "America's public enemy number one."⁵⁷ "Fifteen years later, in May 1986, Ronald Reagan warned that "illegal drugs were every bit as much a threat to the United States as enemy planes and missiles."⁵⁸ Congress responded, enacting sweeping legislation with severe penalties like the Comprehensive Crime Control Act of 1984 and the Anti-Drug Abuse Act of 1986.⁵⁹ And a decade later, on the eve of his reelection, President Bill Clinton reported "we passed 'three strikes and you're out' and the death penalty for drug kingpins and cop killers," touting the accomplishments of the Violent Crime Control and Law Enforcement Act of 1994.⁶⁰ The laws from this era put in place harsh mandatory minimums for a variety of offenses, including drug offenses, and introduced the now-discredited 100-to-1 ratio between crack and powder cocaine.⁶¹

⁵⁶ See Kevin Krause, *Synthetic Marijuana Prosecutions Get Mixed Results Due to Legal Complications*, Dallas News (Dec. 25, 2020), <https://bit.ly/3uGANxe>.

⁵⁷ Richard Nixon, *Remarks About an Intensified Program for Drug Abuse Prevention and Control* (Jun. 17, 1971), <https://bit.ly/3t9mHUT>.

⁵⁸ *Remarks on Signing the Just Say No to Drugs Week Proclamation*, Ronald Reagan Presidential Library & Museum (May 20, 1986) <https://bit.ly/3t9HPKt>.

⁵⁹ See Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, tit. II, 98 Stat. 1976 (Oct. 12, 1984); Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (Oct. 27, 1986).

⁶⁰ The President's Radio Address, 32 Weekly Comp. Pres. Doc. 2282 (Nov. 2, 1996), <https://bit.ly/3uz5fR0>; Violent Crime Control and Law Enforcement Act of 1994, Pub. L. No. 103-322, 108 Stat. 1796 (Jan. 25, 1994).

⁶¹ See Rachel E. Barkow, *Categorical Mistakes: The Flawed Framework of the Armed Career Criminal Act and Mandatory Minimum Sentencing*, 133 Harv. L. Rev. 200, 212 (2019) (Categorical

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What in 1971 was labeled “public enemy number one,” is now being described as “a tsunami” of “legalized poison.”⁶² But while the rhetoric of today is the same as that of the past, we know our actions must be different. We have three decades of evidence proving that increasing sentences does not make communities safer and it does not drive down drug supply or demand.⁶³ A 2014 report commissioned by the Department “found that lengthy prison sentences are not the best way to deter crime,”⁶⁴ and data indicate that long sentences can actually be criminogenic and increase recidivism.⁶⁵ To avoid detection, users are less inclined to seek treatment and are instead more likely to engage in risky drug-use behaviors.⁶⁶

Nor have these policies incapacitated high-level traffickers, “managers of drug enterprises,” and “king-pins.”⁶⁷ Out of all persons incarcerated for drug crimes in federal prison, only 14% are identified as the managers, leaders, and organizers Congress intended to capture.⁶⁸

Because Congress legislated without evidence or the advice of experts, more than 2.2 million people are behind bars in America today and one in three adults possesses a criminal record.⁶⁹ We cannot repeat these mistakes. There is a growing, bipartisan consensus that the war on drugs has failed.⁷⁰ Those lessons apply to

Mistakes); see also Ranya Shannon, *3 Ways the 1994 Crime Bill Continues to Hurt Communities of Color*, Center for American Progress (May 10, 2019), <https://ampr.gs/3wNZx0r>.

⁶² See Attorney General William P. Barr Delivers Remarks at the Grand Lodge Fraternal Order of Police’s 64th National Biennial Conference, Dep’t of Justice (Aug. 12, 2019), <https://bit.ly/3wNuFoU> (“A tsunami built up and has been crashing over the country, bringing death and destruction.”).

⁶³ See, e.g., Rachel E. Barkow, *Prisoners of Politics: Breaking the Cycle of Mass Incarceration* 42-44 (2019) (*Prisoners of Politics*) (collecting studies); see also Pew Charitable Trusts, *More Imprisonment Does Not Reduce State Drug Problems* (Mar. 8, 2018), <https://bit.ly/3dVw8ks>; Drug Policy Alliance, *Rethinking the “Drug Dealer,”* 12-13 (2019), <https://bit.ly/2QjZG3a> (*Rethinking the Drug Dealer*); Letter from FreedomWorks, Prison Fellowship, R Street Institute, et al., to the Hons. Lindsey Graham & Dianne Feinstein, at 1 (Jul. 2, 2019), <https://bit.ly/2PXDBau>.

⁶⁴ *Prisoners of Politics*, at 43 (citing National Research Council, *The Growth of Incarceration in the United States: Exploring Causes and Consequences*, ed. Jeremy Travis and Bruce Western (2014)).

⁶⁵ See *id.* at 44.

⁶⁶ See *Rethinking the Drug Dealer*, at 13.

⁶⁷ See e.g., *United States v. Dossie*, 851 F. Supp. 2d 478, 479-80 (E.D.N.Y. 2012) (collecting legislative history).

⁶⁸ See *Categorical Mistakes* at 217, n.138.

⁶⁹ See *Prisoners of Politics*, at 2.

⁷⁰ In 2010, Congress enacted the Fair Sentencing Act to reduce the unjust disparity between crack and cocaine from 100-to-1 to 18-to-1. Fair Sentencing Act of 2010, Pub. L. No. 111-220, 124 Stat 2372

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fentanyl and its analogues. Indeed, a 2019 Rand fentanyl study concluded that “[t]here is little reason to believe that tougher sentences, including drug-induced homicide laws for low-level retailers and easily replaced functionaries (*e.g.*, couriers) will make a positive difference.”⁷¹

III. Policy Recommendations

President Biden has pledged to embrace a public-health approach to drug policy,⁷² to move away from the failed war on drugs by ending the use of mandatory minimums⁷³ and to eradicate racial inequities in the criminal justice system.⁷⁴ These principles should guide the Subcommittee’s deliberations about how to respond to the daunting challenge of the overdose crisis. It is time for the government to adjust its drug policy to prioritize evidence-based strategies to effectively fight this critical public health issue. The only way to stop the demand for drugs is through prevention and treatment. It goes without saying that we cannot incarcerate our way out of a public health crisis.

Several legislative proposals under consideration in the 117th Congress hold the potential to move drug policy in our country in the right direction, including:

- H.R. 955, the Medicaid Reentry Act of 2021. This bill provides a bridge for individuals reentering the community by providing health care 30 days prior to release and on reentry. Ninety-five percent of the more than 2 million adults who are incarcerated in the United States will be released and the transition back into the community is a critical period for those with mental illness and substance use disorder.⁷⁵ One study found that risk of a fatal

(Aug. 3, 2010). Two years ago, Congress passed the First Step Act of 2018 with overwhelming bipartisan support, reducing sentences for certain drug offenses and making the Fair Sentencing Act of 2010 retroactive. First Step Act of 2018, Pub. L. No. 115-391, 132 Stat 5194 (Dec. 21, 2018).

⁷¹ See Bryce Pardo, et al., *The Future of Fentanyl and Other Synthetic Opioids*, Rand Corp. (2019), https://www.rand.org/content/dam/rand/pubs/research_reports/RR3100/RR3117/RAND_RR3117.pdf.

⁷² Exec. Off. of the President Off. of Nat’l Drug Control Pol’y, *The Biden-Harris Administration’s Statement of Drug Policy Priorities for Year One*, (April 1, 2021), <https://bit.ly/327EsYQ>.

⁷³ Joe Biden, *The Biden Plan for Strengthening America’s Commitment to Justice*, <https://bit.ly/3216Abb> (last visited April 12, 2021).

⁷⁴ Proclamation 10171, *A Proclamation on Second Chance Month, 2021*, 86 Fed. Reg. 64, 17689–90 (March 31, 2021), <https://bit.ly/328V8ze>.

⁷⁵ See Lakeesha Woods et. al., *The Role of Prevention in Promoting Continuity of Health Care in Prisoner Reentry Initiatives*, 103 Am. J. Pub. 830–8 (2013), <https://bit.ly/3mGuA1N>.

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drug overdose is 129 times as high as it is for the general population during the two weeks after release.⁷⁶

- H.R. 1384, the Mainstreaming Addiction Treatment Act of 2021. This bill eliminates the redundant “X-waiver” to prescribe buprenorphine for substance use disorder treatment. Buprenorphine is one of the three medications approved by the FDA to treat opioid use disorder and reduces mortality by up to fifty percent.⁷⁷
- H.R. 2366, Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021. This legislation proposes a comprehensive health- and evidence-based response to fentanyl and its analogues. Rather than turn to policing and incarceration, the STOP Fentanyl Act adopts an evidence-based response to the opioid crisis.
- H.R. 2379, the State Opioid Response Grant Reauthorization Act. This legislation reauthorizes State Opioid Responses (SOR) and Tribal Opioid Response (TOR) grants for five more years. These grants help states, tribal organizations, and other community stakeholders implement health and evidence-based responses to overdoses and opioid use disorder.

In addition to these proposals, the most important step that Congress and the Administration could take to remediate America's harmful and ineffective drug policy would be to enact legislation to end mandatory minimums and apply those changes retroactively. Mandatory minimums have contributed to mass incarceration of Black and Brown communities, distorted the traditional role of the judge, and escalated prison costs. Any such sentencing reform legislation provisions must also ensure that the new law will be applied retroactively to those who have already been sentenced, and make the sentencing reforms enacted in the First Step Act of 2018 retroactive.

IV. Conclusion

Classwide scheduling would be a step backward and mark a return to the failed approaches of the war on drugs. The Department has used existing tools to successfully and aggressively prosecute harmful fentanyl analogue cases. Unlike classwide scheduling, those tools do not disrupt the balance between, on one hand,

⁷⁶ See Ingrid A. Binswanger, et al., *Release from Prison—A High Risk of Death for Former Inmates*, 356 New Eng. J. Med. 157-65 (Jan. 11, 2007), <https://bit.ly/3uDbMTE>.

⁷⁷ Nat'l Acad. of Sci., Eng'g, and Med., *Medications for Opioid Use Disorder Save Lives* (2019), <https://bit.ly/3uJfWto>.

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enforcement, and on the other, science, prevention and public health. Again, I thank the Subcommittee and appreciate the invitation to share my perspective on this issue.

Ms. ESHOO. Thank you so much for your testimony. We will now go to Mr. Vargo.

The Chair recognizes you for your 5 minutes of testimony, and thank you again for your willingness to be with us and the work that you do. You are now—make sure you unmute, please.

STATEMENT OF MARK VARGO

Mr. VARGO. Thank you, Chairwoman Eshoo, Ranking Member Guthrie, and to the rest of the committee. I am proud to be here to represent the National District Attorneys Association and very grateful that you invited us to participate in this very important set of hearings on this topic, which we all know is extremely dire at this moment.

I was struck as I prepared to address you today by Director LaBelle's characterization in an article she wrote a few years ago that addiction is the only disease where we expect people to diagnose themselves by hitting rock bottom. But then, you know, it dawned on me that perhaps we don't rely on them but rather that all of you have been relying on me, because it feels like we define rock bottom as arrest, incarceration, and criminal prosecution. And it is at that moment that we want to mobilize the forces of addiction recovery.

It is my hope that today we can discuss about ending that mentality. And so everything that I tell you I want to put through the lens of moving the point of the intercept. Because the costs of waiting to intercept drug addiction are disastrous, they are disastrous for the addict. And Representative Kelly and Representative Cárdenas, along with Dr. Wilson, in her written testimony, have talked about how early treatment is necessary and how our communities of color are being deprived that early treatment.

It is also disastrous for our communities and our families. Fentanyl and all other drugs lead to abuse, neglect, and poverty. And methamphetamine, which remains a scourge in western South Dakota, adds to the problem. It is paranoia, hypervigilance, and aggression. People on methamphetamine are 10 times more likely to be violent if they use every other day than a—even a meth addict who is presently in remission. And it is the only drug for which the most recent NIDA figures show an increase in drug overdose deaths, not just in combination with fentanyl or other synthetic opioids but on its own.

As prosecutors, we do what we can from where we are with what we have, and I am very proud of what we are doing from the point of intercept that has been assigned to us onward. Our diversion programs, which I went into extensively in my written testimony, are just one example of how we are trying to change the way that we engage with people who have addictions to ensure that they have the best chance possible to become productive, functioning members of our community. I am very proud of my staff, who with very little budget have put together a tremendous array of programming to give diversion candidates a chance of success.

Because we have very little funding and because we never ask our offenders to pay, we rely on a wide variety of community resources, including governments like the Oglala Sioux Tribe and cul-

tural and community programs like the Wambli Ska Pow-Wow, an indigenous American legacy.

We tried to change behavior without the criminogenic consequences of a conviction. I would like to mention to you that NDAA has specifically supported Representative Tonko's MAT Act, Representative Curtis and Peters' Methamphetamine Response Act, and we support the extension of classwide fentanyl analogue scheduling, and we support the EQUAL Act, which would reform sentencing.

But I want to take the little time that I have left to ask you three things.

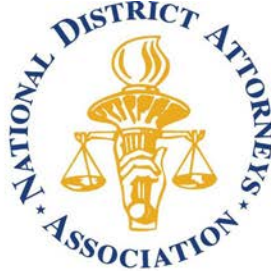
I am asking you to move the intercept point. The descriptions of the needs of our communities, our at-risk communities and our communities of color, are very stark. We need from Congress money in both the criminal justice system and before the criminal justice system. In other words, we need you to lead.

Secondly, we need you to use us in State and Tribal government as the laboratories of innovation. Representative Tonko, who in the last session talked about Buffalo MATTERS, an outstanding program that has been spearheaded by my friend and colleague John Flynn in Erie County—programs like that within the criminal justice system, and programs like treatment programs that are being dealt with by programs like Native Healing and Native Women's Health Care, here in South Dakota, are very important. In other words, we need you to follow.

And then finally, I ask you to reduce the Federal collateral consequences of State court drug convictions. The origins of our diversion were that we recognized that people with minor drug convictions had major problems, largely based on Federal law. In other words, we need you to get out of the way.

And so, with apologies to both Mr. Paine and to General Patton, we need you to lead, we need you to follow, and we need you to get out of the way.

[The prepared statement of Mr. Vargo follows:]



Written Testimony of Mark Vargo
Pennington County (SD) State's Attorney
Chair, National District Attorneys Association Legislative Committee

*An Epidemic within a Pandemic: Understanding Substance Use and
Misuse in America*

U.S. House Committee on Energy & Commerce
Subcommittee on Health

Wednesday, April 14, 2021

Chairwoman Eshoo, Ranking Member Guthrie and Distinguished Representatives:

Thank you for the opportunity to testify before you and for the work that you are doing and have done on behalf of the nation with respect to the drug epidemic that is ravaging our country. I am proud to speak to you on behalf of The National District Attorneys Association, the nation's oldest and largest association of prosecutors, with over 5,000 members nationwide.

The challenges that we face are daunting. Systemic use and over-use of opioids has led to fentanyl, an opioid so potent that the five-pound weights that my 95-year-old father-in-law uses to exercise would constitute a lethal dose for every person in the state of South Dakota. For frame of reference, this is what a lethal dose of fentanyl looks like:



Alongside this crisis, we are seeing a continuation and a resurgence of methamphetamine, perhaps the most addictive controlled substance of wide-spread abuse we have ever seen and one for which there was, until recently, no Medication-Assisted Treatment (MAT) model. "While there are U.S. Food and Drug Administration-approved medications for other substance use disorders, no medications have yet received FDA approval for methamphetamine use disorder."¹ That has changed. The good news of this ground-breaking study is that it more than quadrupled early success in methamphetamine treatment. The bad news is that the success rate went from 3.4% to 16.5%.² This illustrates the challenge that addiction to methamphetamine poses for individuals attempting to get clean.

¹ <https://www.nih.gov/news-events/news-releases/combo-treatment-methamphetamine-use-disorder-shows-promise-nih-study>

² Ibid

Dealing with methamphetamine must also be a priority, as methamphetamine carries with it long-term consequences in brain activity and, during use, leads to paranoia, hyper-vigilance and aggression. In my 32 years as a prosecutor, only PCP has ever rivaled methamphetamine as a leading indicator of violence. In fact, an individual using methamphetamine is substantially more likely to engage in violent behavior compared with when they are not, even after adjusting for other substance use and socio-demographics. Using the number of days of use in the past month, a person with 1–15 days of use multiplied violent behavior by a factor of 2.8. A person with 16 or more days of use multiplied violent behavior almost ten-fold, a factor of 9.5.³ All illegal activities carry a risk of violence. Methamphetamine use, even if entirely legal, would still carry risks to others.

Prosecutor History as Innovators

In the face of these threats, I am proud to detail the work of our nation's prosecutors, who have long led the way in finding and implementing improved mechanisms for communities ravaged by drug abuse.⁴ Shortly after I began working for her, Janet Reno created the first Drug Court, then a ground-breaking model that used not just intensified probation services, but offenders in group settings to give a chance to offenders who were otherwise heading to long-term incarceration.⁵ From that beginning emerged what are often categorized as specialty courts, dealing with defendants in drug and DUI cases. A similar model is common for Mental Health courts and Veterans' courts. One would be hard pressed to find a county, much less a state, where offenders did not have access to one or more of the courts that spring from this lineage.

As positive as the specialty courts have been, the model upon which they were based was inherently limited to those offenders who were otherwise facing prison. The initial thought was that those offenders were most likely to be desirous of seeking a change in their lives and that the threat of prison was important to ensure participation and compliance with the program requirements. It is certainly true that the specialty courts have been proven to be successful in modifying behavior. But there are costs, both to the offender and to the community. If intensive treatment is reserved for repeat offenders, we run a grave risk of making addiction the only disease where "we expect people to diagnose themselves by 'hitting bottom.'"⁶ Families and

³ Does methamphetamine use increase violent behaviour? Evidence from a prospective longitudinal study. Rebecca McKetin, Dan I. Lubman, Jake M. Najman, Sharon Dawe, Peter Butterworth, Amanda L. Baker
First published: 08 January 2014 <https://doi.org/10.1111/add.12474>

⁴ An overview of prosecution perspectives and changes can be found in To Prosecute, Interviews about Early Decision-making, Emily LaGratta, 2020.
<https://static1.squarespace.com/static/5d260fabfdbd0000011668cb/t/5f33f2ca0f254020169d5139/1597240019869/To+Prosecute%2C+Interviews+About+Early+Decision-making+booklet.pdf>

⁵ Federal Probation, No. 72, vol. 1; https://www.uscourts.gov/sites/default/files/72_1_2_0.pdf

⁶ Regina LaBelle, Criminalizing Addiction Isn't Working. Prevention and Treatment Deserve a Chance. August 23, 2019. <https://www.cato-unbound.org/2019/08/23/regina-labelle/criminalizing-addiction-isnt-working-prevention-treatment-deserve-chance>

communities are also left with the consequences of that on-going substance abuse, with behaviors that range from neglect and poverty to theft and violence.

The Rise of Prosecutor-Led Diversion

Recognizing these limitations, prosecutors over the last five to ten years have increasingly added diversion programs, and like Ms. Reno, are some of the earliest developers and implementers of diversion programming. These programs are not intended to replace the specialty courts, but rather to fill a gap which those courts cannot. There are many different models of diversion. Some of the important distinctions include:

1. Time of intervention
 - a. Pre-arrest
 - b. Pre-charge
 - c. Post-charge
2. Offenses covered
 - a. Misdemeanors (often DUT's and domestic violence cases are not eligible)
 - b. Drug offenses (sometimes only certain drugs are eligible, usually marijuana)
 - c. Property crimes (these may include both misdemeanor and felony theft)
3. Offender Eligibility
 - a. Young adults (often 18-25)
 - b. All adults
 - c. Juveniles

In Pennington County, our program began in 2016 with misdemeanor charges of Possession of Marijuana and Petty Theft. We now have diversion programs that are available to persons of all ages who are arrested on virtually all non-violent misdemeanors and many non-violent felonies. We started slowly, looking for proof of concept. We owe a great deal to Cy Vance, District Attorney in Manhattan, and Darcel Clark, District Attorney in The Bronx, both of whom gave us a great deal of assistance and guidance as we first began to create this programming.

Our Diversion programs all follow the same procedures. We begin post-charge. An offender who is eligible, on an eligible offense:

1. Receives an intake interview (usually about an hour), is given a contract tailored to his/her specific needs, and admits guilt and, where appropriate, makes plans for restitution⁷;
2. Completes the contract (for Young Adult diversion, we target completion within 30-90 days), at which point the underlying criminal case is dismissed; and
3. Begins a 1-year period of "obey all laws." If successful, the offender can (with our assistance) seal and expunge both the criminal case and even the arrest.

⁷ In South Dakota, restitution is a constitutional right of the victim, which we do not waive (although we frequently have victims voluntarily waive restitution as part of diversion).

We tell our community that we have four basic rules for diversion:

1. It will be harder than pleading guilty (in terms of personal effort);
2. It will be achievable for the accused;
3. It will give the offender and the community a better chance at long-term success; and
4. There will never be a fee to participate. Even if there is programming associated with the contract, the costs of that will be borne by someone other than the offender.

There is no pay to play.

One of the most important and difficult aspects of our diversion is ensuring that the contract is tailored to the offender's history, the offense behavior and the underlying causes of that history and behavior. Because we have limited resources, we rely on community resources, including government agencies and NGO's, along with civic, church and charitable organizations. There are four kinds of contract clauses that are the most common.

1. Effort-based: Community service, letters of apology and group works are the most common. Community service is permitted in any non-profit or government organization that is chosen by the offender (assuming that they are equipped, insured, etc.) and in any community, not just in Rapid City.⁸
2. New Peers: All manners of civic and cultural associations are included. The idea is that an offender who has a renewed purpose and a social group built around that purpose is at substantially less risk of re-offending.⁹
3. Education/Counseling: This might include GED classes, drug treatment, parenting classes or any other self-improvement education.¹⁰
4. Employment: This includes job-shadowing, job internships and even job apprenticeships, which carry a full-time, living wage job if successful.¹¹

In 2020, just before the outbreak of COVID-19, we initiated programming for methamphetamine and opioid users. Up until that point, we did not feel that we had any mechanisms available to give participants a realistic chance of success. But in 2018, Pennington County opened its "Care Campus," which provides an alternative to jail with "safe beds" Detox services, mental health crisis care and, in 2019, residential meth/opiate treatment beds. Just last week, we signed an MOU with the Oglala Sioux tribe, which will allow us to place Native American diversion participants in Native Women's Health Care and Native Healing, which provide a wide range of health care options, including residential substance abuse treatment, beginning in June 2021.

⁸ Two of the most popular examples include our Humane Society and Habitat for Humanity.

⁹ The cultural component of activities is important for some offenders. We work with a wide range of groups, including the Wambli Ska Pow-Wow and Indigenous American Legacy (IAMLegacy), among many others. For some insight into how cultural considerations are made part of the programming, there is a Tedx Talk: Lighting a Path for At-Risk Youth; <https://www.youtube.com/watch?v=0Kk1BJv3LvA>

¹⁰ Our most frequent partners include Lifeways and Love, Inc., along with school district and other local educational institutions.

¹¹ Our apprenticeship opportunities are exemplified by Scull Construction, which has taken diversion candidates both as interns and as apprentices. Our internships and apprenticeships are all paid.

The Role of Criminal Justice in Addiction

The Sheriff in Pennington County, Kevin Thom, has said that our communal response to addiction needs to be a three-legged stool consisting of prevention, enforcement and treatment. Just as we cannot incarcerate our way out of an epidemic, neither can we ignore it and expect it to go away. I certainly believe that we need to be treating addiction more like a medical crisis, but that mentality needs to be more than mere rhetoric. Merely calling for legalization or decriminalization is not the answer. The families and communities that are being torn apart by meth and opioids deserve protection.

Instead, we need to invest in human capital just as we invest in infrastructure...and with the same understanding of the short-term costs. I guarantee that every prosecutor and every sworn law enforcement officer in the country would be thrilled to take to the sidelines of our national struggle with addiction (and for that matter, mental illness and homelessness). We are all well aware that we are not experts in those matters. But inch by inch, we have found over the last 50 years that the institutions designed to deal with addiction, mental health and homelessness were poorly-run, expensive, or both. So, they ended up being under-funded or eliminated.

And we left the consequences of that abdication to the criminal justice system. Instead of dealing with the addict, we wait until the addict has caused a problem for someone else and, when they do, law enforcement is required to respond. Leading up to the criminal case, there are untold consequences to families, neighbors, children and friends. There are victims of theft and assault, even of rape and murder. So, this process needs to be initiated much earlier, with investment in treatment and intervention long before the criminal justice system would be needed. Every intervention that prevents violence is a step narrowing and focusing the role that law enforcement is required to fill.

That will not be easy, but there are steps that Congress can take.

First, provide additional funding and resources to match the Congressional rhetoric about the need to break down the silos between the criminal justice system and the public health sphere. Take seriously the description that this is a medical problem. Allow Medicaid and Medicare funding to pay for MAT models even for off-label uses. At the same time, move up the intercept point. Instead of waiting until I am involved, government and community treatment and prevention programs need to be active in finding and helping people.

Second, do not try and figure everything out in DC. NDAA represents more than 5,000 members who serve in the nation's 2,341 independent prosecutors' offices. We do not pretend to have all of the answers, but we are exceptional laboratories of innovation and we talk to each other.¹² The more you can do to incentivize that innovation, as with Comprehensive Addiction and Recovery Act (CARA) and subsequent legislation to address the disease of addiction, the better.

Third, remove the federally-imposed collateral consequences of state drug convictions. If a young person convicted of a state charge of Possession of Marijuana cannot get student loans, is disadvantaged in seeking work on a construction crew on a federal contract and cannot get HUD (or NAHASDA) housing, it should surprise no one that much of their income will be from selling drugs to (or stealing from) those among us who are most vulnerable.

¹² NDAA is in the middle of a collaborative effort with the Urban Institute Justice Policy Center to create an interactive tool to allow prosecutors and interested partners to research and find diversion programming around the country.

Ms. ESHOO. Mr. Vargo, thank you for your excellent testimony, really grabbing the attention of every single Member. Thank you, and thank you for the superb work you and your organization do.

Now the Chair would like to recognize Dr. Westlake. Welcome to the committee. Thank you for being willing to be a witness and give testimony today, and for your patience in waiting for panel two to begin.

So please unmute so that everyone can hear you. And welcome, again.

STATEMENT OF TIMOTHY WESTLAKE, M.D.

Dr. WESTLAKE. Great, thank you. Thank you, Chair Eshoo, Ranking Member Guthrie, and members of the subcommittee. Thank you for the opportunity to talk with you and for your leadership. My name is Tim Westlake. I am a full-time emergency physician and the immediate past chair of the Wisconsin Medical Examining Board. I am a licensed provider and prescriber of buprenorphine and provide the medical control for the statewide peer-to-peer recovery network that provides free Narcan education and access. I was also the physician architect of the Wisconsin Prescription Opioid Reform Strategy starting in 2014.

I originated the idea of targeted fentanyl class scheduling while serving on the Wisconsin Controlled Substance Board and got it enacted first in Wisconsin in 2017. The DEA then temporarily put in place the same language federally in 2018. Before that point, scheduling of fentanyls was like a lethal game of Whac-a-mole, as you have heard before, except for me it was literally waiting for kids to die before we could control and stop the spread.

As an emergency physician, I was beyond weary and heartbroken having to tell parents, sometimes even friends of mine, that their kids were never coming home again after overdosing.

The inspiration for the fentanyl class scheduling reform arose out of the tragedy of my friend's son, Archie Badura. Archie was an altar server alongside my daughters in church. Archie first got hooked on prescription pills and then IV opioids. I resuscitated him on his second-to-last overdose. We pulled out a body bag and laid it out for him, warning him that he would end up in it if he didn't reach out for help. He was able to stay clean for 6 months after that, but then fentanyl caught up with him and ended his life like it has for hundreds of thousands of other kids in our country. His mom, my good friend Lauri, remembers seeing me showing him the body bag in the emergency department. And the next time she saw that bag, Archie was being zipped up into it and taken away to the morgue.

In 2020 Congress enacted a temporary extension of what I like to refer to as the "Archie Badura Memorial Fentanyl Class Scheduling Language," closing a loophole in Federal drug law which cartels have been exploiting for years to create and then legally distribute these deadly substances. Now is not the time to eliminate a proven harm reduction and overdose prevention strategy.

When looking for policy and legislative solutions to the fentanyl devastation that is wreaking havoc in our country, it is critical to look at this situation from the proper perspective. Unlike marijuana, hallucinogenics, cocaine, or even heroin, fentanyls are so

toxic and lethal that they can be classified and actually can be used as chemical weapons. A lethal dose is 2 milligrams, meaning that one teaspoon—which is what is in this packet of sugar—can kill 2,000 people. Twenty-four pounds is more than enough to kill all 5.4 million residents of metropolitan Washington, DC.

The effects of the 3 years of fentanyl class scheduling are clear: the creation and distribution of finished fentanyl and fentanyl-related substances from China has ground to a halt. Most importantly, according to the National Forensic Laboratory Information System, overdose deaths related to fentanyl-related substances—newly created fentanyl-related substances—have effectively ceased. In Florida, in comparison, between 2016 and 2017 there were 2,500 deaths attributed to fentanyl-related substances themselves. During that same time in New York City, there were 900 deaths in the city alone.

Concerns about potential negative consequences on research and increased incarceration simply really have not materialized. Most research concerns raised in opposition are theoretical and seem to be focused on schedule I research writ large and are not specific to fentanyl-class research itself. In clarification, there are an exceedingly small number of researchers who have studied and—registering to study the fentanyls, approximately 30 in total, with many of these being DEA and Department of Defense subcontractors focused exclusively on the analysis, detection, and attempt to understand the harm of these substances. The only dampening or restricting of research has been purely theoretical.

Fentanyl and its derivatives have been extensively researched since discovery in 1960, and in that time not one fentanyl-based reversal agent or medication-assisted treatment has ever been found in the 60 years since.

Naloxone and Narcan work exceedingly well at reversing overdoses from all opioids, including fentanyl and fentanyl-related substances. This is something I, unfortunately, see sometimes on a daily basis. If it wears off, then more can easily be administered. Kids die because they ingest a lethal dose of toxic opioids, not because Narcan isn't effective.

Opposition posits that the Analogue Act is sufficient to control any new fentanyl-related substances. But if that were the case, all 50 attorney generals, including then-California AG Xavier Becerra, wouldn't have crossed the aisle, coming together 2 years ago to ask Congress to enact this language, and we wouldn't be discussing it here in this hearing right now.

It is important to understand using the Analogue Act is a reactive strategy. It often reacts to the deaths of hundreds or thousands of our kids. Overincarceration has simply not been seen. In fact, in the 3 years since the class scheduling has been in place, there have been a total of eight Federal prosecutions, half of whom already have known ties to drug cartels. It is because this is not a law enforcement bill, this is a prevention bill.

Regarding the mandatory minimums, the amount that triggered the minimums are 10 and 100 grams, which at first glance seems harsh. But it is critical to remember that that is enough to kill 5,000 and 50,000 people, respectively.

Also setting the record straight, there have been zero prosecutions for nonbioactive fentanyl-related substances. This is due to the fact that all fentanyl-related substances encountered and researched to date have been found to be strong and potent opioids. Benzyl fentanyl is not classifiable as a fentanyl-related substance.

I would suggest that so little incarceration is occurring as a result of the fentanyl class scheduling because it is, first and foremost, an overdose prevention and harm reduction tool and strategy originated by me, an emergency physician, who was beyond weary having to tell more parents that their children would never be coming home.

Ms. ESHOO. Dr. Westlake, can you just summarize in a sentence or two, because your time has expired?

Dr. WESTLAKE. I am sorry, yes. The solution is not to allow the expiration of the fentanyl class scheduling. Congress should enact the Archie Badura Memorial Fentanyl Class Scheduling language seen in the bipartisan FIGHT Fentanyl Act.

We need to deploy every——

Ms. ESHOO. Thank you very much. Thank you, Doctor, we appreciate you being with us and for your testimony.

[The prepared statement of Dr. Westlake follows:]

April 14th, 2021

Thank you Chairwoman Eshoo, Ranking Member Guthrie and members of the Committee for your leadership and this opportunity to testify on this critical public health epidemic.

In 2020, the temporary extension of the emergency scheduling of fentanyl related substances (FRSs) was signed into law. Unless Congress takes immediate action, this extension will expire on May 6, 2021. It's the reason for this testimony: to present the facts in support of a permanent legislative solution to ensure that deadly fentanyl variants can be scheduled and, as a result, thousands of lives continue to be saved. The death toll at the hands of opioids -- especially illicit fentanyl -- is on the rise. According to the CDC, from July 2019 to July 2020 in the United States there were over 50,000 deaths attributable to illicit fentanyl/synthetic opioids. The global pandemic has only served to exacerbate and accelerate what was already a horrific situation. Now is not the time to eliminate proven strategies in the fight to save lives.

Background on Fentanyl Class Scheduling Legislation

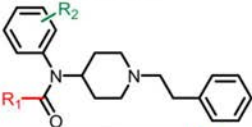
Fentanyl class scheduling by design is preventative, not punitive, it is in reality the ultimate expression of harm reduction. As a primary architect of the fentanyl class scheduling legislation, my goal was to stop the creation and spread of deadly new fentanyl related substances from transnational drug trafficking organizations, not to incarcerate people with substance use disorder. I am a full-time emergency physician and part-time medical regulator in Wisconsin. I provide medical direction for a statewide peer to peer recovery program that provides naloxone and training, in addition I prescribe medication assisted treatment when needed. I'm the immediate past Chairman of the Wisconsin Medical Examining Board and a former member of the Wisconsin Controlled Substances Board (responsible for controlled substance scheduling at the state level) and was architect of the Badger State's prescription opioid reform strategy.

As way of background, I have been on the front lines in the opioid battle for more than 30 years and have been deeply saddened by having to tell far too many parents and families their loved one was never coming home due to an opioid overdose. As an emergency physician, I was beyond weary and broken-hearted at times having to tell parents (sometimes even friends of mine) they would never see their child again after a lethal overdose. The inspiration for the fentanyl class scheduling reform arose out of the tragedy of my friend Lauri's son Archie Badura. Archie was an altar server with my daughters in church. Archie got hooked on prescription and then IV opioids. I resuscitated Archie on his second to last overdose. We showed him a body bag and warned that he would end up in it if he didn't get help. He got into rehab and stayed clean after that for 6 months, but then fentanyl caught up with him and snuffed his life out like it has for hundreds of thousands of other kids in our country.

At the time I came up with fentanyl-class control legislation over four years ago, Doctors and other health care professionals in Wisconsin alone were battling at least nine almost identical fentanyl variants. Each was responsible for multiple overdose deaths in state and across the U.S., but were still considered "legal" substances, having not yet been scheduled federally by the DEA or at the state level by the Controlled Substance Board (CSB). In Wisconsin, when deaths result from new novel substances, the CSB can use its emergency scheduling authority.

It was like a lethal game of “Whack a Mole”. We had to literally wait for the body count to pile up before we could find and schedule the new fentanyl variants one at a time.

Table 1. Examples of recent structural modifications to fentanyl observed on the illicit market.



The chemical structure shows a piperidine ring substituted with a benzyl group at the 3-position and a 1-(R1-phenyl)ethyl group at the 4-position. The R1 group is attached to the carbonyl carbon of the amide, and the R2 group is attached to the para position of the phenyl ring.

Substance	R ₁	R ₂
fentanyl ¹⁴	-CH ₂ CH ₃	H
acetyl fentanyl	-CH ₃	H
butyryl fentanyl	-CH ₂ CH ₂ CH ₃	H
furanyl fentanyl	-furan-2-yl	H
4-fluoroisobutyryl fentanyl	-CH(CH ₃) ₂	<i>para</i> -F
acryl fentanyl	-CH=CH ₂	H
<i>ortho</i> -fluorofentanyl	-CH ₂ CH ₃	<i>ortho</i> -F
tetrahydrofuranyl fentanyl	-tetrahydrofuran-2-yl	H
methoxyacetyl fentanyl	-CH ₂ OCH ₃	H
cyclopropyl fentanyl	-cyclopropyl	H
valeryl fentanyl	-CH ₂ CH ₂ CH ₂ CH ₃	H
isobutyryl fentanyl	-CH(CH ₃) ₂	H
<i>para</i> -chloroisobutyryl fentanyl	-CH(CH ₃) ₂	<i>para</i> -Cl
<i>para</i> -methoxybutyryl fentanyl	-CH ₂ CH ₂ CH ₃	<i>para</i> -OCH ₃
cyclopentyl fentanyl	-cyclopentyl	H
ocfentanil	-CH ₂ OCH ₃	<i>ortho</i> -F
<i>para</i> -fluorobutyryl fentanyl	-CH ₂ CH ₂ CH ₃	<i>para</i> -F

After countless heartbreaking times telling yet another family their child was never coming home, I knew something had to change. Hence came my idea to selectively schedule likely bioactive fentanyls as a class and remove the incentive foreign transnational drug trafficking organizations and chemical/drug manufacturers had in modifying the fentanyl molecule. For too long, these entities would simply add or delete one minor chemical group to stay ahead of US scheduling. They would develop new legal drugs that could not be stopped until they killed many young Americans -- until the Wisconsin law, whose provisions were embraced by the DEA nationally, stopped this deadly cycle.

My calculation was simple. If we could get it done in Wisconsin, we could then scale it nationally so it would have global implications, including in China and elsewhere where these lethal fentanyl variants have largely been manufactured. Working with the DEA, DEA then modified and updated the fentanyl-class scheduling language being used in the UK to work in the U.S. This targeted fentanyl-class scheduling language (the Archie Badura memorial fentanyl

class scheduling language) was the basis of the Stopping Overdoses of Fentanyl Analogues (SOFA) Act, or Wisconsin Act 60, which was passed unanimously in the state legislature under then WI Senate Leader and current US Rep Scott Fitzgerald (WI 5th) and signed into law in Wisconsin on November 9, 2017.

Within the first week of this new law being on the books in the Badger State, the DEA published the intent to use emergency scheduling powers to temporarily schedule fentanyl as a class federally. This took effect February 2018. The results have been incontrovertible: the creation of new fentanyl related substances has ground to a halt internationally. From 2016-2018 there were 32 new fentanyl related substances (FRSs) found to have caused thousands of overdose deaths in multiple states across the country. Since 2018, 12 new fentanyl related substances were found and with significantly fewer deaths attributed; it is suspected that many of these new FRSs may have already been in development prior to the temporary scheduling. NFLIS (National Forensic Lab Information System) data show 7,058 encounters for FRSs in 2016-2017, and a decrease in 2018-19 down to 758 encounters [a 90% decrease], and of these, the vast majority were for already scheduled FRSs. Most importantly the fentanyl/FRS flow from China has ground to a halt, and reports to NFLIS of overdose deaths related to new fentanyl-related substances have nearly ceased altogether.

CONCERNS RAISED AND CONSIDERED

Increased Incarceration

The goal of fentanyl class scheduling isn't to lock up low-level drug users, but to stop the development of deadly fentanyl poisons at their origin, namely, in drug labs overseas. Those opposed to fentanyl class scheduling initially suggested there would be an large rise in the societal costs due to increased incarceration of people suffering from substance use disorder, but that has just not proven to be the case. In the three years since fentanyl class scheduling was first placed into regulation, throughout the entire U.S. there have been 8 prosecutions using the temporary fentanyl class scheduling language; with half of these defendants having known ties to transnational criminal organizations/drug cartels.

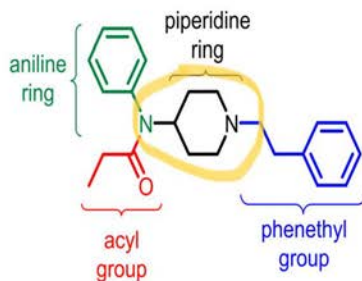
Opposition also mischaracterizes fentanyl class scheduling as a flawed law enforcement-first approach. This is a fundamental misunderstanding of the point that halting the creation of new drugs naturally results in decreased existence and thus supply which results in a decrease in harm, deaths and incarceration. This underscores the primary strategy of harm reduction. When considering societal effects, it is also critically importantly consider the effects on mortality. In Florida alone in 2016 and 2017 there were over 2500 deaths from FRSs, since 2018 FRS deaths in the US are almost nonexistent. Now, instead of opposing because of concerns for over incarceration, (after 3 years of data proving otherwise), it is being argued that fentanyl class scheduling is suddenly unnecessary because of the low number of prosecutions to date (8). This line of thinking actually proves the point of the importance of continuing the class scheduling, because without it, there would doubtlessly be more arrests, prosecutions and (as I have seen far too often up close and personal) inevitably more overdose deaths.

We have already been seeing the positive societal impact of the fentanyl class scheduling including that thousands more Americans are alive today who would otherwise not be had new fentanyl-related substances been created and trafficked in the US. Not only are people with opioid use disorder not being incarcerated, they are actually being kept alive. **Fentanyl-class scheduling is the ultimate form of harm reduction and prevention: you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist.**

Impeding General Research

Concern about not wanting to impede general research was thoughtfully considered, and great care was given to insure the language would be specific and narrowly crafted. The DEA looked at more than structural similarity when arriving at the definition of fentanyl-related substances (FRSs). Structure-activity relationship considers the relationship between changes in chemical structure relative to changes in pharmacological activity and was the basis of the definition to make sure substances meeting this definition have a high probability of retaining opioid-like pharmacological and psychoactive activity. In fact, the detailed scheduling language includes specific modifications to only those five portions of the fentanyl molecule with documented high likelihood of structure-activity relationship. The FRS language is the equivalent of a surgical scalpel, not a hand grenade.

Fentanyls fall into the 4-anilidopiperidine class (defined by the aniline ring in the 4-position of the piperidine ring). By definition, in order to structurally classify as a fentanyl-related substance under the FRS language, the base chemical structure must be that with Nitrogen at the 4-position of the piperidine ring (highlighted in yellow below).



Any chemical without that exact base structure and any of the specified modifications would not be included in the class scheduling. All elements of the basic fentanyl molecular chemical scaffolding must be present. If there are any deletions from the scaffold, the chemical wouldn't be included, and if there are any substitutions not specifically included in the specific language, those chemicals would also not be included in scheduling.

(The Archie Badura Memorial) Fentanyl Class Scheduling Language:



one or more of the following-

- (A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;
- (B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halo haloalkyl, amino or nitro groups;
- (C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxy, halo, haloalkyl, amino or nitro groups;
- (D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle and/or
- (E) By replacement of the N-propionyl group by another acyl group.

The targeted language was intentionally designed to capture only the modifications [already well described in the scientific and medical literature] being used by transnational criminal organizations to exploit the legitimate research information on structure activity relationships. By staying one step ahead of the CSA and Analogues Act, they continued the spread of these deadly poisons in the U.S. and internationally. There is an excellent detailed discussion on the chemistry and history of fentanyl and fentanyl related substances in a statement from Michael Van Linn, PhD taken from testimony before the United States Sentencing Commission in December, 2017: <https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20171205/Van-Linn.pdf>

Fentanyl was first created in 1960 and has been studied extensively since then. As noted in the Van Linn testimony, many of the new FRSs responsible for recent overdose deaths in the U.S. are well described in the patent and scientific literature, often accompanied by pharmacological data and detailed instructions on synthesis. Essentially, these are precise maps that guide legal - as well as illicit - drug labs and chemical manufacturers in creating new FRSs that are almost certain to be bioactive. The pathway to synthesize fentanyl and FRSs is relatively straight

forward and well-defined, and creation of a new FRS is as simple as plugging in or removing a different chemical precursor at one step or another in the process of synthesis. The ease of creating new FRSs is attractive to medicinal chemists and, unfortunately, also illicit chemists.

Reversing Overdoses and Medication Assisted Treatment

Some opposition in the research community suggest that fentanyl-class controls would hamper research into possible chemicals that could be used to reverse overdoses or treat opioid use disorder. To date, in over 60 years of extensive research done since fentanyl was first discovered, during which exhaustive structure-activity relationship studies have been conducted, registered researchers and published research have failed to highlight any activity in developing a fentanyl based antagonist/ reversal agent or medication assisted treatment.

It should also be noted that the pharmacological and overdose effects including lethal respiratory depressant effects of fentanyl/FRSs are similar to those of other opioid agonist drugs such as morphine, heroin and oxycodone etc. Naloxone (Narcan) has been shown to be effective in reversing the respiratory depression that leads to death caused by opioids like heroin, as well as semisynthetic and synthetic opioids including fentanyl. Pharmacologically, naloxone's ability to reverse the adverse effects of opioid toxicity is influenced by the receptor's binding affinity and ligand-receptor association and dissociation kinetics, and are not related to the particular chemical agonist structure. In other words, naloxone is a very effective reversal agent/antagonist. Deaths do not occur because naloxone doesn't work or isn't strong enough. Rarely it can wear off and if it does, the solution is to give more. Overdose deaths occur because of the ingestion of lethal doses of highly potent and toxic opioids, and are not due to a lack of potency or effectiveness of naloxone in reversing opioid toxicity when given in time.

With regard to medicinal treatment of opioid use disorder (medication assisted treatment/MAT), relapse rates have no correlation with current MAT options. Relapse or drop-out rate of patients is attributed to many factors such as cost, access to doctors/treaters and/or lack of behavioral treatments among other factors, and are not related to the specific opioid being abused. Nor have there been discovered or created any fentanyl/FRS based medication assisted treatments. **To recap, not one reversal agent/antagonist or MAT has ever been found or investigated in the six decades of research done into fentanyls.** All current research is focused on detection, analysis and understanding the harm of these substances, the fentanyl class is just not being researched as a possible therapeutic prior or since the DEA emergency control in 2018. Currently, there are over 30 researchers studying FRS and many are DEA contract researchers, who will evenly study all of the FRSs encountered to date.

Most if not all of the academic and research concerns regarding FRSs appear to be theoretical in nature and fall into the category of general concern about doing schedule I research writ large. These mostly include the hurdles of coordinating the three layers of regulatory oversight required to conduct schedule I research -- academic institutions, state and federal government - and include the most common complaints about the process being "time consuming and confusing." When analyzed, many, if not most, process delays are due to incomplete

applications by the researchers themselves. All researchers that have applied to study FRSs have been granted registrations in a reasonable amount of time, a few months at most. According to DEA the median overall review time to approval of a completed application was 53 days.

Sufficient Oversight & Collaboration Across Agencies

Another opposition area of concern voiced by some is the potential for decreased oversight into research on schedule I substances altogether, and seems not to be a particular concern with fentanyl class scheduling itself. There seems to be no distinction regarding what type of schedule I research is being undertaken. Marijuana and hallucinogens do not have the same risk profile of FRSs. A main general reason given by academics for needing to study schedule I substances is to “find out what makes these substances dangerous.” Yet this is already well studied with fentanyl/FRSs. The danger comes from the known high affinity for the mu opioid receptor and the resulting respiratory suppression.

In the normal sequence of events, the DEA reviews and investigates chemical compounds individually, then collaborates with HHS and the FDA in making a final decision in the scheduling process. Concerns about bypassing consultation with HHS and the FDA in this narrow circumstance by which the DEA can schedule certain fentanyl-related substances based on the specific, limited, targeted criteria were thoughtfully considered. As a result, the language was narrowly crafted to only include likely bioactive modifications based on the already known structure-activity relationships. Furthermore, ongoing research accommodations have been negotiated to the point that HHS, NIDA, FDA, and NIH all signed off in an administration interagency position statement in December 2019 based on the sought after accommodations for researchers and criminal justice reform advocates.

Proactively, and also in response to research concerns raised by HHS, the DEA has already addressed and significantly simplified the research requirements for FRSs, for example, requiring a single registration for all chemicals in the fentanyl class instead of separate registrations for each individual substance like it does for all other substances. Currently, there are in total 28 research registrations for fentanyl-related substances. It is significant to note that more than half of the 11 new research registrants for the new fentanyl class since 2018 were for DEA subcontractor chemical analysis or submitted through the Department of Defense. Ultimately, research is driven by funding and there does not appear to be a current investment in FRS research after 6 decades of studying the class. A final point on this: nearly all development of new fentanyl-related substances has been done overseas [in China mostly] and not by American scientists and researchers.

A vocal few have voiced concern about the lack of research on other chemicals in certain schedule I drugs like marijuana and hallucinogens. Marijuana and the thousands of chemicals that compose it are organic molecules found in nature, and are non-lethal, except for near non-consumable levels of THC. FRSs are not natural substances and only exist due to intentional and already well researched chemical synthesis. Comparing marijuana research to fentanyl research is not apples to apples. Proper perspective in framing the discussion is critical. One cannot

reasonably consider all schedule 1 drugs in the same light. If we had have one and only one drug class to be scheduled as a schedule 1, it would be fentanyl. Fentanyl is slightly less deadly than VX nerve gas and almost as deadly as the nerve toxin Ricin. FRSs that are less potent than fentanyl are even still dozens of times more potent than morphine or heroin.

Lethal Doses of Chemical Warfare Agents and Narcotics

Chemical Agent/Drug	Lethal Dose	Route
Botulinum Toxin	.00007mg	Inhaled/Ingested/Injected
Tetanus Toxin	.0001mg	Inhaled/Ingested/Injected
CARFENTANIL	.02mg	Inhaled/Injected
Tabun Nerve Agent	1-1.5mg	Inhaled/Ingested/Percutaneous
Ricin	1.78mg; 10mg	Inhaled/Injected;Percutaneous
FENTANYL	2mg	Inhaled/Injected
VX Nerve Agent	2.1mg; 10mg	Inhaled/Injected; Percutaneous
Strychnine	70-140mg	Ingested
HEROIN	70mg	Inhaled/Injected
Cyanide	100-200mg	Ingested
MORPHINE	200mg	Inhaled/Injected
Methamphetamine	200mg	Inhaled/Injected
Cocaine	200mg	Inhaled/Injected
MDMA (Ecstasy)	1000mg	Ingested
THC/Marijuana	4000mg (pure THC)	***Not realistically achievable in humans by all methods of marijuana consumption per the WHO

Lethal Doses of Chemical Warfare Agents and Narcotics

Chemical Agent/Drug	Lethal Dose	Route
	One teaspoon of Fentanyl is enough to kill 2,000 people	

Lethality and Potency, as Deadly as Chemical Weapons

The most accurate way to view fentanyl-related substances is as weapons of mass destruction, not just simply as recreational drugs or intoxicants like marijuana, cocaine, and even heroin. In a 2019 paper by John P. Caves, Jr., a Distinguished Research Fellow in the Center for the Study of Weapons of Mass Destruction (CSWMD) at the Institute for National Strategic Studies at the National Defense University, called "Fentanyl as a Chemical Weapon" covers the topic well. <https://www.hsdl.org/?view&did=832803>. Opposition to fentanyl class scheduling has likened it to cocaine legislation in the 1980's and as an extension of the war on drugs, but this perspective does not consider the differences in the chemical weapon like level lethality that exists with FRSs and the resulting mortality.

In September 2018, 52 members of the National Association of Attorneys General (NAAG) sent a letter urging Congress to adopt the Wisconsin law on scheduling FRSs. The unanimous bipartisan support of all 50 State Attorneys General, as well as from Washington DC and Puerto Rico, is unheard of in today's political climate. <https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/Letter-to-Congress-SOFA-Act-8.23-1.pdf>. Signors included current HHS Secretary-designate Xavier Becerra in his former role as California Attorney General. It speaks to the non-partisan importance of this matter as a critical national public safety measure.

Targeted control of specific fentanyl-related substances as a class and not as discrete chemicals is not a minor change to the US Controlled Substance Act (CSA). It has been carefully and thoughtfully crafted and wouldn't even be considered, but for its significant impact already seen in the worst drug epidemic in the modern era. Annualized deaths caused by illicit fentanyl and known analogues now surpass heroin and are responsible for the overdose death spike and lowering of the average life expectancy for Americans in the modern era for the first time since development of immunizations and antibiotics.

Analogues Act of the CSA is Not Sufficient

Some suggest the Analogues Act of the CSA is sufficient to give DEA and DOJ the power needed to act against fentanyl-related substances and that fentanyl class scheduling would only make it

easier to incarcerate people. That is patently not accurate. In order to use the Analogues Act, a substance must be proven substantially similar to a listed schedule I or II, and also must be proven to be intended for human consumption. This is highly problematic because those findings must be adjudicated in court in each and every case, even when the substance has been proven to be an analogue in a previous case. In addition, the usual threshold to even trigger looking at a substance as an analogue is purely reactive and not proactive or preventative when it is found to be killing people, usually many people across multiple states.

According to the 2019 Florida Medical Examiners Commission Report, deaths in the Sunshine state directly attributable to FRS overdose rose 65% in just one year from 965 in 2016 to 1,588 in 2017. That is over 2,500 deaths, or 3.4/families losing a loved one/day every day for 2 years. Between 2017 and 2018 in New York City alone there were over 900 deaths from FRSs. Thousands have already died due to the existence and availability of fentanyl related substances. It's why Governor Cuomo called for fentanyl class scheduling language in NY and why other states and nations are following Wisconsin's lead. We cannot go back to the way it was before fentanyl class scheduling was put in place.

Concerns over Prosecutions for Non-Psychoactive FRSs

Concerns raised about increased prosecution of people distributing non-psychoactive FRSs that would be inappropriately classified as schedule I is an extremely unlikely scenario for the following reasons:

- 1) First and foremost - **every single FRS ever encountered and researched to date has been found to have potent opioid effect bioactivity, dozens or more times more potent than heroin and morphine**
- 2) Simple charges of possession and lowest level dealing of FRSs are simply not aggressively prosecuted by federal prosecutors.
- 3) FRSs do not exist naturally, they are synthesized in illicit clandestine overseas labs by chemist suppliers to transnational criminal organizations. The process of FRS synthesis is intentional and based on researched and readily available information of the roadmaps of the structure-activity relationships. It isn't grown in a back yard. There is no bathtub lab manufacturing occurring. There is never going to be accidental synthesis, manufacturing and distribution of a new FRS.
- 4) The low likelihood of transnational criminal organizations/drug cartels synthesizing, manufacturing, and distributing new FRSs that aren't bioactive/psychoactive. It's simply not plausible they would go to the trouble of not in some fashion testing their product and risk putting new FRSs in their distribution networks that were duds (non-psychoactive). How long would they be able to sell them if they didn't get users high?

Due to the specific and targeted nature of the SOFA language based on stopping the exploitation of known fentanyl/FRS structure activity relationships, it is almost certain that a newly developed FRS covered under the Archie Badura memorial fentanyl class scheduling

language that is then manufactured and then internationally trafficked would be bioactive. If the bioactivity was similar to fentanyl, it would be at the level of chemical weapons lethality—one teaspoon deadly enough to kill 2,000 people. Of all the new FRS's studied between 2018 and 2020 (11 in total), all have been found to be psychoactive with high abuse potential, and no FRS's have been non-psychoactive. In fact there has never been an FRS found that did not exhibit highly potent opioid bioactivity.

Those opposed use the implausible rationale for not enacting permanent fentanyl class scheduling that theoretically a drug trafficker could be incarcerated for distributing a FRS that was actually beneficial or an antagonist like naloxone. Even though as has been previously mentioned, in the over 60 years of research done on fentanyls, not one substance with antagonistic properties has ever been researched. Of importance to note is that rescheduling can also be done rapidly in the highly unlikely circumstance where the substance being trafficked turns out to be non-psychoactive, as has been addressed in the Administration Interagency Position agreement previously mentioned with the research and criminal justice communities.

Mandatory Minimum Sentencing

Under current federal sentencing guidelines, the sentence is 5 years for 10 grams of fentanyl/FRS, and 10 years for more than 100 grams. On first glance, that may seem harsh, but it is important to remember the lethality and consider that 10 grams of a FRS is enough to kill 5,000 people, and 100 grams of a FRS could kill 50,000. In comparison, the lethal doses for THC and many hallucinogens [upon which much opposition to schedule I research restrictions from academia seem to be based] are hundreds or thousands of times higher.

FRS Bioactivity

There is incorrect information being disseminated that there have been prosecutions for FRSs that are not bioactive. This is just not factually correct. As mentioned previously, every single FRS ever encountered and researched to date has been found to have potent opioid effect bioactivity, dozens or more times more potent than heroin and morphine. The newest most recent new FRS studied was just found to be 4-8 times more potent than fentanyl.

Benzyl fentanyl has often been pointed to as an example of a fentanyl analogue that was scheduled under emergency order and then unscheduled (in 1985 and 1986), but in fact it would not fall under the fentanyl class scheduling language to qualify as a FRS. In fact the benzyl fentanyl modification and similar modifications were specifically excluded from the scheduling language because of their known non-bioactivity. It is also misstated by opposition that since 2018 prosecutions of the fentanyl analogue and List 1 precursor benzyl fentanyl have occurred under FRS scheduling, but in fact they have occurred under precursor controls. (This is because benzyl fentanyl can be easily modified to create fentanyl, therefore it was controlled as a List 1 precursor). To restate clearly, **there have been Zero prosecutions for FRSs that are not bioactive.**

Remifentanyl

There is also a factual error that needs to be corrected in the recent GAO report. In the discussion of possible negative effects on FRS research it is noted that remifentanyl would have fallen under FRS scheduling language, and theoretically it's development could have been hampered. However, remifentanyl in fact does not have a chemical structure that falls under FRS classification under the fentanyl class scheduling language.

International Coordination (with China Especially)

In recent trade negotiations with the Chinese government, the U.S. included targeted fentanyl-class scheduling among its priorities. As a result, China permanently enacted fentanyl class scheduling language in May 2019. The United Nations includes it in its toolkit of model opioid legislation for member nations. Several other countries and many American states have adopted similar fentanyl-class scheduling language. In this case of harm reduction to benefit American citizens, even the Chinese Communist Party sees the value in permanent fentanyl class scheduling. It is not inconceivable and many would say likely that if the US doesn't permanently enact fentanyl class scheduling, then China may not continue their prohibitions on fentanyls.

CONCLUSION

It is incontrovertible that temporary targeted fentanyl class control has already been an extremely effective harm reduction tool and has eliminated the incentive for traffickers to create new FRSs, closing the fentanyl-related substance loophole at home and overseas and saving countless lives in the process. If Congress allows the fentanyl-class scheduling to expire in May 2021, it's only a matter of time before other countries like China and even India could restart fentanyl-related substance creation and unleash the devastating consequences.

As an emergency physician, parent of young adult daughters and medical regulator, that is what drove me to design a legislative solution to prevent the development of new FRSs by illicit overseas chemists. We absolutely needed to shut down the FRS mine but at the same time not incarcerate people with substance use disorder or impede critical research. The Archie Badura memorial fentanyl class scheduling language found in 2017 Wisconsin Act 60, the SOFA Act, the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, and now the FIGHT Fentanyl Act threads that needle. It already has a track record as a powerful proven harm reduction/preventative solution.

Congress has in its power to extend this important fentanyl class scheduling legislation through the FIGHT Fentanyl Act and SOFA Act and continue to save countless lives. There is no question, if we turn our collective backs on the progress that's been made to stem the tide of opioid abuse in America, thousands more deaths will occur annually from the reemergence, existence and widespread availability of these deadly chemical agents. Now is the time to make this crucial reform permanent.

Thank you for the opportunity to testify and thank you for your leadership on this critical public health issue.

Timothy Westlake, MD, FFSMB, FACEP
 Wisconsin Medical Examining Board, Immediate-Past Chairman
 Wisconsin Controlled Substance Board, former Member
 Governor Walker's Task Force on Opioid Abuse

(Following is a one page take home summary).

SUMMARY

April 14th, 2021

Background

In 2020, Congress enacted a temporary extension of the emergency scheduling of fentanyl related substances (FRSs). This closed a loophole in federal law which drug cartels had been exploiting for years to legally create and then distribute these deadly substances. This scheduling language by design is not punitive, it is the ultimate expression of prevention and harm reduction. Unless Congress takes immediate action, this extension will expire on May 6, 2021. With the death toll at the hands of opioids the highest ever recorded and on the rise due specifically to an increase in illicit fentanyl overdoses, now is not the time to eliminate a proven strategy in the urgent fight to save lives:

- Between July 2019 and July 2020, over 50,000 deaths were attributable to illicit fentanyls – a horrific situation made significantly worse by the global pandemic.
- Unlike marijuana, hallucinogens, cocaine or even heroin, Fentanyl/FRSs are so toxic and deadly that they can be classified -- and actually have been used -- as chemical weapons.
- A lethal dose is 2 mg, meaning one teaspoon can kill 2,000 people and 24 pounds is more than enough to kill all 5.4 million residents in metropolitan Washington DC.

Findings to Date

In the three years since the emergency temporary scheduling order took effect, the intended results are incontrovertible: the creation of new fentanyl-related substances and flow of fentanyl and FRSs from China and elsewhere have ground to a halt; most importantly, overdoses related to FRSs have effectively ceased altogether. So too, concerns about potential negative consequences whether on research or increased incarcerations have not materialized:

- To date and as a consequence of the temporary scheduling order, there has been no dampening or restricting of research. Significant accommodations regarding fentanyl research have been reached. Most remaining concerns are theoretical and seem to be focused on schedule I research writ large, and are not specific to FRS research itself. As well, there is an exceedingly small number of researchers who have registered to study the FRS class -- 28 in total with many of these being DEA and Department of Defense subcontractors. FRS research is focused exclusively on the analysis, detection and understanding the harm of these substances. Fentanyl has been exhaustively researched since its discovery in 1960, and not one fentanyl based reversal agent or medication assisted treatment agent has been found in the 60 years since.

- Regarding concerns about increased incarceration, in the 3 years since the emergency fentanyl class scheduling has been in place, there have been less than 10 federal prosecutions of defendants, half of whom have known ties to drug cartels.

Solution

Instead of allowing the temporary extension of the emergency scheduling of FRSs to expire, Congress should enact the FRS scheduling language from the bipartisan *Federal Initiative to Guarantee Health by Targeting (FIGHT) Fentanyl Act* and the *Stopping Overdoses of Fentanyl Analogues (SOFA) Act*, and make these critical reforms permanent. We must employ every effective harm reduction tool in our arsenal. **The fact is, you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist.**

Ms. ESHOO. Last but not least, the Chair recognizes Dr. Wilson for 5 minutes for his testimony, and—your testimony.

And thank you again for your patience in waiting for panel two to begin, and we are ready to hear from you. So thank you very much. Lovely to see you, and thank you for joining us.

Dr. WILSON. Chairwoman—

Ms. ESHOO. And please unmute.

STATEMENT OF DEANNA WILSON, M.D.

Dr. WILSON. Chairwoman Eshoo and Chairman Pallone, Ranking Members Guthrie and Rodgers, and members of the committee, thank you for the opportunity to speak with you today. My name is Dr. Deanna Wilson. I am a pediatrician and internist with subspecialty training in addiction medicine. I am an assistant professor at the University of Pittsburgh, where I teach students and physician trainees about addiction, and I also conduct research focused on improving health equity and reducing disparities among vulnerable populations with substance use disorders.

The worsening overdose crisis and the setting of the COVID-19 pandemic has both unmasked significant health inequities but has also created opportunities for us to rethink how we deliver care in ways that, one, prioritize equity; two, increase treatment access; and three, increase our workforce's capacity to treat addiction.

In cities like Philadelphia, while rates of overdose deaths fell by 31 percent among White Americans, there was a concurrent increase by more than 50 percent among Black Americans. The racial and ethnic disparities and overdose rates today reflect our failure to center the needs of Black and Latinx communities and address the underlying systemic inequities, social inequalities, and structural racism that drive differential access and disparate treatment outcomes.

For example, we know that medications like buprenorphine and methadone substantially reduce the risk for both all-cause and overdose mortality, making them truly lifesaving. And yet your race determines how likely you are to receive them. Black patients have 77 percent lower odds of receiving a buprenorphine prescription during an office visit compared to White patients.

We must re-imagine how we deliver addiction treatment, partnering with community organizations like faith-based groups to rebuild trust and reduce stigma, supporting low-threshold models of care that minimize barriers, preventing marginalized groups from being well-served by traditional health systems.

We need greater investment in how to support these programs, to document their efficacy, and to scale up their use.

Secondly, we need improved treatment access. In response to the COVID-19 emergency there has been greater flexibility and funding to support telemedicine for the induction and maintenance of buprenorphine. Our ability to engage patients who are unable to physically make it into clinic allows us to see patients who may never have linked to or may have fallen out of care. We need legislation that permanently supports our ability to use telehealth, but we also need initiatives making sure that telehealth is more equitable, such as supporting digital literacy and improving access to broadband coverage.

Similarly, opiate treatment programs were granted flexibility to increase take-home doses of methadone. Preliminary studies show no increase in fatal overdose. This suggests the intense regulation of methadone distribution may be unnecessarily restrictive. We urgently need studies to further examine outcomes from this period so we can reform methadone regulations to become both more evidence based and patient centered.

In light of rising use of stimulants like methamphetamines and cocaine, we need to invest in research on effective medical therapies. We also need to remove current coverage gaps, limiting our ability to offer evidence-based behavioral treatments like contingency management.

Similarly, we need to reform policies that contribute to lags in addiction care for incarcerated individuals post-release. Incarcerated individuals are 129 times more likely to die from an overdose within the first 2 weeks after release compared to the general population. Lengthy lag times in reactivating insurance post-release contributes to potentially fatal return to use.

In addition, we must recognize that abstinence-only approaches to substance use treatment can further stigmatize and marginalize patients. Harm reduction services are not only effective at reducing harms associated with drug use, but by engaging patients who may be ambivalent over time. They provide critical access points to link patients to addiction treatment when they are ready. We must remove regulatory barriers and thoughtfully implement and study promising harm reduction interventions.

Thirdly, we need to increase the capacity of our health provider workforce to treat and normalize the care of patients with addiction. The regulatory barriers associated with prescribing buprenorphine, the X-waiver, have unnecessarily restricted access to lifesaving therapies. Removing the X-waiver is low-hanging fruit with the potential to drastically increase patient access. But at the same time we need to support training in addiction medicine for all providers.

For example, requiring education in addiction, including logistics on buprenorphine prescribing as part of DEA registration, would empower all providers with a DEA license learn how to recognize and treat patients with addiction.

If I may leave you with these three thoughts: one, we need to center equity in our policies and programming; two, we have to use evidence-based strategies to expand access to addiction treatment; and three, we must remove regulatory barriers and normalize the treatment of addiction by all providers.

Thank you. I am happy to take any questions.

[The prepared statement of Dr. Wilson follows:]

**Testimony
of
Deanna Wilson, M.D., M.P.H.
Assistant Professor of Medicine and Pediatrics
University of Pittsburgh School of Medicine**

before the

**Subcommittee on Health
House Committee on Energy and Commerce
U.S. House of Representatives**

Hearing on “An Epidemic within a pandemic: understanding substance use and misuse in America.”

April 14, 2021

Chairwoman Eshoo, Ranking member Guthrie, and members of the committee, thank you for the opportunity to speak with you today on the importance of addressing substance use and the ongoing epidemic of opioid-related deaths in the United States.

My name is Dr. Deanna Wilson. I am a pediatrician and internist with subspecialty training in addiction medicine. I am an Assistant Professor of Medicine and Pediatrics at the University of Pittsburgh and I treat patients at UPMC and UPMC Children's Hospital of Pittsburgh. I provide care to patients across the life spectrum—currently, I am treating patients ages 13 to 74 with substance use disorders in both the hospital and outpatient settings. My institution serves a large catchment area including the city of Pittsburgh and also Eastern Ohio, Northern West Virginia, and Western PA. I conduct research focused on understanding how we can improve health equity and reduce disparities among vulnerable populations with substance use disorders, particularly focused on patients who inject opioids.

I am honored to speak with you all today and grateful that even while confronted with the ongoing COVID-19 pandemic, we are not forgetting the co-occurring public health crisis related to opioids and other substance use in America. While COVID-19 has unmasked significant health inequities, it has also created opportunities to rethink how we deliver care to patients with substance use disorders in ways that prioritize equity, increase access, and reduce morbidity and mortality.

Racial and ethnic disparities in addiction treatment

COVID-19 has brought to the forefront the striking racial and ethnic disparities that impact millions of Black and Brown Americans—people from racial and ethnic minority groups have disproportionately borne the burden of the pandemic as a result of long-standing systemic health and social inequities.¹ As disparities related to the COVID-19 pandemic are driven by pre-existing inequities, such as a lack of access to primary care

providers, disparate financial resources, racial segregation, and policies driven by and supporting systemic racism, so too has the opioid crisis.²

During this past year, over 81,000 drug overdose deaths have occurred with striking racial disparities in overdose rates.³ In cities, like Philadelphia, where there was an increase by more than 50% in overdose deaths among Black Americans, rates of overdose death fell by 31% among white Americans.⁴

The acceleration of overdose deaths among Black communities is a result of earlier policy missteps. As someone who trained in Baltimore for seven years, the patients I cared for came from communities that had been dealing with heroin for decades, long before the opioid crisis became a very visible public health problem centering white, suburban middle-class families. My patients would comment on the irony of addiction now being seen as a disease requiring medical treatment when they lived in communities devastated by the War on Drugs and mass incarceration—the treatment strategies they had been offered. These policies devastated families, communities, and entire neighborhoods. They shared deep frustration with me that financial resources and solutions to the epidemic were focused on better-resourced, White communities and ignored the needs of Black urban communities. The racial and ethnic disparities we are seeing in opioid overdose rates today are what happens when we design treatments and interventions focusing on offering equal access to treatment without thinking of the need for equitable access—without centering the unique needs of communities of color and without addressing the systemic inequities, social inequalities, and structural racism that drive differential access and disparate treatment outcomes.

For example, we know that medications like buprenorphine and methadone are efficacious in retaining people in treatment, suppressing illicit opioid use, decreasing opioid craving and treating opioid withdrawal.⁵ They substantially reduce the risk for all-cause and overdose mortality—making them truly life-saving medications.⁶ And yet, your race determines how likely you are to receive them. Studies have shown that while rates of opioid use disorder are similar for Black and white Americans, for every 35 white patients with OUD who receive a buprenorphine prescription, only 1 racial or ethnic minority patient will receive one: Black patients have 77% lower odds of receiving a buprenorphine prescription during an office visit for OUD.⁷ This is unjust. Even among pregnant women, for whom the use of medications like methadone and buprenorphine have been associated with improved maternal, fetal, and pregnancy outcomes, Black and Latinx women were significantly less likely to receive any medications to treat OUD compared to white women.⁸ This further propagates inequities to the next generation.

Access to medications to treat opioid use disorder is often driven by racial segregation with differences in access determined by demographics at the neighborhood level.⁹ Stigma is also an important contributor. Stigma, defined as a social process by which individuals are labeled, stereotyped, and marginalized based on real or perceived status or attributes,¹⁰ is well-documented in patients with opioid use disorder.¹¹ Stigma from healthcare clinicians, and embedded within the healthcare system, negatively impact the quality of care.¹² For example, stigma causes clinicians to underestimate the

efficacy of evidence-based treatments and implicitly or explicitly create environments where patients feel unwelcome.¹³ Effective, targeted interventions to eliminate stigma in addiction treatment are desperately needed to improve health. Stigma associated with OUD may be compounded by racial bias, leading to worse outcomes for Black, Indigenous, and Latinx patients.

Racial bias or racism contributes to inequitable prescribing practices and treatment approaches, which in turn results in disparities for racial and ethnic minorities. Disparities in pain management are well-known and documented, including lower rates of opioid prescribing and increased oversight for Black patients.¹⁴ In addition to being less likely to receive medications to treat opioid use disorder,¹⁵ Black patients are also less likely to receive naloxone for overdose prevention and are also less likely to be retained in treatment if they are started.¹⁶ Opioid use disorder and racial bias intersect to create overlapping and compounding systems of disadvantage, which contributes to lower quality of care and worse outcomes for racial and ethnic minorities.

And so, what do we need to do? As a physician treating patients at a low-threshold program in Baltimore based out of a community-based organization, I cared for many patients who would never have sought treatment within the walls of my hospital clinic, but who were willing to seek care from me because I was practicing at and partnering with a trusted community site. Similar to the efforts taken by states to facilitate equitable distribution of COVID-19 vaccine, we need to fund addiction treatment models, which center the needs of and recognizes the strengths of communities of color. We need research and funding to support innovative models that reimagine addiction medicine treatment and leverage community partnerships, such as engaging the faith-based community and delivering care in churches, offering medication to treat opioid use disorder alongside well-entrenched and well-trusted needle and syringe exchange programs, and with low-threshold models that minimize the barriers that have traditionally prevented marginalized groups from being well-served by traditional health systems. We need greater investment in research demonstrating how best to support these programs, to document their efficacy, and to scale-up their use. We need additional investment in models that train and support peer recovery specialists from our target communities who can leverage their lived experience to connect with and support patients.

Additional vulnerable groups are those who have been recently incarcerated. We also know that people of color are disproportionately represented in the criminal justice system. Incarcerated individuals are 129 times more likely to die from an overdose within the first two weeks after release compared to the general population and this is particularly heightened for those with opioid use disorder. We need to reform how we approach the care of individuals who are incarcerated and to offer comprehensive behavioral, social, psychological, and evidence-based pharmacological treatments for their substance use disorder. Anything less is inhumane and contributes to ongoing racial and ethnic disparities. Lengthy lag times in the reactivation of insurance coverage from the time people leave jail or prison create a dangerous situation that predisposes individuals to a possibly fatal return to use. We need to reform payment policies so that

individuals who leave jail or prison can quickly connect and get linked back into substance use disorder treatment.

Expand access to current medications and treatment for addiction

The COVID-19 pandemic has created several opportunities for re-imagining the way that addiction care is delivered in the US. While these guidelines were designed to be temporary solutions to the pandemic, they have shown significant promise for increasing access to treatment for vulnerable populations, including for rural Americans.

Guidelines have allowed greater flexibility and funding to support telemedicine for the initiation and maintenance of buprenorphine. This has been essential at maintaining contact with existing patients during the pandemic. I can call patients that are unable to make it to clinic because of transportation or childcare barriers and I can conduct a telehealth visit minimizing the risk they will fall out of care. I can treat patients who would otherwise have to travel long distances—at times over an hour—to see me in person, but for whom I can build relationships, offer medication, and monitor their progress all through telehealth. These are patients who otherwise may never have initiated or linked to care. I have seen patients virtually from a homeless encampment where they have called me from their tent, from their living rooms, from streets in their neighborhoods. Each encounter allowing me to get a greater glimpse into their lives outside my clinic. We need legislation that permanently supports our ability to use technology to expand access to treatment for patients, support maintenance, and help prevent patients from falling out of care. We also need to take care that as we expand access to telehealth we are thoughtful about supporting other initiatives that make telehealth more equitable, such as supporting digital literacy and improving access to internet broadband coverage.¹⁷

Additionally, while methadone has been a highly effective treatment for many Americans, it is only able to be offered in certified opioid treatment programs. These are often located in urban settings and require patients to attend daily, most days of the week to take their medication. Federal guidelines for dispensing unsupervised take-home doses of methadone focused on minimizing diversion and misuse, but these policies are overly restrictive and make it challenging for patients to integrate methadone treatment into their work or school day. I treat many patients who reside in rural areas who may prefer methadone but are unable to access it because of daily dosing requirements and the long distances they would need to travel.

In response to the COVID-19 state of emergency, opioid treatment programs were granted flexibility allowing increased take-home doses of methadone and requiring reduced toxicology testing. Preliminary studies from this period show no increase in fatal overdose among patients and suggest that the intense regulation of methadone distribution may be unnecessarily restrictive.¹⁸ We urgently need studies that further examine outcomes from this period and we need to use these findings to reform methadone regulations to become more evidence-based and patient-centered.

While I focused thus far on opioid use disorders, we are now seeing growing numbers of patients that use stimulants predominantly or in conjunction with opioids. We have limited effective pharmacotherapies to treat stimulant use from stimulants like cocaine or methamphetamines and need research to identify novel therapies. We also need funding to support behavioral health interventions, like contingency management, which have evidence showing they are efficacious at incentivizing individuals to quit using stimulants.¹⁹ Also, licensed residential treatment programs should be required to offer evidence-based medications as part of their complement of behavioral treatment as they have been shown to reduce mortality, however, only a third of residential facilities offered buprenorphine and only 2% offered methadone.²⁰

Improve capacity of providers to treat patients with addiction

While increasing access to medications to treat opioid use disorder is essential, we also need to increase the capacity of the provider workforce to treat patients with addiction more broadly. As of 2019, only 35 percent of people with OUD receive treatment for their addiction, leaving an estimated 2.2 million people undertreated.²¹ Certain populations, like adolescents and young adults, are underserved with only 1% of waived providers identifying as pediatricians.²² Certain areas are also underserved with approximately half of all rural counties lacking a provider waived to prescribe buprenorphine, contributing to the high rates of overdose deaths in rural areas such as Appalachia.²³

While the Drug Addiction Treatment Act of 2000 and the subsequent Comprehensive Addiction and Recovery Act of 2016 aimed to expand treatment capacity by allowing first physicians and then nurse practitioners and physician assistants to receive training allowing them to receive a waiver to prescribe buprenorphine. The buprenorphine waiver requirement or “x-waiver” has unnecessarily restricted buprenorphine access. Only 5% of medical providers are licensed to prescribe buprenorphine²⁴ and the training and associated regulatory barriers to receive the “x-waiver” are onerous and serve as critical barriers to care.

The “x-waiver” requirement also reinforces stigma that treating patients with substance use disorders is different from delivering other types of medical care. It reinforces false beliefs that prescribing buprenorphine is more clinically challenging or riskier than other forms of medical treatment, such as starting patients on insulin or even prescribing opioids for pain, both things that require more nuanced management than managing buprenorphine. The regulatory barriers, such as DEA audits, imposed by the “x-waiver,” intimidate physicians and can cause waived providers to stop prescribing.²⁵ The time requirements and costs of the waiver training are particularly onerous for front-line primary care providers who have limited time and resources to complete the training despite being the group most likely to see and treat patients with addiction. Many states inhibit the ability of nurse practitioners and physician assistants to treat patients with buprenorphine even if they have completed “x-waiver” training unless they also work with a collaborating physician who also has an “x-waiver.” Removing the “x-waiver” is low-hanging fruit that has the potential to drastically increase

access to buprenorphine for many more patients. There are multiple models from other countries showing buprenorphine can be more liberally prescribed without adverse public health outcomes. In France, for example, they deregulated buprenorphine and the rate of opioid overdose decreased by approximately 80%.²⁶

I also recognize that physicians, in general, do not receive sufficient education on how to recognize and treat substance use disorders. We need to require training in addiction medicine to be integrated into medical education and residency training for all providers. As health professional schools work to implement this, including education on addiction as part of DEA licensing requirements would enable all providers with a DEA license to know how to treat recognize and treat patients with opioid use disorders.

In addition, as we think about increasing the capacity of our workforce, we should also think about the importance of building a more diverse workforce capable of treating our diverse communities. America has a shortage of physicians of color in general, and addiction medicine trainees are no different. Among fellowship trainees in ACGME-certified Addiction Medicine fellowships, only 5.1% are Black and 11.4% are Latinx.²⁷ We need to support the recruitment of a diverse addiction medicine physician workforce to better care for our diverse communities and incentivize Addiction Medicine subspecialty training and practice through targeted loan repayment programs.

Need better integration and support for harm reduction services

Harm reduction is a set of practical strategies focused on reducing negative consequences of health behaviors, such as drug use.²⁸ Not every patient I see is ready for abstinence or to quit using substances. Abstinence-only approaches to substance use treatment can further stigmatize and marginalize patients who are not yet ready to stop using substances from care. They can serve as a deterrent for patients who may be open to reducing their use or using in less risky ways. Not only are harm reduction services effective at reducing harms from drug use, like preventing transmission of HIV and hepatitis C or reducing fatal overdose, but by engaging patients who may be ambivalent over time they can also serve as access points for individuals to link to medical care and addiction treatment.²⁹

In the setting of exponential increases in overdose deaths, we must look to the science to think creatively about how best to keep patients who use drugs safe, including those who do not yet want to quit. For example, a byproduct of the transition to synthetic opioids like fentanyl, with a faster onset and shorter duration, are potentially more frequent injections leading to an increased risk for infectious complications.³⁰ This is demonstrated by the secondary epidemic of hospitalizations for infectious complications from injection drug use, like infective endocarditis.³¹ We need to more aggressively distribute sterile injection supplies and fentanyl testing strips to patients who use drugs across the country and educate them on how to use them. There has been growing evidence supporting the use of novel interventions, such as supervised consumption sites, which have been shown in other countries to reduce mortality, decrease ambulance calls, and decrease HIV infections without significant harms.³² We need

research to thoughtfully implement and study the impact of interventions like these in the United States.

In summary, I appreciate your time and the ability to share my clinical experiences and an overview of the science. If I may leave you with these four thoughts:

1. **Racial and ethnic disparities exist in the treatment of substance use disorders, particularly opioid disorders.** We need research and public programming focused on the delivery of equitable addiction care that addresses the systemic inequities, social inequalities, and structural racism that drive differential access and disparate treatment outcomes.
2. **We need to use data to identify those at high-risk for substance-use related harms and need research and public programming** that targets these groups: for example, reducing regulatory barriers that prevent the recently incarcerated from linking to substance use disorder treatment upon release or coverage gaps preventing the use of effective treatments, such as contingency management, for those with stimulant use disorders.
3. **We have a large treatment gap with an insufficient number of providers trained to treat all those with addiction.** We need to remove onerous barriers, such as the x-waiver, that reinforce stigma and make it harder for all providers to treat patients with addiction. We also need to better integrate training in addiction medicine into health professional education and as part of DEA licensing requirements.
4. **We need better integration and support for harm reduction services** as these are essential, evidence-based programs that reduce mortality and morbidity associated with substance use.

Thank you for the honor and privilege of sharing these thoughts with you today and for your consideration of these recommendations.

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Ms. ESHOO. Thank you very much, Doctor. The Chair recognizes herself for 5 minutes of questioning.

I would just note that, amongst you, the five witnesses, there seems to be a really sharp diversion on the issue of the expiration date and how that should be handled. So I am not going to go into it, but know that it is clearly noted that there are just really sharp differences.

We have two lawyers, two doctors, a researcher. This is really a very fine panel.

In listening to you, I cannot help but think of FEMA coming into New York and other communities, setting up beds, treatment being made available to those that were tested positive for COVID. Now, I don't want to underestimate what treatment for opioid addiction is, but it seems to me that we need to ramp up on the urgency of this.

I mean, to hear the doctor talk about the young person and showing him a body bag and saying that if he didn't do such-and-such a thing that he would end up being zipped into it, and he was. So would each one of you want to comment on this?

Don't we need more beds, more treatment, that we need to ratchet this up so that it matches the urgency that we all know this is?

I just don't think that when we say that it is urgent, that we have to stem the tide of the deaths—I think that we need strike teams. I think people in every community and every State around the country have to see that we are taking this seriously and that we are going to do something about it.

I mean, the number—over 540,000 deaths due to COVID in this last year, 88,000 just for opioid. I mean, what, are we going to be satisfied with these numbers?

So I invite any one of you to tell me that I am off track, that we need more treatment, we need more beds, we need help for people. I think our system is really fragmented.

So I have used my time to really dump my thinking and my frustration and my emotions on you. But you are the experts, so I want to hear what you think. You can say yes or no to more beds, more treatment, more people trained, more money in the effort, if that is what it takes.

But we need to—I think that we have the capacity in this great country to go to near elimination of this.

And when the district attorneys describe what they are left with, because we are not doing everything that we need to do—these people are sick. They don't belong in the criminal justice system. Then we have to find money to pay for the people that are in jail, and in prisons before they leave. I mean, what are we doing?

So who would like to start?

Dr. Wilson, would you like to take it?

Dr. WESTLAKE. Sure, I think—

Dr. WILSON. Yes—

Dr. WESTLAKE. Oh, sorry.

Ms. ESHOO. Dr. Wilson?

Dr. WILSON. Yes. Thank you so much, Chairwoman Eshoo. I think that is a critical point. We absolutely need additional treatment. We need more access to evidence-based therapies, and we

need to make sure that we have equitable access to evidence-based—

Ms. ESHOO. Are therapies not the right ones? I mean, have we not settled on what works?

Dr. WILSON. We have wonderful evidence that medications to treat opioid use disorder, like buprenorphine and methadone, are highly effective at keeping people alive. So I think the evidence and science is clear to show that that is the case.

The problem is we are not getting the medical therapies to the patients and communities that need them. And so that is the huge treatment gap that we need urgent attention and action to address. And that means—

Ms. ESHOO. So like trying to get the vaccines, enough allotments, into the States and into the arms of people.

Another one of the doctors want to comment? My time is just about gone, because I talk too much.

Yes?

Dr. WESTLAKE. Yes, Chairwoman, I think you are spot on with that.

In the emergency department I would estimate between 10 and 30 percent of the patients that I see, there is something to do relating to substance use disorder. Usually it is untreated. And so this is—I think we are going to look back 30 years from now and say, you know, I can't believe that we were doing—

Ms. ESHOO. You can't—you don't have the ability to refer them anywhere?

Dr. WESTLAKE. Well, it depends on where you are at. So I am in a resource-rich community, and so I can. But so much of the State, especially the rural parts—and that is where the telehealth expansion is really helpful. But there is so much that can be done, I think, moving forward.

Ms. ESHOO. Well, I thank each one of you. My time has expired, and I think you clearly know where I am.

So now I would like to recognize, really, a wonderful, important member of our subcommittee, the ranking member, Mr. Guthrie, for his 5 minutes of questions.

Mr. GUTHRIE. Thanks, Madam Chair. And I want to say I think when—somebody said it, they understand the politics and optics, and I certainly don't say there is not politics and optics in Washington, DC, but I will tell you all of us are trying to figure this out, to get it right, because it is people's lives that we are dealing with.

And one that really springs to me, I was touring a lot of opioid recovery centers when we were working on the SUPPORT and the CARES Act, and one guy—Kentucky has a law that you can get—if you are a minor user or so forth—expunged, but you can't get expunged if you sell. And that makes sense, when you think about it. But I met an individual who said about everybody who is addicted had some selling in their background, because "I would buy 30 pills and sell three so I could afford the 30." But it was—"I was selling to support my habit." And so—but if you read the book "Dreamland," there are completely pure criminal enterprises that prey on people like him.

And so I don't think it is all one or the other. I think we have to figure out how we punish those who are truly criminal and those

who are being—who are committing crimes—committing to support their habit, if you—and I said in my opening statement—if you can help them with their addiction, then you help them with—then the crime goes away with that.

And so—but I am concerned about the truly criminal enterprises that we have to deal with. And Dr. Westlake, in your testimony you did say that the goal of the fentanyl class scheduling is not to—not locking up low-level drug users but to stop the development of deadly fentanyl poisons at their origin, namely in drug labs overseas. That is the quote. And could you explain—expand on this point, and further describe how the scheduling order is meant to prevent large-scale importation and distribution and not target individuals with substance use disorder?

Mr. Vargo, after, if you would comment on how you use this, as well, to focus on the—more the large-scale criminal than the low-level user.

So, Dr. Westlake?

Dr. WESTLAKE. Sure, thank you. Thank you. The—I think that the main point of the whole Act was to—or the whole set of languages—is to stop the creation of these substances, so that—these substances have been very well—there is very well-researched structure activity, pathways that go back 60 years. And so it is simply—it is as simple as plugging in a different chemical in a formula structure, like a cookbook.

And so what that—and those are very well laid out. And if you look at my testimony, my written testimony, I go through this in detail. I don't think I have the time to do that now.

But the goal was to make those so that those would be illegal, so that the—and they wouldn't be created because, again, it was this Whac-a-mole game, where they are going around what is legal and waiting for the Analogue Act, or waiting for the CSA to catch up with it, which would be a year or so, or maybe a couple thousand deaths.

So this—what this does, was this stops the—and it disincentivizes them from doing that. I mean, granted, they may have switched over to producing illicit fentanyl, you know, but what it has done is it shut down the new fentanyl-related substance creation machine, the mine of new fentanyl-related substances, by—again, by eliminating the incentives for that to happen.

Mr. GUTHRIE. Mr. Vargo, instead of answering that, can I just focus on a specific part of that?

So—and it was said earlier in testimony that if the descheduling goes away, that they still remain illegal. But you have to use the Federal Analogue Act for them if they are not scheduled. And so could you talk about how that could be inconsistent jury findings?

You have to present to a jury for—that they fall under the Federal Analogue Act, and not—that they are not illegal by law, they are illegal if you can prove they are illegal to a jury. Could you talk about that process and why it would hamper your prosecutions of major criminals?

Mr. VARGO. Certainly, Representative Guthrie, and I will tell you that, obviously, I as a State prosecutor don't do a great deal of that

now. I was, for 15 years, a prosecutor in the Federal system, so I have some familiarity.

I will tell you that it does appear that the—both the goal and the effect of the classwide scheduling have been effective. If we look at the—what was happening before, we have kind of a before-and-after control group, if you will. And, as Dr. Westlake pointed out in his written testimony, the number of analogues that we are seeing at the border fell significantly after the passage of that legislation. In other words, the legislation worked in changing the game of Whac-a-mole that we were playing with the Chinese laboratories that were creating new versions of fentanyl analogues.

The—as far as prosecution goes, I think it is illustrative that the article by the Sentencing Guideline Commission recently identified only two cases since the passage of that legislation that were actually scheduled—or sentenced under the fentanyl analogue classwide scheduling. So it has not led to a large-scale incarceration or even large-scale prosecution, but it has been effective in reducing the number of new analogues that we see.

The difficulty becomes, if we went under the Analogue Act, you have to prove individually that it is an analogue, and then you have to prove the person who was distributing it or possessed it knew that it was a controlled substance or had a controlled nature. Both of those would be very difficult under the Analogue Act with every new substance.

Mr. GUTHRIE. Thank you. I would—I will yield back my time.

Thank you for those answers, I appreciate it.

Ms. ESHOO. The gentleman yields back. The Chair recognizes the gentlewoman from California, Ms. Matsui, for your 5 minutes of questions.

Ms. MATSUI. Thank you again, Madam Chair, and I do thank the witnesses for their testimony today, and I think you feel and see the frustration in our voices because all of us are troubled by the rise in overdose deaths, especially over the past year. And despite the enormity of the COVID-19 pandemic, which is, you know—and the overdose deaths and the substance uses have been exacerbated. So we can't lose focus on addiction crisis in this country.

Now, over the past several years we have worked in a bipartisan way to support targeted efforts that have finally begun to reverse some of the overdose trends. But the pandemic has robbed us of that progress. So in a way we are talking today about what are we going to do moving forward.

The bills presented today represent an opportunity to take a much-needed, broader and bolder approach to address the cross-cutting facets of the addiction epidemic.

You know, the task to combat the crisis continues to evolve. We know that. And as our witnesses have stated, we are now seeing fentanyl increasingly mixed into drugs like cocaine or meth, and that is presenting unique challenges to those on the front lines. And in some parts of States, including California, stimulants are the primary drugs of choice.

Mr. Vargo, you brought attention to the issue of meth. Can you talk more about how Americans who use meth may differ from those who use opioids?

Mr. VARGO. Thank you, Representative Matsui, I would be glad to.

Methamphetamine is one of our most challenging substances because every drug that is illegal, every substance that is illegal, creates a criminogenic factor because you are dealing with it illegally. In the old words of Glenn Frey, you always carry weapons because you always carry cash. So we know that we create problems any time something is illegal.

Methamphetamine, though, is, if not unique amongst drugs of abuse, certainly the most prominent [inaudible] drugs of abuse. It carries with it biological factors that render those people more dangerous: the hypervigilance, the paranoia, hallucinations, the aggression that comes with it. Even if meth were 100 percent legal at every level, it would create criminality because it creates violence. It is very much like PCP was back in the 1980s. I am that old that I remember that.

So methamphetamine presents a particularly difficult circumstance and, more importantly, presents a very difficult treatment because it is one of the most difficult drugs to treat. Until recently we didn't believe there was medically assisted treatment available. There is some hope in that regard, but it is a very difficult drug, both in its use and in its treatment.

Ms. MATSUI. OK. Dr. Wilson, you also discussed in your testimony the growing number of patients that use stimulants either as a primary drug or mixed in with other opioids. How does this impact how you care for patients?

And how are treatment recovery services for these patients different from those who—primary for opioid disorders?

Dr. WILSON. Thank you so much for that question. You know, I think it is really important to recognize that, while we have really effective medications to help patients with opiate use disorder, we do not have effective medical therapies to support patients who have stimulant use disorder like methamphetamines or cocaine. There are some medications that have very modest effects, but the primary treatments that have been shown to be effective for patients with stimulant use like methamphetamines have been behavioral health treatments.

The sort of greatest evidence base supports things like contingency management, where you reinforce patients who are having negative urines and remaining abstinent, for example. But it is really hard to operationalize those kind of therapies within sort of traditional kind of outpatient treatment programs. And so getting access to sort of efficacious behavioral therapies for patients with stimulant use disorders is more challenging.

Many of the patients that I see who use stimulants are also using other substances. And so I think it becomes really sort of challenging to figure out sort of how can you link and engage patients in care and get them access to a full complement of results. So—

Ms. MATSUI. It seems to me that we don't have as many effective treatments for patients that use stimulants.

Dr. WILSON. That is absolutely true.

Ms. MATSUI. Right, and so we need to have more research in order to find some way to deal with this, because meth has been

around forever, in essence. And I know, in California, people don't hear about it as much as they hear about opioids, and yet meth is still growing, in essence.

So I see I am running out of town. Thank you for—time. Thank you very much, and I yield back.

Ms. ESHOO. The gentlewoman yields back. It is a pleasure to recognize the ranking member of the full committee, Mrs. Cathy McMorris Rodgers.

Mrs. RODGERS. Thank you, Madam Chair. I want to just thank you again for holding this important hearing today. I know it has been a long one, but it is really important. And a big thank you to all the witnesses for joining us today, sharing your perspective, your stories.

To Dr. Westlake, just thank you for sharing your own heart-breaking story. It, unfortunately, is repeated too often right now in America. And my heart just breaks for you. I wanted to start with a question to you, Dr. Westlake, as well as Mr. Vargo.

GAO's recent analysis found that a number of reports of unscheduled fentanyl analogues decreased by 90 percent after DEA issued the classwide scheduling order. So they found that after DEA issued this classwide scheduling order, the fentanyl analogues decreased, the number of reports of it decreased, by 90 percent. So specifically, in 2016 and 2017 there were over 7,000 law enforcement reports, 7,058 law enforcement reports of encounters with these substances. So that was 2016, 2017. You look at 2018, 2019, the encounters were down to 787, so over—yes, 7,000 to 787.

Why did classwide scheduling so significantly reduce the encounters?

And I will start with Dr. Westlake, and then Mr. Vargo.

Dr. WESTLAKE. Sure. Thank you for the question, Congresswoman.

I have a—there is a phrase that I want to drive home, if there is, like, one point that I want to get brought out of this hearing. It is that you can't die from something that has never been created, and you can't be incarcerated for selling something that doesn't exist.

And so that is what has happened, is, you know, in conjunction with our scheduling language—the Chinese actually knew about the language coming up. We have been, you know, partnering closely with them, trying to get them to control the fentanyls, and eventually that happened. And so that just stopped. So it is not just that there is no new fentanyl-related substances that are being seen, or very few.

The NFLIS, the National Forensic Lab Information System, shows that there is almost no deaths that are occurring from new fentanyl-related substances. So you are still seeing deaths from the older fentanyl-related substances that are now fentanyl analogues, but you are not seeing deaths from the new ones. And so that was the goal of this. The whole—this is not a law enforcement bill. The vehicle is a law enforcement vehicle for scheduling, but the bill is ultimately opioid, you know, harm reduction, and opioid reduction of overdoses, overdose prevention.

Mrs. RODGERS. Thank you.

Mr. Vargo?

Mr. VARGO. Thank you, Madam Chair. I will tell you that it is hardly surprising that criminal enterprises go where the money is, and where the criminality is least likely to be punished. I think that the response that we have seen from these organizations—I wish I could tell you that I don't think they are dealing drugs anymore. I doubt that is the case. But it means that they haven't tried to go into the area of new fentanyl analogues, because that is no longer profitable and it is more likely to be punished.

So I think that that, again, kind of speaks to the question of whether or not the original Analogue Act itself was sufficient. It was not. And it is the reason that I believe that an extension, at least until we get some other format in place, is absolutely essential.

Mrs. RODGERS. Thank you. Thank you. I appreciate that.

Mr. Vargo, in your testimony you mentioned the work with the Sioux Tribe, and the importance of cultural competency. I represent several Tribes in eastern Washington. I wanted to ask if you would just speak about what you are doing to meet the needs of the Tribal communities who have consistently experienced larger increases in drug overdose mortality. I know that the Colville Confederated Tribe in my district is building a new treatment facility, and just—would you speak briefly as to what role Congress can play in aiding these efforts?

Mr. VARGO. Yes, absolutely. Thank you, Representative.

The Oglala Sioux Tribe is the closest Tribe to us, but we also have the Cheyenne River Sioux Tribe and the Rosebud Sioux Tribe that are very much part of our geographic area. They face extreme poverty, 90 percent unemployment, and they have been hit hardest by methamphetamine probably of any group, certainly in South Dakota, possibly in the Nation. And they are fighting, literally, for their lives in a lot of instances.

I think that Congress's role here can be to enhance and support what they are trying to do, both on the reservations and off.

Native Women's Health Care is an organization that provides healthcare to, primarily, pregnant women. We are partnering with them as diversion partners. So we send pregnant women with criminal offenses to them. If they successfully complete their medical program, we dismiss the criminal cases.

We have also not only partnered with but invested in an organization that involves a Tribe called Native Healing. That is a residential drug treatment facility. Unfortunately, because of COVID, they are not going to be open until June of this year. They were supposed to be open April of last year. But it is 25 beds. To give you a frame of reference, though, we had over 1,200 arrests last year for methamphetamine, so 25 beds is a great beginning, I believe it gives people hope, but it is hardly enough. And I think Congress needs to take a close look at those communities to whom the United States has a very particular and special relationship.

Mrs. RODGERS. Thank you. Thank you very much. My time has expired. I yield back, thank you.

Ms. ESHOO. The gentlewoman yields back. The Chair now recognizes the gentleman from California, Mr. Cárdenas, for your 5 minutes of questions, and thank you.

Mr. CÁRDENAS. Thank you very much, Madam Chairwoman and Ranking Member, for us having this incredibly important hearing that affects every single person in America. And I would hope and pray that we can be an example for the world of how to handle drug addiction and how to make sure that we curtail this method in the United States that—we have been trying to incarcerate our way out of this, which never works. It has never worked anywhere on the planet, and it is something that we can do better here in the United States.

And I do appreciate the testimony of every single person on this panel. And it appears that you all are, in some fashion, in agreement that we need to look at this as treating addiction rather than incarcerating our way out of this. So thank you so much for all of that.

And I want to thank all of my colleagues for all the legislation that you have done in the many various positions that we have all been in. For example, when I was in the State legislature we passed the Schiff-Cárdenas Act, which is the Juvenile Justice Crime Prevention Act, which provided \$120 million per year to local communities to fund prevention and intervention programs.

Also, today in Congress, my colleague Representative Griffith and I led the At-Risk Youth Medicaid Protection Act, which was signed into law in the SUPPORT Act. This bill allowed a young person who is otherwise eligible for Medicaid to continue their healthcare coverage immediately following release from the juvenile justice system.

And also we are considering many great bills today. One bill I am incredibly supportive of is my colleague Representative Tonko's Medicaid Reentry Act. This bill would extend Medicaid eligibility to incarcerated individuals 30 days prior to their release. Passing this bill is critical to improve access to substance use disorder treatment. Ninety-five percent of adults who are incarcerated in America will transition back into our communities, and data shows that individuals released from incarceration are 129 times more likely—that is 129 more likely—to die of a drug overdose during their first 2 weeks after release.

Dr. Wilson and Ms. Richman, can you each please share your thoughts on this bill, as well as the role Medicaid and access to healthcare plays in addressing substance use and misuse in America?

Ms. RICHMAN. Thank you so much for that question. I am happy to answer it, and I am very grateful for the work that is being done and proposed in both of those bills.

As a Federal public defender, many of my clients who had grown up in Baltimore did not receive the opportunity for either mental health or substance use, or sometimes even just core healthcare, until they entered the incarceration system, whether it be when they were a juvenile or when they were an adult. And what I saw in a lot of those clients' lives was a cycling in and out and a discontinuity in their treatment because of their movements in and out of incarceration and because of the lack of resources in the community. So I am very glad to see work in this crucial area.

Mr. CÁRDENAS. Thank you.

Dr. WILSON. Thank you. I think this is a critical point, and an important piece of legislation.

So we know that access to substance use treatment within the correctional system is a critical public health and ethical issue. And research shows that, if we start medications like methadone or buprenorphine for the treatment of opiate use disorder while individuals are incarcerated, that improves the likelihood that they will enter treatment and it reduces their risk for dying post-release. And so reinstating Medicaid coverage before reentry to the community is an important and essential way to keep people alive and facilitate their entry into evidence-based treatment.

Mr. CÁRDENAS. Thank you, yes, evidence-based treatment is something that, unfortunately, in my opinion is a little too new in the United States. We were stuck on just tough on crime for far, far too long. And unfortunately, this has affected almost every family. We have actually had Members of Congress admit to the fact that some of their family members have been subjected to addictions, et cetera, and everybody wants to see their loved ones treated with respect and dignity, not be treated like criminals because they have fallen prey to being addicted to some kind of substance. So I really appreciate the opportunity for us to bring this to light.

And also, I would like to point out that this issue of addiction has been going on for hundreds and hundreds of years across the planet, and certainly has been going on since the founding of our country. So, hopefully, during this Congress we can actually make substantive changes and have the kind of programs funded so that we can treat everybody with dignity and respect.

So my time has expired, and I yield back. Thank you.

Ms. ESHOO. The gentleman's time—the gentleman yields back. I now would like to recognize the gentleman from Virginia, Mr. Griffith, for your 5 minutes.

You need to—

Mr. GRIFFITH. Thank you, Madam Chair. Yes, ma'am.

Thank you, Madam Chair. My mask fell down there, so you all can hear me.

Mr. Vargo, as we have discussed, last year Congress extended the order temporarily classifying fentanyl analogues as schedule I substances. If Congress does not further extend that order, what will be the status of fentanyl analogues come May 7, 2021?

[Pause.]

Mr. GRIFFITH. Mr. Vargo, can you hear me?

Mr. VARGO. I knew I was going to do it at some point. Sorry to do it on your time.

Mr. GRIFFITH. That is all right.

Mr. VARGO. Thank you for the question, Representative. Those analogues are at least arguably legal. And certainly, if Ms. Richman were defending one of those defendants, she would say that those analogues had not been scheduled and were not illegal or that her client did not know that those analogues were illegal and therefore cannot be prosecuted.

And so it is certainly something that is possible to argue, that under the old Analogue Act we can try to stop that importation and we can try to bring criminal prosecution, but it would be much less likely to be successful.

And I believe that just the before-and-after has shown us that it emboldens folks when they are not specifically scheduled.

Mr. GRIFFITH. Well, and I appreciate that. And I can assure you, having been a criminal defense attorney myself for a big part of my career, that is exactly what Ms. Richman would argue, and properly so. She has got a duty to defend her clients. Our job is to make sure the law doesn't create loopholes that folks who are trying to do bad things can drive a Mack truck through—which, by the way, are made in my district, some of them.

Mr. Laredo, some folks have said keeping fentanyl analogues in schedule I inhibits scientific research. Yet DEA has approved nearly 800 applications to research schedule I-controlled substances, and half of those have been approved in just the last 5 years. Do you believe valuable research could continue if analogues remained in schedule I?

Mr. LAREDO. Thank you so much for the question. I do believe that research can continue. There would be much, much less of it if you folks don't provide some exemptions for researchers on the research field so that they can really do that work.

There, you know——

Mr. GRIFFITH. So——

Mr. LAREDO [continuing]. For the time that I was at NIDA, it was almost a daily occurrence that I would get a phone call from a researcher in the field complaining about something about that.

And even now, I would strongly recommend you reach out to the National Institute on Drug Abuse and the College on Problems of Drug Dependence, who have been compiling more information about this. I personally believe they should be compiling even more. But there are some documents that I think that they have now that should be shareable with the committee that would help you as you talk about this.

Mr. GRIFFITH. Well, and so, from listening to your comments, do you believe that my bill—and I think you do—but do you believe my bill, the Streamlining Research on Controlled Substances Act, would improve the landscape for conducting this research?

Mr. LAREDO. I thought you might be going in that direction.

Mr. GRIFFITH. Yes.

Mr. LAREDO. I do. I would like to study the bill just one more time to look at all the details, but overall I very much appreciate your approach.

Mr. GRIFFITH. Well, and as I have said before, I am a big believer in trying to do research. And sometimes we find—out of odd and strange things you find a cure or a treatment for something that you weren't even necessarily looking for. So I want to make sure we——

Mr. LAREDO. Exactly.

Mr. GRIFFITH [continuing]. The American medical science community, because they do amazing things, as we have seen this year with the coronavirus. And I want to make sure they have all the tools available. I want it to be done legally. I want it to be done in a way that—we are looking for a way to use these substances, if possible, for medicine. And I think that the bill does that.

However, that being said, if you or any of your colleagues has a way that we might improve the bill, I am always happy to take a look at that as well.

Mr. LAREDO. Thank you. I would be glad to look at that again.

Mr. GRIFFITH. Thank you. And I invite anybody who wants to sponsor it, it is H.R. 2405. If they have concerns in this area like I do, please jump on the bill and cosponsor it on both sides of the aisle.

And Director LaBelle said in her testimony, Mr. Vargo, that early data suggests a steep rise in overdose deaths during the pandemic. When do you expect that we will have a full picture on how the pandemic has affected illicit drug use?

Mr. VARGO. Boy, that depends on when the pandemic ends, doesn't it, Representative?

Part of that is going to be we have to basically get back to some kind of normal. We have to readjust for the fact that we probably spent a year to maybe 2 years not doing the things that we wanted to do. And then we have to guess what things might have been.

I would say that your effect of the pandemic is going to be at least as long as the pandemic. So after it is over, it is going to take at least as long as that to determine what it meant.

Mr. GRIFFITH. All right. And then you don't think now is the time that we should be lightening up on the analogues, do you?

Mr. VARGO. Absolutely not.

Mr. GRIFFITH. I thank you very much.

And Madam Chair, I yield back.

Ms. ESHOO. The gentleman yields back.

Before I recognize Ms. Kuster, Ms. Richman, your name has come up several times. Do you want to just take 1 minute to—for any kind of response? I think that it would only be fair to do that, but for a limited amount of time, though. You have, like, a minute, a minute and a half at the most.

Ms. RICHMAN. I thank you for the opportunity. A couple points I would like to respond to. I think it is tempting to draw simple causal connections, but the fact is that the GAO report could not analyze a connection between classwide scheduling and the decrease in novel substances because of multiple confounding factors.

With respect to the Analogue Act, I do understand there have been many complaints about it. But the Department only relied on it five times between 2015 and 2019 to prosecute fentanyl analogues. In all other cases they have been able to make good use of individually scheduled substances, which still comprised most substances that are charged.

In addition, most of these cases are polydrug cases, the overwhelming majority, meaning that the presence of the fentanyl analogue doesn't make the difference about whether something is interdicted or not. It acts, in essence, as a sentencing enhancement that triggers mandatory minimums for any trace of a fentanyl analogue in a substance weighing 10 paperclips. It is 5 years. And so that is the source of many of our concerns.

Thank you for the opportunity.

Ms. ESHOO. Thank you. The Chair now recognizes the gentleman from New Hampshire, Ms. Kuster.

You need to unmute, Annie. I have got to hear you.

VOICE. I am sorry, it is Dr. Ruiz.

Ms. ESHOO. Oh, you know what? I made a mistake, Annie. The next one up is a fellow Californian, Dr. Ruiz.

You are recognized for 5 minutes.

Mr. RUIZ. Thank you.

Ms. ESHOO. I am sorry.

Mr. RUIZ. Thank you. No worries. Thank you to all the witnesses for taking the time to be here today. We have heard in today's testimony about the increasing rates of substance use and overdoses in the United States over the last year.

However, disparities in prevention, treatment, and recovery strategies continue to plague communities of color. A 2020 issue brief by the Substance Abuse and Mental Health Service Administration lists a number of barriers to care for Hispanic individuals, including a lack of culturally responsive prevention and treatment, less access to medically assisted therapy such as buprenorphine and Naltrexone than White individuals, and a higher likelihood of relying on detox alone.

A stigma and misperception within the Hispanic community, with only 5 percent of Hispanics with a substance use disorder thinking they need treatment, is also an issue. And one of the most commonly cited issues regarding prevention, treatment, and recovery strategies in the opioid crisis: language barriers for substance use disorders, materials, and treatments, and culturally relevant treatment from providers who understand the communities. In other words, diversifying the workforce, the provider workforce.

So it is clear that we need to examine the policies that we consider through a health equity lens and make sure that they address prevention and treatment services in high-risk communities.

Dr. Wilson, can you speak more about barriers to prevention and treatment services that drive inequalities in outcomes for minority communities?

And in your experience, what are the most common barriers?

Dr. WILSON. Thank you so much. I think we know that stigma related to addiction, to opioid use disorder and other substance use disorders exist, and stigma related to that, as well as racial bias, really intersect to create overlapping and compounding systems of disadvantage. So this contributes to lower quality of care and worse treatment outcomes for racial and ethnic minorities.

We have another—a number of physicians who often, due to racial bias or structural racism, have inequitable prescribing practices and treatment. So we see that, for example, when we look at well-known disparities in pain management, for example, with lower rates of opioid prescribing or increased oversight for Black patients, and we see similar things when we look at disparities in the prescription of medications to treat opiate use disorder, with much lower rates being prescribed to patients with opiate use disorder in communities of color.

And so, you know, I think, when we think of barriers, it is essential that we train our workforce, and we train our workforce to provide care to communities of color, and we also increase the number of providers of color treating those communities.

Mr. RUIZ. So, Dr. Wilson, I practice medicine, emergency medicine, and I do a lot of public health work in underserved, medically

undeserved areas. And would you say that the driving force of the decrease in access to prevention and treatment is more the systemic barriers that exist, the lack of providers, the lack of clinics, the lack of language, the lack of knowledge to empower, the lack of services focused in these underserved areas, versus the stigma portion?

Dr. WILSON. I mean, I think all of those things come together, right? I think that patients in these communities, families within these communities, are desperate for help. I think historically our solutions for those communities have been mass incarceration and failed policies.

And so I think what we really need to do is invest in widespread treatment, and I think that means partnering with community organizations where patients have had positive experiences, increasing culturally competent care, and increasing a workforce that is able to provide competent and equitable services to those communities.

Mr. RUIZ. You know, one of the risk factors that have been cited in the social studies literature is the lack of social capital within communities, or the lack of communities that are—so do you think the promotora community health worker models by individuals in the communities—

Dr. WILSON. Yes.

Mr. RUIZ [continuing]. To keep people together should be expounded on in our country?

Dr. WILSON. Absolutely. I think—I learned a lot of what I learned from addiction from amazing peer recovery specialists with lived experience in addiction. And I think that there is nothing that you can do to sort of help prescribe hope to patients other than showing them somebody who has lived through addiction and has come out on the other side. And so I think supporting and investing in those models is essential to increase that sort of treatment access in communities of color.

Mr. RUIZ. Great. So with your 15 seconds remaining, what other recommendations do you have that Congress can do to help relieve these disparities?

Dr. WILSON. I think one essential thing is to support training in addiction medicine and to support sort of building a more diverse addiction medicine workforce. And so that means sort of supporting physicians of color and building and supporting the pipeline and incentivizing physicians of color to go into addiction medicine.

Mr. RUIZ. Thank you. I agree. I yield back my time.

Ms. ESHOO. The gentleman yields back, and it is a pleasure to recognize the gentleman, the very patient gentleman, from Ohio. He has been with us, I think, since we began at 10:30 this morning. I kept asking my staff, "What about Mr. Latta? What about Mr. Latta?" So here he is, and the gentleman has 5 minutes for his questions.

And it is great to see you, thank you.

Mr. LATTA. Well, let me thank the Chair, the gentlelady from California, for allowing me to waive on today, and I really appreciate it. And again, this is such an important subcommittee hearing that you are holding today, so I really appreciate it. And I also want to thank our witnesses for today.

But, you know, over a year ago the lives of every American changed due to the coronavirus. And every day we are getting closer to ending the COVID-19 pandemic and returning to normalcy. However, long before COVID-19 dominated the spotlight, we were dealing with another crisis in this country, and that epidemic is still ongoing, which is the opioid crisis that has been significantly heightened due to lockdowns and immense stress on those already struggling with addiction.

And before COVID-19 we were beginning to see some light at the end of the tunnel, you might say, that—we saw that the number of deaths were going down for the first time in decades. And however, you know, we already talked about today—is that we have seen in the last year, from August of 2020, that over 88,000 people died from drug overdoses in this country, which is the largest ever in a 12-month period.

So substance use disorder, SUD, and mental health have been overshadowed through the pandemic. And those suffering from SUD have shown that they are particularly susceptible for contracting COVID-19. So we must go back to work in defeating this deadly, ongoing crisis, and prepare to meet the needs in a post-pandemic world.

And I have introduced several bills that would help curb the opioid pandemic, increase telehealth services, and assist those struggling with mental health. One bill that will immediately assist in stopping the illegal distribution of drugs is H.R. 1910, which is the Fight Fentanyl Act that I introduced with my colleague from Ohio, Mr. Chabot.

In addition, my fellow Ohioan, Senator Rob Portman, and Senator Joe Manchin also introduced a Senate companion.

In February of 2018 the DEA issued a temporary scheduling order to schedule fentanyl-related substances to allow our law enforcement to crack down on criminals flooding our neighborhoods and communities with this deadly drug. However, the order is set to expire on May the 6th, 2021. And so the Fight Fentanyl Act will simply codify the DEA's precedent to approve a schedule fentanyl-related—currently scheduled fentanyl-related substances as a schedule I drug.

So, again, I want to thank our witnesses for being here today and, if I could, ask my first question to Dr. Westlake.

In your written testimony you discussed how the goal of fentanyl class scheduling isn't to lock up low-level drug users, but to stop the development of deadly fentanyl poisons at their origin. Do you believe that the permanent scheduling of fentanyl as a schedule I substance, as my bill the Fight Fentanyl Act accomplishes, would—will help lower overdose death rates and help stop the influx of the illicit fentanyl into our communities?

Dr. WESTLAKE. Thank you, Congressman Latta. Yes, absolutely. So I think, to be clear, it will definitely decrease the existence and availability of newly created fentanyl-related substances. That has already happened. There has been a 90 percent decrease coming over from China that—the fentanyl-related substances that are new are not being seen in overdose deaths. And so that is definitely a part of it.

So I think it is a huge piece, and I think that, you know, the language is very surgically targeted. If you look at my testimony, the written testimony, you can see that it is only very specific modifications to the molecule that have already been proven to have bioactive structure activity chemical relationships through the 60 years of research into the class. And so the language in your bill exactly, you know, is the perfect language to stop the creation of those likely bioactive substances.

So, yes, I think it is a necessary—and from an emergency medicine perspective, you know, I am glad that I don't have to resuscitate people that are dead from a fentanyl-related substance. Unfortunately, we are seeing other, you know, illicit fentanyls coming through, and that is a whole different—there is only so much you can do at a time, and that is one thing we can do.

Mr. LATTA. Great. Well, let me ask—you know, as I mentioned, we have seen the largest overdose in our history in the last year, with 88,000 deaths. You know, what do you believe is the best way to address the crisis as we move forward, you know, while also addressing the needs of those who are suffering out there?

Dr. WESTLAKE. Yes, I think it is a huge—the issue for me—so I looked at this, and I led the Prescription Opioid Reform Strategy in Wisconsin over the past 7 years, since we became aware of it.

And so it is a really, really difficult issue. I mean, addiction goes back probably forever in human history. I don't think there is any time that we are ever going to get rid of addiction. I think that is, you know, like, you can't get rid of cancer, you are not—you know, it is a disease. What we have to do is, you know, we try to destigmatize it.

I think the medication-assisted treatment part, and making it so that you can prescribe medication-assisted treatments—I am running out of—I think you are out of time—is really important and critical, because I can prescribe, as a physician, without any restrictions other than a DEA license, I can prescribe as much Oxycotin as I want, but I have to take 8 hours to prescribe buprenorphine. And that makes—that has put a stigma on the prescribing of buprenorphine. And so that is something that is concrete that you guys can do that would make a big effect, just like it did in France, as was mentioned previously.

Mr. LATTA. Well, thank you very much. Yes, I appreciate the witnesses today.

And Madam Chair, again, thank you very much for allowing me to waive on today. I appreciate it.

Ms. ESHOO. Well, you are always, always welcome, Mr. Latta. You enhance our subcommittee any time you are with us.

Mr. LATTA. Thank you.

Ms. ESHOO. We all feel that way about you.

The Chair is pleased to recognize the gentlewoman from New Hampshire—I think I am correct this time—Ms. Kuster, for your 5 minutes of questions.

Ms. KUSTER. Thank you so much, Madam Chairwoman. I apologize for my technical difficulties, but thanks to all the witnesses on the panel, and I appreciate your perspectives on the addiction epidemic in this country and your efforts to find solutions that will save lives and our communities.

This is the reason that 7 years ago I founded the bipartisan Congressional Opioid Task Force and why this Congress we have now expanded it to the Addiction and Mental Health Task Force, to include this complex crisis that needs comprehensive solutions.

It also is why I waited 6 years to join the Energy and Commerce Committee, and I am so delighted to be on the Health Subcommittee at this point. I want to commend you all for the incredible work that you do on substance use disorder and mental health, most recently working to include \$4 billion in support for substance abuse and mental health services administration as part of our incredible American Rescue Plan.

But that is not enough. We must do more to address the new realities of this epidemic defined by illicit synthetic opioids as well as ensure that our policies don't reinforce the mistakes of our past that disproportionately have impacted communities of color.

So my legislation with Congresswoman Lisa Blunt Rochester, known as the STOP Fentanyl Act, is comprehensive in its public health approach to addressing fentanyl. And I want to take the time with all of you today to discuss some of those provisions.

Ms. Richman, thank you for joining us. You stated the STOP Fentanyl Act takes a comprehensive health- and evidence-based response to fentanyl and fentanyl-related substances. Why do you think that this approach is necessary to addressing the addiction crisis in our country?

Ms. RICHMAN. Thank you so much for that question and the opportunity to comment on your legislation, Representative Kuster.

I appreciate this putting sort of the work into finding what are the evidence-based science solutions that we can turn to. If you dive into the history of—the legislative history between—behind the draconian War on Drugs laws that were put on the books in the 1980s and 1990s, you will see that they were passed with the intent to incarcerate manufacturers, kingpins, to keep things from ever being brought into our country.

And yet we are seeing substances that have been subject to harsh penalties for 30 years—methamphetamine is a case in point—proliferate new versions of it that are stronger. We are seeing new types of synthetic opioids, not fentanyl analogues, proliferate. U-47700 is beginning to see—beginning to be seen in more drugs.

The truth is that most individuals who are incarcerated for drugs in our country are low-level dealers, are individuals who are minimally involved. And in the case of fentanyl analogues, many of them have not made a conscious choice to include that substance in whatever they are consuming or selling. So it is just acting as a way of bringing these harsh penalties onto communities of color that have been disparately impacted for far too long.

Ms. KUSTER. Well, thank you. And one provision of our STOP Fentanyl Act includes Good Samaritan protections to ensure that there are no impediments or fears and judiciary repercussions to assisting during an overdose, or reporting an overdose. Can you explain why these types of reforms are necessary to save lives?

Ms. RICHMAN. Gosh, I think that these are so very important, and I think that the stigmatization and punitive approach to drug

use in our country really makes people afraid to reach out for help when people are in crisis.

In particular, there is a 20-year mandatory minimum in the Federal system for giving or selling drugs to somebody that results in death. And we have heard of circumstances where people are in a sober house together, one user shares with the other one, that person begins to overdose. Their response to that may be inhibited by their fear of exposure to criminal penalty, and that harms public health.

Ms. KUSTER. Great.

And Ms. Wilson, the STOP Fentanyl Act includes funding directed at community-based organizations that provide harm reduction services. Why are these services particularly critical for our fentanyl response policies?

Dr. WILSON. Thank you so much. You know, I take care of a lot of patients who are at various points of interest in sort of stopping the use of substances, and it is important for us to offer sort of treatment and services to everyone, regardless of where they are. You know, it is—the harm reduction axiom is “Meet people where they are, but don’t leave them there.” These services help keep people alive, keep them engaged and linked to care, so that when they are ready they are able to actually access and get plugged into treatment.

Ms. KUSTER. Great. Well, my time is up. Thank you, Madam Chair, for including our bill, the STOP Fentanyl Act. Thank you. I yield back.

Ms. ESHOO. The gentlewoman yields back. I want to—oh, we still have two Members, OK.

The Chair recognizes the gentleman from Florida, Mr. Bilirakis, for your 5 minutes of questions.

Mr. BILIRAKIS. Thank you, Madam Chair. I appreciate it. This question is for Dr. Westlake.

Higher-dosed pills from improperly mixed batches known as hot spots that led to overdose and death in a given area were often the way the medical community and law enforcement learned that fentanyl or an analogue had been introduced into a local drug market, which in turn would beget reactive scheduling in States or, as you put it in your testimony, a lethal game of Whac-a-mole. This led to work to remove the incentive that these international drug traffickers had in modifying the drug molecule by targeting likely bioactive fentanyls as a class.

Can you discuss how fentanyl class scheduling is critical not only for law enforcement but for patient and community health as well?

And should this scheduling ban expire, is it realistic to expect an increase or even sharp increase in overall deaths?

Dr. WESTLAKE. Yes. Thank you for the question, Congressman.

I think, you know, when you look back at what was happening with fentanyl-related substances before the scheduling language was in place in your State, in Florida alone, in 2016 to 2017 there were 2,500 deaths from two different fentanyl-related substances. We happen to have the similar deaths from similar substances in Wisconsin. So we scheduled them, we were the first State to schedule them. We are not seeing those any more. NFLIS is not reporting those, as I have said before.

So I think it will definitely decrease the deaths and availability of those particular fentanyl-related substances. I think there are a lot of other things that need to fall into place to start to eliminate deaths, you know, writ large.

I think also that, again, the important thing to remember about the scheduling is that it is surgically specific to only target the likely bioactive fentanyl molecules. It is not all potential fentanyl modifications. There is one fentanyl molecule, benzylfentanyl, a fentanyl analogue, that was found to be nonbioactive, and they did not include that in rescheduling for fentanyl-related substances. And so it—there has never been a nonbioactive fentanyl-related substance found.

Mr. BILIRAKIS. Thank you. This question is for Mr. Vargo.

While patients were not criminals, some career criminals do pose as patients or, in some cases, are even providers themselves, as recently observed in my district, unfortunately. As you alluded to throughout your testimony, prevention is worth a pound of cure, and treatment can be more successful than incarceration.

From your conversations with district attorneys across the Nation, what law enforcement gaps, if any, exist within the current prescription drug monitoring program to detect and track?

So again, yes, again, to detect and track patterns of abuse. Can you answer that question for me, please?

Mr. VARGO. Yes, certainly, Representative, thank you for the question.

Mr. BILIRAKIS. Of course.

Mr. VARGO. I would say that we have done a fairly good job over recent years of making sure that our data has improved, but there is very much still room to take another step.

Twenty years ago in South Dakota, if I wanted to prosecute somebody for doctor shopping, that was almost impossible. I would have to go to every doctor that they might have talked to, and we didn't have a central clearinghouse. And so our ability to say that you were doctor shopping and getting multiple prescriptions for the same reason was very, very limited. We took care of that clearinghouse now, and that has been very effective in making sure that people are only getting the prescriptions that they should, and that doctors have all the information that they need in making sure they are not double-prescribing.

But I would guarantee you that there are circumstances where diversion still takes place. And so the monitoring and the tracking that—I believe could still very much be improved.

Mr. BILIRAKIS. Thank you. Given the current opioid crisis in our Nation, the fact that all opioids are controlled substances, and our efforts to curb and eliminate doctor-shopping, would you consider it to be a best practice for States to require patients to show ID when retrieving an opioid prescriptions, similar to purchasing alcohol, Sudafed, or even retrieving an MLB ticket from Will Call?

What do you think about identification?

Mr. VARGO. I would say that we want to make sure that the person receiving the prescription is the person for whom the prescription was made. And by whatever means that occurs, whether it is because it happens at the doctor's office, where the doctor would have direct knowledge, or whether it occurs at a linked pharmacy—

again, where they would have direct knowledge, or whether there is an identification factor that guarantees it, that is very important.

Mr. BILIRAKIS. Thank you so much.

Madam Chair, my bill, H.R. 2355, the Opioid Prescription Verification Act, would encourage States to adopt systems that require pharmacists to check IDs to dispense opioids and require CDC to work collaboratively with other Federal agencies to provide guidance to pharmacists on ID verification while deferring to States on acceptable forms of identification, allowable immediate danger exemptions, of course, in addition to other State-specific needs that may need to be addressed. I encourage my colleagues to review this particular bill and consider joining my efforts by co-sponsoring the bill.

So I will yield back, Madam Chair. Thank you so very much.

Mr. BILIRAKIS. You are very welcome for the extra 23 seconds.

The Chair now recognizes the gentlewoman from Delaware, Ms. Blunt Rochester, for your 5 minutes of questions.

Ms. BLUNT ROCHESTER. Thank you, Madam Chair, and thank you to the witnesses for joining us for the second panel.

It is clear our Nation's ongoing overdose crisis isn't limited to one community, one region, one race, or one socioeconomic class. Previous congressional efforts to reduce the number of fatal drug overdoses have helped us make progress. But as our chairwoman has said, it is far from enough. States like Delaware continue to be in the middle of a public health crisis due to the rise in synthetic opioids like fentanyl.

We are anticipating a total of over 500 overdose deaths for 2020, an all-time high for my State. That is why Congresswoman Kuster and I introduced the Support, Treatment, and Overdose Prevention of Fentanyl Act, STOP, a comprehensive package of public health policies to address the proliferation of synthetic opioids without the mainly punitive measures used in previous approaches to drug control.

Dr. Wilson and Ms. Richman, how will a public health response to substance use disorder address some of the challenges you have seen throughout your careers? And we will start with Dr. Wilson.

Dr. WILSON. Yes, thank you. I mean, I think it—as a physician, it is absolutely clear that addiction is a disease, and this is a huge public health crisis.

We cannot schedule our way out of this epidemic, and we cannot incarcerate our way out of this epidemic. We absolutely need evidence-based and informed public health solutions. So expanding access to treatment, we need to get effective therapies to communities that need them. We need to partner with community organizations that are already embedded within communities to strengthen those communities and provide greater links from sort of our health care systems to sort of organizations already doing the work on the ground in local community settings.

We need to keep people alive, which means we need to expand access to harm reduction services to prevent morbidity and mortality associated with opiate use, recognizing that not everybody is going to be ready to quit today but they may be tomorrow, and we have to keep them alive so that they can reach that point.

Ms. BLUNT ROCHESTER. Thank you.

Ms. Richman?

Ms. RICHMAN. Yes, thank you, Representative Blunt Rochester, I appreciate the opportunity to comment.

I have also been very grateful for Mr. Vargo's response and remarks today about shifting the intervention point. And I think directing resources away from enforcement and towards public health gives the opportunity to bring those interventions earlier, and keep individuals from going down a path that will be very damaging.

When I look at the lives of my clients, I see so many different intervention points that there could have been: with their mother, before she overdosed; when they were a child, to be placed in a setting where they would be given holistic, educational, medical substance abuse services; all the way into the criminal justice system.

I will never forget working with my social workers and just spending hours on the phone for clients who came in suffering from substance use disorder to try to find them some sort of residential placement where they could go so that the court wouldn't send them to jail. A lot of my clients did not have a home to go to. They were struggling, and it would be incredibly difficult to find that place. And then you just cross your fingers and hope it worked.

Ms. BLUNT ROCHESTER. Well, I thank you for sharing all of that.

Included in our STOP Fentanyl Act is dedicated funding and support for overdose prevention and treatment programs, including grants for harm reduction providers and improving our understanding of evidence-based overdose interventions.

Dr. Wilson, I think you also may have talked about harm reduction and the benefits of it. Can you tell us what scientific evidence there is that shows that there is a benefit for harm reduction efforts?

Dr. WILSON. Absolutely, I think the evidence is really clear that programs, for example, that distribute naloxone are—there is a dose response, which is sort of one of the sort of strongest relationships in the medicine.

So the more you integrate overdose prevention within communities, the greater the naloxone you distribute within communities, the lower the risk of having fatal overdoses, and your mortality rate will actually decrease. So there is great evidence showing that needle and syringe exchange programs, for example, reduce hepatitis C, reduce HIV, and infections related to injection drug use.

And so, again, you know, I think we have to think broadly about this. Our goal is not just to reduce overdose, it is also to reduce sort of infectious complications, like infective endocarditis, associated with injection drug use. You know, we have to keep people alive so that we can get them access to treatment and harm reduction services. There is really a strong evidence base that these things are effective at doing that.

Ms. BLUNT ROCHESTER. Thank you. The STOP Fentanyl Act is the long-term solution that our Nation needs to respond to the overdose epidemic. And I look forward to working with the committee to advance this critical legislation.

Thank you, Madam Chairwoman, and I yield back.

Ms. ESHOO. The gentlewoman yields back. The Chair now recognizes the gentlewoman from Minnesota, Ms. Craig, for your 5 minutes of questions.

Ms. CRAIG. Well, thank you so much, Madam Chair, and thank you to the panelists here today, the witnesses, for your incredible expert opinion that helps guide our policymaking.

Mr. Vargo, you said something in your testimony that I would like to highlight. You wrote that, "Just as we cannot incarcerate our way out of an epidemic, neither can we ignore it and expect it to go away." I completely agree with you, Mr. Vargo. And incarceration is not the answer to our current substance use epidemic. I would argue that we need additional public health support.

I am proud to represent Minnesota's 2nd congressional district, where our county and local law enforcement partners have launched programs that focus on intervention, rather than incarceration for nonviolent offenders struggling with addiction.

The Shakopee Police Department offers a scholarship program to cover the cost of drug or alcohol treatment funded by drug and alcohol forfeiture cases. Scott County's drug court provides supervision and treatment, an effective alternative to incarceration that saves taxpayer dollars and directs participants to long-term recovery.

Mr. Vargo, starting with you, thank you again for your testimony here today. As you all know, one of our great colleagues, Representative Annie Kuster, put forward H.R. 2366, the Support, Treatment, and Overdose Prevention of Fentanyl Act. One provision requires HHS to report on how SAMHSA can provide and support health services to underserved individuals, taking into account drug courts.

Can you talk a little bit more about how drug courts work, and the overall impact they may have in combating drug use and abuse, from your experience?

Mr. VARGO. Thank you, Representative Craig, I would be happy to. Drug courts are near and dear to my heart.

I am an old prosecutor, and I started in Miami in 1988, when Ms. Reno was the State attorney down there. And in the fall of 1988 into the spring of 1989 she began the Nation's first drug court. And so that has always been something that has—I have paid attention to. You could not find a county in America that doesn't have some access to one of these what we call specialty courts.

The weakness of specialty courts, drug courts, DUI courts, even mental health courts, is that they tend to be aimed at those who are in the last steps before a penitentiary sentence. So they are wonderful. They do divert people from the penitentiary. They do not divert people from conviction, and they do not divert people at the beginning of their criminal justice involvement. That is why we believe that diversion, which we unabashedly stole from Manhattan and the Bronx, are answers that need to be more widely incorporated with prosecutors' offices from here on out.

So I really am thrilled to hear about what is going on in Minnesota. I know some of your wonderful prosecutors—Mr. Freeman, Mr. Orput—are good friends of mine, and I am glad to hear what they are doing.

I will tell you that I would love to see in the STOP legislation—the numbers are sometimes daunting. When you talk about HHS making reports on SAMHSA, we are in the process of looking for a grant or a diversion opportunity to test out the medical-assisted treatment model for methamphetamine. When working with our partners here who already provide opioid MAT treatment, they inform me that for half a million dollars a year I could probably treat 25 people. In a small county that is a daunting number, even on a grant funding.

And so I am thrilled to hear that we are going to be documenting just what happens, because ultimately that 25 people, that is still cheaper than putting them in the penitentiary. So in the end, if we can get that to work, that is great. But I do know that it is daunting and that the SAMHSA numbers are going to be stretched very thin. And so that is part of the hope that I would send to you, which is that you would treat this as even more important than the other infrastructure projects that you are presently considering. Human capital has to be our first goal of infrastructure.

Ms. CRAIG. Thank you so much for that thoughtful answer.

And with that, Madam Chair, I will yield back.

Ms. ESHOO. The gentlewoman yields back. The Chair now recognizes the gentlewoman from Washington State, Dr. Schrier, for your 5 minutes of questions.

Ms. SCHRIER. Thank you, Madam Chair, and thank you to all of our witnesses today for talking in such frank terms about how to take away stigma and address the real issues at hand, which are, you know, drug addiction and treatment and finding the right time, and mitigating mortality. I very much appreciate that focus on how to care for our families and our communities. I want to turn to Dr. Wilson for my question.

Doctor, I very much appreciate your candor about how physicians in general do not receive sufficient education on how to recognize and treat substance abuse disorders. My State of Washington has been a leader in working to integrate behavioral health into primary care and utilize care coordination so people with complex conditions, whether that is diabetes and depression, or co-addiction to opioids and methamphetamines, can get the care that they need. And yet, personally, as a pediatrician, the extent to which I personally treated substance use disorder was screening for it and then, if I found it, ensuring immediate safety and then referring out to specialists.

And so I was wondering, you know, from a pediatrician's perspective, could you just talk about what it looks like to treat a patient with substance abuse disorder in the primary care setting?

Dr. WILSON. Absolutely.

Ms. SCHRIER. Thanks.

Dr. WILSON. You know, I often think of addiction as a pediatrics disease that we often fail to recognize and treat during childhood, which leads to worse outcomes later in life. The vast majority of adults who use substances have actually started using those substances during their adolescence. And so this is a huge missed opportunity to really shift the life trajectory of a generation of adolescents and young adults. So I think it is essential that we do a

much better job, as a profession, of recognizing substance use in young people.

As a pediatrician and adolescent medicine provider, I think I am the sort of perfect person to recognize substance use in my patients. You know, pediatricians have the ability to build deep relationships with patients and their families over time. We provide lots of anticipatory guidance and education about what to expect as they grow up about puberty, about all sorts of things that we know are going to impact the lives of our patients. And we know that substance use is a huge potential area that would have serious impact on their future. And so I think it is natural for us to be the ones to sort of have those kind of preventive conversations and start the conversations with patients.

We also see patients regularly for well child visits, and that is a perfect opportunity to screen patients as we are doing a lot of preventive healthcare.

And then to sort of offer treatment in the setting, it helps sort of remove some of the stigma that both patients and their families might have about the disease of addiction, right? So I don't say, "You have an addiction, you have to go someplace else." I say, "You have a disease, just like you have asthma. And as your doctor, I am going to treat you." And there is something that is so powerful about sort of flipping that narrative for parents. There is nothing shameful about dealing with addiction. It is a disease, and we have effective treatments, and our job as physicians and pediatricians are to get those effective therapies to children and their parents.

Ms. SCHRIER. So I really appreciate that perspective. And I think it is really nice to destigmatize it like that. I guess—here is my next question.

I am in a generation that did not receive this kind of training in medical school or residency. And I understand that, you know, that the X-waiver may not be ideal. But then again, less than, I think, 1 percent of pediatricians have ever even applied for the X-waiver so aren't in a situation to do this testing.

Can you talk about—if it is not—you know, what your thoughts are with the X-waiver and, if it is not that, how do you catch the more experienced doctors up to speed on treating substance use disorders?

Dr. WILSON. I think—

Ms. ESHOO. Excuse me, if you could, just summarize your answer, because the gentlewoman's time has expired.

Ms. SCHRIER. Oh, I missed that.

Ms. ESHOO. Oh, it hasn't. I am sorry, I am sorry. You have 37 seconds. I am sorry.

Dr. WILSON. I think we have to both integrate for sort of our learners into health professional education and medical residency programs, better education in addiction.

And I think the X-waiver training is sort of an additional regulatory hurdle. I think we should eliminate the X-waiver training but integrate basic tenants of addiction medicine as sort of linked to, for example, DEA licensure. So as you sort of obtain your DEA license, you have to complete a certain amount of hours related to—basics related to addiction and buprenorphine prescribing, so all prescribers who are able to prescribe controlled substances are

actually also able to recognize, treat, or refer to treat patients with addiction.

Ms. SCHRIER. Great, thank you very much.

Ms. ESHOO. The gentlewoman's time has expired, and excuse me for interrupting.

The Chair now recognizes the gentlewoman from Massachusetts, who has been with us all day, and I think that is the quality of the hearing, right?

Mrs. TRAHAN. Absolutely.

Ms. ESHOO. Yes. Congresswoman Trahan, you are recognized for your 5 minutes, and thank you. You are a wonderful addition to our subcommittee.

Mrs. TRAHAN. Well, I so appreciate that, Madam Chair, and I really do appreciate you convening us on this important issue and prioritizing it. Your leadership on substance use disorder is unparalleled. And I want to thank all the witnesses today. I know it has been a long day, but your contribution to our policymaking is so important.

So in 2016 Max Baker was 23 years old when he died of an overdose after suffering from heroin addiction. Prior to his passing, Max's father, Dr. James Baker, a hospice care physician who works in my district, he sought help for his son through his own primary care doctor. But the answer Dr. Baker received was not at all encouraging: "I hope he finds the help he needs." And this particular primary care doctor didn't have the working knowledge to treat Max's addiction or even the tools to refer him to someone who could.

And that isn't a criticism. You know, it is a description of an all-too-common problem, as Dr. Schrier just mentioned. In fact, even over Dr. Baker's 35 years of practicing medicine, he hadn't learned how to treat opioid use disorder, not in his coursework at Johns Hopkins or Harvard, not in his medical school residency, and not in his public health education.

So, Dr. Wilson, I am going to stay with you. Why should all medical professionals know how to identify and treat SUD?

And what would you say to your medical colleagues across different medical specialties if they questioned why requiring education on treating patients with SUD is important to improving addiction treatment for all Americans?

Dr. WILSON. Yes, thank you so much. You know, I think the sort of key takeaway point is there should be no wrong door for a patient who is seeking help, right?

And so I think that we historically have had separation—have separated addiction treatment from medical treatment. And so historically, providers, physicians have not learned about addiction medicine as part of routine sort of education or curriculum offered in medical school or as part of their residency training.

And so, you know, I would call this out as a failure of our profession. And I think part of the treatment gap that we are seeing right now is because we haven't recognized that, you know, addiction and addiction medicine is part of the care that we need to offer all of our patients, right?

And so you may not provide sort of really in-depth medical sort of addiction medicine when you see patients, but you should be

able to screen, to diagnose, to recognize that a patient is struggling with addiction and to know how to refer them to treatment, and what treatments exist.

You know, I take care of patients in the hospital who often are admitted with—for many things that have nothing to do with their addiction. And that is an opportunity for us to see them, offer treatment, and sort of really alter the course of their lives.

Mrs. TRAHAN. Sure. So let's imagine that the X-waiver requirement were eliminated, and so a barrier to treating patients with buprenorphine, for example, was no longer an issue. That is a powerful drug which many prescribers may not be familiar with. And it strikes me that under that scenario it would be even more important for our prescribers to understand how to use buprenorphine to properly treat SUD.

So would standardized education on treating addiction lead to better treatment for those suffering with SUD, especially if some treatment barriers are soon eliminated?

Dr. WILSON. Yes, so I actually think that we often—and, in part, I think this is related to stigma around addiction—we prescribe many things which are far more dangerous for patients like morphine, like oxycodone, like the medications that started this crisis to begin with, that do not have the regulatory hurdles like prescribing buprenorphine. It should not be easier for us to prescribe pain medicine than it is for us to prescribe buprenorphine to treat someone with an opiate use disorder.

So I think part of that is helping providers recognize it is actually not that challenging. This is something you can do, you are empowered to do it, and with sort of a short sort of kind of educational module, an hour or two focused on the medication of buprenorphine and how you start it, all providers will, I think, realize that they too can recognize and treat patients with opiate use disorders.

Mrs. TRAHAN. And that is a huge part for us, eliminating the stigma.

I mean, look, had standardized education been the protocol a few years ago, perhaps Max Baker would have received the early intervention and the support that he needed. And parents like—patients like him show up in medical offices across the country, and the medical community, frankly, needs to be ready to spot problems of this sort, whatever their specialty.

I mean, this is, after all, a national crisis, and it is going to require all of us to do a bit more to keep patients healthy and safe, which is what the MATE Act aims to do.

So I really appreciate your contribution to today's conversation, Dr. Wilson, and I yield back the remainder of my time.

Ms. ESHOO. The gentlewoman yields back, and I think the final recognition of a wonderful Member is going to be our last one, and that is the gentlewoman from Texas, Mrs. Fletcher. Are you there?

Mrs. FLETCHER. Thank you—

Ms. ESHOO. There you are.

Mrs. FLETCHER. Thank you so much, Chairwoman Eshoo. Yes, and thank you to all of our witnesses for testifying today about this critically important topic, and for being with us throughout the day. It really is important. And I want to touch on one thing that

we haven't, to my knowledge, touched on in this panel and get insights from all of you.

I have the privilege of representing a lot of medical professionals in my district in Houston, just outside the Texas Medical Center. And I have heard from a lot of the doctors and other medical professionals in my district that a lack of insurance coverage can significantly impact an individual's recovery.

You know, for example, a person may be on medication-assisted treatment and doing very well, but they are laid off or get dropped from their partner's coverage. There are a lot of scenarios, unfortunately, that we have seen over the last year where people have lost their coverage, and then they can no longer afford their treatment and they relapse.

So Medicaid is the largest payer of mental health and substance use disorder treatment in the country. Unfortunately, in States like mine that have not expanded Medicaid, you know, many people who are struggling with substance use disorders are unable to get the coverage they need.

So I want to start with Dr. Wilson. In your testimony you discuss the many barriers that can exist to accessing addiction treatment. In your opinion, would Medicaid expansion help reduce barriers and expand access to critical substance abuse disorder treatment?

Dr. WILSON. Absolutely. It is really a no-brainer. You know, I think it is cost-prohibitive for people to pay out of pocket for addiction treatment. And I see patients all the time who have been doing great, are in sustained recovery, doing well, taking medications, engaged in recovery services, and they lose insurance coverage through no fault of their own and then have withdrawal from the medications that have been helping them stay sober and abstinent from illicit opioids and really lose access to all the recovery support services that have helped them stay in long-term recovery.

And that can be—we know that any return to use could be a potentially fatal return to use. And so this is really a conversation about how we keep people alive and keep them getting access to medications and treatment that can help save lives.

Mrs. FLETCHER. Thank you, Dr. Wilson, and I would love to just open that question up to anyone, especially since I am the last—last couple of minutes of the hearing, just to see if anyone else wants to weigh in on that question about how we can keep getting people access to critical services, or—really, if somebody else has something to say that we didn't get to and you want to use this minute, I would be glad to hear your thoughts as we wrap up.

Mr. VARGO. If I might, Representative?

Mrs. FLETCHER. Go ahead.

Mr. VARGO. Well, thank you very much for giving me the opportunity. I will tell you that it is not just the existence of or the lapse of insurance. It is whether they have it in the very first place.

As I said, we have got a 90 percent unemployment rate on the Pine Ridge Indian Reservation. So that means that the ACA makes no inroads as far as insurance goes.

And I will also, though, point out one other difficulty, which is the ability of Medicaid and Medicare to reimburse for off-label uses of proven drugs that would be of assistance. It makes it prohibitively expensive for those people to seek treatment, and for us, as

governments, to then pay for that treatment, because we are essentially out of pocket. So even before you get to Medicaid expansion, the capacity—I would rather that a doctor like Dr. Wilson, who knows what she is doing and she makes a decision that this drug is necessary for a patient's care, even if it is off label, it strikes me that that should be reimbursed by Medicaid.

Mrs. FLETCHER. Thank you, Mr. Vargo, I appreciate that.

And I think that, Mr. Laredo, you had your hand up.

Mr. LAREDO. Thank you so much. Just following on what Mr. Vargo just said, you have a nationwide, systemwide problem of complete lack of services compared to the need. So, whether there is insurance or not, whether there is Medicaid expansion or not, it is another example of needing an all-of-the-above approach and, unfortunately, a truly dramatic increase in funding across the board to pay for these services.

The public health system, as we have seen throughout the COVID pandemic, is in deep, deep trouble. And that translates through the substance use and addiction treatment system. It is—frankly, calling it a “system” is a little bit of an overstatement. So anything at all—you don't always want to throw money at a problem. This is a problem that has for decades required significantly more funding than it has ever received.

Mrs. FLETCHER. Well, thank you so much for that, and I am at the end of my time here.

So, Chairwoman Eshoo, thank you again for holding this incredibly informative hearing, and thank you to all of our witnesses for your testimony here today. I yield back.

Ms. ESHOO. The gentlewoman yields back. I don't see any other hands for Members, whether they were part of the subcommittee or waiving on.

I want to thank each one of you. You have really given superb testimony. What always makes it very interesting in a hearing is, you know, the two sides of an issue from two professionals. And, you know, none of these issues are—well, I think the issue of, you know, the whole—the schedule I issue, and that we are going to have to sort out, it is an important one, but I can't give you an answer right now of where I am on it, because people have made excellent points about it. And that is the point of a hearing, is that we get the expert testimony. No one can say to any one of you that you don't know what you are talking about. You bring decades of professional experience to the Congress of the United States.

And we are not only very deeply grateful to you, we are proud of you. When I listen to all the professionals I always think to myself, what a country we have, what a country we have, individuals that are so committed, so committed to the public health system, to research, to the criminal justice system. I could go on and on. So you have the collective gratitude of our entire committee, and you have been highly instructive to us. You have been highly patient for us to take up your panel, and we are lastingly grateful to you.

So thank you, thank you, thank you, and know that we will circle back with you with the questions that Members submit. If they didn't have the opportunity, they will submit questions, and I trust that you will answer them in a timely way.

So keep doing your extraordinary work. Our country and this issue really need you. And hopefully, we will shape policies that are going to really put a—really address what—as I said earlier, this scourge in our country.

I mean, it just has wiped out—wrecked lives, wrecked families, taken tolls on communities across the country. And it doesn't matter what ZIP code people live in. Not a surprise, in poorer areas it is even worse. So thank you again.

Now, I have a request of my wonderful—our wonderful ranking member. I have 37 documents to enter into the record. They are all wonderful and important, and organizations weighing in. And I would like to request a—make a unanimous consent request to enter into the record the 37 documents that have been submitted to our subcommittee.

Mr. GUTHRIE. OK, thanks, and before—I don't object, so I won't object. But I just want to say again, to echo what you said, to have our witnesses here today, to spend an entire day of your time—I know you got to listen to the morning session and then spend your entire afternoon with us is—I know your time is valuable, but it is helpful. It really is helpful, because a lot of us are really trying to sort this out, and not coming with preconceived views or optics or anything like that. We really want to come up with the right answer. And we appreciate your time.

And I do not object to your unanimous consent request.

[The information appears at the conclusion of the hearing.¹]

Ms. ESHOO. Well, thank you. Thank you very much. And I appreciate it. And yes, 5 hours and 10 minutes total.

But I think it also—I think that, as you—before you turn off your laptops, I am very proud of our subcommittee and the Members on both sides of the aisle. You heard so many thoughtful, probing questions.

So while, you know, Congress has always been kind of the—at the—well, let's just put it that way, a lot of fingers pointed at us, we are made fun of or mocked in different ways. Sometimes it is earned. But I think most of the time, frankly, it isn't. You saw and heard firsthand the deep concern of Members, the knowledge that they have about the subject matter, and they are reaching out with deep respect to each one of you to probe further and seek your professional advice. So I am very grateful, and I am very proud of our subcommittee. It is a very important one. And I know that Mr. Guthrie shares that view, as well.

So God bless each one of you. I know you are going to keep serving our country well. You have served us so well today.

And with that, I adjourn the Health Subcommittee hearing of today, April 14th, the birthday of my son.

[Whereupon, at 3:43 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

¹The GAO report has been retained in committee files and is available at <https://docs.house.gov/meetings/IF/IF14/20210414/111439/HHRG-117-IF14-20210414-SD021.pdf>.



April 13, 2021

Dear Chairwoman Eshoo & House Energy and Commerce Health Subcommittee,

We are reaching out to submit a statement for the record concerning the Subcommittee on Health of the Committee on Energy and Commerce legislative hearing on April 14, 2021, entitled "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America." Thank you for hosting such an important hearing. No matter what we look like or where we come from, the overdose crisis reminds us that at our core we are all human. Our ability to get and stay well depends on everyone having what we need to prevent, treat, and recover from illness.

People's Action is a national network of 40 state and local grassroots, power-building organizations across 30 states with 1 million members, united in fighting for justice. People's Action's Overdose Crisis Cohort works to uplift the long-running epidemic of overdose in the United States. We are people who use drugs, people in recovery, harm reductionists, and people who have lost loved ones due to the War on Drugs and the Overdose Crisis. We come from urban, small town, suburban and rural communities and from Black, white, and brown constituencies. We are united by our shared experiences as survivors of the failed war on drugs and the overdose crisis. Together we are taking action for a future where all of us are valued and supported to live fulfilling, healthy lives - no matter our relationship to substances.

As you well know, the United States is currently in the midst of an overdose crisis. In order to stop the unprecedented overdose pandemic ravaging our communities, Congress must follow science and lead with compassion that invests in evidence-based treatment and harm reduction solutions. Criminalization of drug use does not and has never saved lives. We must leave this failed approach behind if we intend to end the overdose crisis.

We write to express our support for H.R. 1384 The Mainstreaming Addiction Treatment Act of 2021 and H.R. 2366 Support, Treatment and Overdose Prevention of Fentanyl Act of 2021. Both of these pieces of legislation will effectively reduce overdose deaths by undoing the harm of the War on Drugs that pharmaceutical and insurance corporations have exacerbated and expanded the scope of the catastrophe. H.R. 1384 and H.R. 2366 follow the lead of science and focus on immediately saving lives.

H.R. 1384 (the MAT Act) would eliminate the DATA 2000 WAIVER requirement that discourages practitioners from integrating treatment in their practices and perpetuates stigma in the medical community against patients who would benefit from buprenorphine treatment. From our members on the ground from Indiana to Vermont to North Carolina - we have heard time and time again the challenge to accessing medication assisted treatment (MAT).

"On March 8th of 2018, my nephew, Kaya Siegel, whose upbringing I was a big part of died of an overdose, after a year in recovery. He was the son of my brother, Johnathon Siegel who died just over 20 years before also while using heroin. Throughout the 7 years of Kaya's battle with substance use disorder, the most prominent recurring theme was that he could not consistently access Buprenorphine. What I did not know then, but do know now, is that the barriers to becoming a MAT provider are huge and they are stigma based rules based on harmful Drug War policies. People in my rural state of Vermont are sometimes having to travel three hours every day to access Buprenorphine because there are no providers near them or the rules for access require them to go to a particular location." - Brenda Siegel, member-leader at Rights and Democracy Vermont

Medication assisted treatment is the gold-standard of treatment and one that anyone seeking treatment for opioid-use disorder should be able to access.

"With MAT I can contain my substance use without losing my quality of life and struggling. Forced and voluntary abstinence has never worked for me. This form of treatment (MAT) is good for my loved ones as well. If I am not dealing with the negative effects of my use and not using chaotically I have more time to be well around my family and enjoy a better quality of life with them." - Brendan Coughenour, member-leader at New Jersey Organizing Project

To effectively respond to the urgency of the overdose epidemic, we need to eliminate barriers that prevent healthcare practitioners from providing evidence-based treatment for substance use disorders such as MAT. Removing the X-Waiver through passing H.R. 1384 is an essential step to ensure that those who want treatment are able to receive it.

H.R. 2366 (the STOP Fentanyl Act) packages together policies that bolster surveillance and research, deploy resources to combat overdose deaths, connect individuals with treatment programs, and support on-going prevention and public safety activities. Criminalization of the current public health crisis has been proven ineffective time and time again.

"We're at a historic moment, and the US just keeps using the same tired tactics that it's used for over 100 years - increased criminalization. This does not work, but instead causes harm and violence in Black, brown, and low-income communities. Overdoses are higher now than they ever have been, and increased criminalization will inevitably dismantle public health efforts. If we truly want to turn the tide on this devastating crisis, we need to implement evidence-based solutions, not fear based, draconian policies that cause more trauma and deaths." - Jasmine Budnella, Director of Drug Policy at VOCAL NY

Punitive measures to address drug use have only proven to increase loss of life. Through this legislation, Congress can help communities address the rise in synthetic opioids without punitive measures that lead to mass incarceration and further fuel the failed drug war.

Thank you for hosting this important hearing, and we look forward to seeing solutions advanced to save lives.

Sincerely,



Ellen Glover
Drug Policy, Harm Reduction and Criminal Justice Campaign Director
People's Action

Overdose Crisis Cohort Member Organizations:

IN - Hoosier Action
MD - Progressive Maryland
ME - Maine People's Alliance
MI - Michigan United
NC - Down Home North Carolina
NH - Rights and Democracy
NJ - New Jersey Organizing Project
NY - Voices of Community Activists and Leaders NY (VOCAL-NY)
OH - River Valley Organizing/UnHarming Ohio
OH - Showing Up for Racial Justice - Ohio (SURJ-Ohio)
VT - Rights and Democracy
WV - Solutions Oriented Addiction Response in WV (SOAR-WV)

United States Senate
WASHINGTON, DC 20510

April 13, 2021

President Joe Biden
The White House
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

Dear President Biden,

We write to express our serious concerns with the Trump Administration's misguided class-wide fentanyl scheduling order and to urge your Administration to pursue a public health response to our country's fentanyl crisis.¹ You have committed to end mandatory minimums, eliminate racial disparities in the criminal-legal system, and ensure fair sentences. As members of Congress, we are eager to work with your Administration to achieve these goals.² However, the criminalization of all fentanyl analogues rejects these objectives and fails to provide our communities with the help and support needed to address the public health crisis. Instead, it revives the erroneous policies of the War on Drugs that funneled countless people, many living with addiction, into prison. Notably, the number of overdose deaths attributed to fentanyl and related substances has continued to rise since 2018 despite the temporary scheduling order.³ Your Administration should embrace the lessons of the past and prioritize evidence-based public health approaches to ending the fentanyl crisis that is devastating our communities.

Fentanyl use is a serious crisis, and combatting substance use—including the use of fentanyl—is an important priority. However, classifying all fentanyl analogues as Schedule I substances is not necessary to allow prosecutors to bring cases. Harmful fentanyl analogues are illegal without class-wide scheduling. The government can prosecute them using the Federal Analogue Act. The data bears this out. Between 2015 and 2019, prosecutions for federal fentanyl offenses increased by nearly 4,000%, and fentanyl-analogue prosecutions increased by 5,000%.⁴ From 2019 to 2020, most fentanyl-analogue prosecutions involved analogues that had been individually

¹ Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020).

² See *The Biden Plan for Strengthening America's Commitment to Justice*, BIDEN-HARRIS (2020), <https://joebiden.com/justice>.

³ Centers for Disease Control, *Opioid Overdose: Fentanyl*, <https://www.cdc.gov/drugoverdose/opioids/fentanyl.html#:~:text=Deaths%20involving%20illicitly%20manufactured%20fentanyl%20or%20the%20rise&text=Overdose%20deaths%20involving%20synthetic%20opioids%20were%20nearly%2012%20times%20higher.involving%20synthetic%20opioids%20in%202019> (last visited April 12, 2021); Press Release, Centers for Disease Control, *Overdose Deaths Accelerating During COVID-19* (Dec. 17, 2020), <https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html>.

⁴ U.S. SENTENCING COMM'N, *FENTANYL AND FENTANYL ANALOGUES: FEDERAL TRENDS AND TRAFFICKING PATTERNS* 24 (Jan. 2021), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf.

scheduled prior to class-wide scheduling.⁵ The federal government must be wary of expanding the reach of these penalties by adopting a policy explicitly designed to expedite drug prosecutions and increase penalties.

Classifying all fentanyl analogues as Schedule I substances will also perpetuate the racial disparities that exist throughout the criminal-legal system. Scheduling these substances would permanently expand the application of mandatory minimum sentences to the entire class of fentanyl-related compounds without considering the unique qualities of each analogue, including the potency and purity of a particular fentanyl-related substance. For example, just a trace amount of a fentanyl analogue in a mixture with a combined weight of 10 grams—10 paper clips—can trigger a five-year mandatory minimum, with no evidence needed that the seller had any knowledge that the substance contained fentanyl.⁶ People of color will disproportionately be subjected to these mandatory minimums. Data shows significant racial disparities in the prosecution of fentanyl cases, with people of color comprising almost 75% of those sentenced in 2019.⁷ This holds true for fentanyl analogues, for which 68% of those sentenced were people of color.⁸ In addition, more than half of all federal fentanyl-analogue prosecutions in 2019 involved a street-level seller or other minor role; only 10.3% of these cases were of individuals who had committed more serious offenses.⁹ At a time when communities of color have been disproportionately impacted by the COVID-19 pandemic, we must not exacerbate health inequities further by deploying the criminal-legal system against another public health crisis.¹⁰

Finally, class-wide scheduling impedes researchers' and scientists' ability to develop evidence-based, public health solutions needed to overcome the fentanyl crisis. In a July 2019 letter to the Department of Health and Human Services (HHS), bipartisan members of the Senate Judiciary Committee warned that the same barriers to research that scientists encounter when attempting to study Schedule I drugs would apply to substances added by a class-wide scheduling policy.¹¹ Senate Judiciary Committee members further warned that "the failure to engage necessary health experts vests far too much authority to a law-enforcement agency and may result in action that will deter valid, critical medical research aimed at responses to the opioid crisis, including efforts to identify antidotes to fentanyl-analogue overdoses and improved treatment outcomes."¹² Similarly, in her January 2020 statement before the House Judiciary Committee Subcommittee on Crime, Terrorism, and Homeland Security, Dr. Sandra Comer, the public policy officer for

⁵ See *id.* at 23 ("Most of the substances identified in the fiscal year 2019 sentencing documents as 'fentanyl analogues' are substances listed in a schedule of the CSA before publication of the DEA's [class-wide scheduling] order.").

⁶ See generally BRIAN T. YEH, CONG. RESEARCH SERV., RL30722, DRUG OFFENSES: MAXIMUM FINES AND TERMS OF IMPRISONMENT FOR VIOLATION OF THE FEDERAL CONTROLLED SUBSTANCES ACT AND RELATED LAWS (2015), <https://fas.org/sgp/crs/misc/RL30722.pdf>.

⁷ See *id.* at 24.

⁸ *Id.*

⁹ *Id.* at 28 (summation of street-level dealer; courier/mule; renter/storer; enabler; and user offender functions at 51.5%, summation of most serious functions, importer/high-level distributor and leader/organizer at 10.3%).

¹⁰ See *COVID-19 Racial and Ethnic Health Disparities*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 10, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html>.

¹¹ See Letter from Senators Richard J. Durbin, Michael S. Lee, Sheldon Whitehouse, Amy Klobuchar, Christopher A. Coons, Mazie Hirono, Cory A. Booker & Kamala D. Harris to Alex M. Azar II, Sec'y, U.S. Dep't of Health & Human Servs. (Jul. 10, 2019), <https://www.durbin.senate.gov/imo/media/doc/Letter%20to%20DOJ%20HHS%207.10.pdf>.

¹² *Id.*

the College on Problems of Drug Dependence, strongly recommended that any legislation on scheduling synthetic opioids should involve HHS's science-based agencies, specifically the National Institute on Drug Abuse and the U.S. Food and Drug Administration.¹³ Recent research has confirmed that the class-wide scheduling action has improperly scheduled substances with therapeutic promise and low abuse potential.¹⁴ By continuing the categorization of all fentanyl analogues as Schedule I substances, the Administration would deter valid, critical medical research aimed at responses to the opioid crisis, including efforts to identify antidotes to fentanyl-analogue overdoses and improved treatment options.¹⁵

We are profoundly concerned about fentanyl-related deaths, and bold actions to end this national emergency are urgently needed. This will take a concerted effort by your Administration to develop and champion the public health solutions that communities so desperately need to defeat it. We look forward to working with you and your Administration to enact just and restorative policies that will meaningfully transform our response to drug use and save lives, and we encourage you to reconsider class-wide scheduling of fentanyl in favor of an equitable, public health-focused approach to the crisis.

Sincerely,



Cory A. Booker
United States Senator



Mazie K. Hirono
United States Senator



Sheldon Whitehouse
United States Senator



Edward J. Markey
United States Senator



Elizabeth Warren
United States Senator

¹³ See Statement of Professor Sandra D. Comer, Pub. Policy Officer, Coll. on Problems & Drug Dependence, Before the Subcomm. on Crime, Terrorism & Homeland Sec., H. Comm. on the Judiciary (Jan. 28, 2020), <https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf>.

¹⁴ Comer, *supra* note 11.

¹⁵ Sandra D. Comer et al., *Potential Unintended Consequences of Class-Wide Drug Scheduling Based on Chemical Structure: A Cautionary Tale for Fentanyl-Related Compounds*, 221 DRUG & ALCOHOL DEPENDENCE 3 (2021), <https://www.sciencedirect.com/science/article/pii/S0376871621000259>.

Statement of the American Property Casualty Insurance Association
House Energy and Commerce Committee
Subcommittee on Health
“An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America”
April 14, 2021

The American Property Casualty Insurance Association (APCIA), supports the House Energy and Commerce Health Subcommittee’s work on legislation to fight opioid addiction, including H.R. 2379, the State Opioid Response Grant Authorization Act, introduced by Representative David Trone; H.R. 2067, the Medication Access and Training Expansion (MATE) Act, introduced by Rep. Lori Trahan; and H.R. 2355, the Opioid Prescription Verification Act, introduced by Rep. Rodney Davis. Collectively, APCIA members represent 60% of the United States property casualty insurance market and approximately 70% of the workers’ compensation insurance market, APCIA is committed to ensuring injured workers receive medical treatment that heals patients and to supporting effective solutions to curb opioid addiction in the states.

APCIA believes that giving states funding and flexibility to combat the opioid crisis is critical to reductions in addiction rates and the devastating health, social, and economic consequences related to opioid dependence. Reauthorization of the State Opioid Response Grant Authorization Act (H.R. 2379) ensures that community organizations have available resources to enhance existing effective prevention, treatment, and recovery programs, to implement innovative approaches that fit the diverse populations they are intended to serve, and to provide funding certainty in the years ahead. APCIA supports the expansion and improvement of prescription drug monitoring programs and increased training for prescribers.

The MATE Act (H.R. 2067) would provide consistent training to prescribers of controlled medication, give them a better understanding of evidence-based addiction and treatment; improve opportunities for easier prevention, identification, and management of opioid addiction in real time; and expand the opportunity to reduce addiction-related stigma and save lives. The Opioid Prescription Verification Act (H.R. 2355) supports establishing and improving drug monitoring programs, enhancing a key tool already in place to combat the opioid epidemic. It is critical that, while supporting these tools already implemented at the state level, federal legislation does not interfere with state-based laws and regulations, particularly workers’ compensation.

Opioid misuse and addiction have worsened because of the COVID-19 pandemic. APCIA members believe that business must continue to support federal, state, and community work to combat the crisis. Last fall, The Hartford, the US Chamber, Shatterproof, ONDCP, and APCIA held a virtual event, **Erasing the Stigma: Ending the Opioid Epidemic**, to highlight the epidemic’s deep reach into workplaces and communities. The Hartford, through its Opioid Aware Program is committed to providing companies U.S. workers, and families with support and resources, including a working toward a cultural shift necessary to neutralize addiction stigma fueling the crisis.

Federal Public & Community Defenders
Legislative Committee

52 Duane Street, 10th Floor
New York, NY 1007
Tel (212) 417-8738

Co-Chairs

David Patton
Executive Director
Federal Defenders of New York

Jon Sands
Federal Defender
District of Arizona

March 2, 2021

Alyssa M. Hundrup
Acting Director, Health Care, United States Government Accountability Office (GAO)
441 G St. N.W.
Washington, D.C. 20548

Re: Response to GAO Report on Synthetic Opioids: Considerations for Class-Wide Scheduling
of Fentanyl-Related Substances (GAO-21-301SU)

Dear Ms. Hundrup:

Thank you for providing the Federal Public and Community Defenders a copy of GAO's draft report on the class-wide scheduling of fentanyl-related substances ("Report")¹ and for the opportunity to comment on its findings. The Report has the potential to offer a critical contribution to the policy discussion surrounding class-wide scheduling of fentanyl-related substances and the best way to respond to fentanyl and its analogues.² Unfortunately, the Report places too much emphasis on assertions by law enforcement about the utility and effect of class-wide scheduling and not enough on the GAO's carefully gathered evidence and findings that demonstrate class-wide scheduling is unnecessary and could lead to over-criminalization. As detailed below, we urge the GAO to revise the Report to provide more emphasis on its own core findings.

I. The Report confirms that the government is well-equipped to prosecute fentanyl analogues without class-wide scheduling.

The Report's Executive Summary ("Highlights") should specify that harmful fentanyl-related substances are already illegal even without class-wide scheduling. Presently, the Highlights section states that "allowing the temporary scheduling order to expire . . . would mean relying on DEA to

¹ U.S. Gov't Accountability Office, GAO-21-301SU, Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-Related Substances (Feb. 2021) (Draft) ("Report").

² This comment refers to "fentanyl-related substances" and "fentanyl analogues." The term "fentanyl-related substances" refers to the specific substances that are defined in the temporary scheduling order that was codified, temporarily, by legislation. *See*, 83 Fed. Reg. 5188 (Feb. 6, 2018); Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020). The term "fentanyl analogues" refers to "synthetic opioids with chemical structures related to fentanyl—including fentanyl analogues that have been scheduled and fentanyl-related substances." Report at 3.

individually schedule specific fentanyl substances, as DEA has done in the past.”³ This framing perpetuates the false claim⁴ that the government cannot already effectively prosecute cases involving fentanyl-related substances and fentanyl analogues.

The Report feeds this false claim in two ways. First, the Report fails to adequately emphasize that the Department of Justice (“Department”) and federal law enforcement agencies have rarely relied on class-wide scheduling. From 2019 to 2020, most fentanyl-analogue prosecutions involved “analogues that had been individually scheduled prior to class-wide scheduling.”⁵ In contrast, the Department prosecuted only eight cases under the class-wide control since its adoption in 2018.⁶ This breakdown confirms that most fentanyl-analogue prosecutions have involved substances that the government used long-existing scheduling authorities⁷ to individually control and that the Department’s repeated claim that class-wide scheduling is necessary for effective enforcement lacks factual support.⁸

Second, the Highlights section omit any mention of the Analogue Act. The Analogue Act equips federal law enforcement to interdict and prosecute fentanyl analogues that are not already

³ Report, Highlights. The Report includes other similarly misleading statements. For instance, the DEA told GAO “if class-wide scheduling expires, fentanyl-related substances would no longer be scheduled and criminal organizations would likely resume or increase production of these substances.” Report, App. IV at 50. The Report footnotes DEA’s statement with a reference to the Analogue Act, but in that note, reiterates law enforcement complaints about the Analogue Act.

⁴ See Fentanyl Analogues: Perspectives on Classwide Scheduling Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 n.18 (Jan. 2020)(Testimony of Kevin L. Butler, Fed. Pub. Defender for the Northern District of Alabama,) (“Butler Test.”), <https://www.congress.gov/116/meeting/house/110392/witnesses/HHRG-116-JU08-Wstate-ButlerK-20200128.pdf> (summarizing claims by law enforcement and the Department of Justice that harmful fentanyl analogues would be legalized without class-wide control); Nancy Gertner, *William Barr’s New War on Drugs*, Wash. Post, Jan. 26, 2020, <https://www.washingtonpost.com/opinions/2020/01/26/william-barrs-new-war-drugs/> (“[Attorney General] Barr recently warned that if his request were not granted, illicit fentanyl analogues would be ‘legal.’ That is false. Dangerous fentanyl analogues have long been illegal and will continue to be under existing laws.”).

⁵ Report, App. IV at 60 (“EOUSA officials told us that most of the fentanyl analogue cases prosecuted were for offenses involving analogues that had been individually scheduled prior to class-wide scheduling.”).

⁶ *Id.* at 54; see also U.S. Sentencing Comm’n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* at 23 (Jan. 2021) (“USSC Report”), https://www.uscc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf (“Most of the substances identified in the fiscal year 2019 sentencing documents as ‘fentanyl analogues’ are substances listed in a schedule of the CSA before publication of the DEA’s [class-wide scheduling] order.”).

⁷ DEA has been empowered to schedule substances administratively based on a scientific and medical evaluation of a substance from the Assistant Secretary for Health since 1970 and to do so on an accelerated basis since 1984. See 21 U.S.C. § 811; Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 Cath. U. L. Rev. 586, 607–08 (1973); Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, tit. II, 98 Stat. 1976 (Oct. 12, 1984).

⁸ Nor has class-wide control meaningfully impacted law enforcement investigations. “Officials from all four DEA field division offices and four OCEDET strike forces . . . indicated that, overall, class-wide scheduling has not or would not have a substantial effect on how they conduct investigations involving fentanyl-related substances, such as the time and resources needed to investigate cases.” Report, App. IV at 53.

scheduled—further undermining the need for class-wide scheduling.⁹ We would expect this existing statutory method of prosecuting unscheduled fentanyl analogues to be at the forefront of the Report’s discussion. It is not mentioned until page 12. And the Report emphasizes Department complaints that Analogue Act prosecutions for fentanyl analogues will be unwieldy and unnecessarily resource-intensive—concerns that lack factual support.¹⁰ According to the Department, prosecutor reliance “on the [Analogue Act] to charge offenses involving fentanyl-related substances and cases for the same substance could generate inconsistent jury findings,”¹¹ and “prosecutors who use the [Analogue Act] have little certainty that a jury will find the substance is an analogue though they are expending a great deal of time and resources to prosecute cases.”¹² But despite these concerns, there is little information about how often the Department has relied on the Analogue Act to prosecute fentanyl analogues and the Department did not provide to GAO any case-specific examples to support its claims.¹³ Further, the Report does not include Defender statements that we were unable to identify any examples of cases that support the Department’s concerns. We found no cases involving a resource-intensive “battle of the experts” over the identity of a purported fentanyl-related substance, nor examples where juries or courts reached different conclusions about whether a fentanyl-related substance was or was not an analogue.

Overcoming an individual’s presumption of innocence is not intended to be convenient for the government. The Analogue Act requires the government to prove that a novel substance meets the Controlled Substance Act’s definition of “controlled substance analogue” before that person can be convicted and punished.¹⁴ Congress carefully designed the elements of that definition to secure convictions for dangerous novel substances while shielding harmless conduct from criminal sanctions.¹⁵ The Report should emphasize that despite the Department’s claims to the contrary, all evidence indicates the implementation of the Analogue Act has successfully achieved this balance, and that class-wide scheduling would disrupt it.

⁹ The Analogue Act, 21 U.S.C. § 813, controls substances that are not otherwise scheduled or FDA-approved that are intended for human consumption if it has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, and (2) an actual, represented, or intended effect that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance in Schedule I or II. Report at 12–13. As in every criminal case, prosecutors are required to meet their burden of proof with respect to the elements of the offense under the Analogue Act.

¹⁰ See e.g., Report at 18; App. IV at 55–56.

¹¹ See Report, App. IV at 55, Report at 18.

¹² *Id.*

¹³ See *Id.* at 55 n. 85 (The Department provided GAO an example of three Analogue Act cases that resulted in inconsistent outcomes, but “[n]one of these cases involved a fentanyl analogue or fentanyl-related substance.”).

¹⁴ See *id.* at 12–13.

¹⁵ Butler Test. at 9–10 (summarizing legislative history of the Analogue Act, including consideration by Congress of testimony from the American Chemical Society).

II. The Report should prominently state that GAO could not substantiate law-enforcement claims that class-wide scheduling has a causal connection to reduced encounters with novel fentanyl-related substances.

The Report repeatedly highlights law enforcement claims about the efficacy of class-wide scheduling but buries the finding that GAO could not substantiate those claims. The Report's Highlights and body repeat that "Federal law enforcement officials said that a benefit of class-wide scheduling—reduced incentives for traffickers to make new and existing fentanyl-related substances to circumvent the law—would be lost if substances were scheduled individually."¹⁶ In contrast, the Report obscures in footnotes and appendices that GAO was "unable to draw any causal conclusions related to class-wide scheduling" and law enforcement encounters,¹⁷ and that "the number of reports of all fentanyl analogues and other related compounds (e.g., precursors), including individually scheduled analogues, have *increased* since the implementation of class-wide scheduling."¹⁸ Front-loading law enforcement's claims, without similar attention to these important factual findings, may lead many readers to wrongly conclude that GAO substantiated these law enforcement assertions.

We urge the authors to add language in the Highlights and in the body of the Report to clarify its findings and directly confront these claims with the absence of factual support.

III. The Report should highlight evidence that class-wide scheduling would improperly criminalize helpful and harmless substances.

The Report should emphasize that class-wide scheduling "preemptively classifi[es] an unknown number of similar substances with unknown effects,"¹⁹ including harmless and therapeutic substances. The class-wide control defines fentanyl-related substances "based on their chemical structure alone and [does] not define them based on their pharmacological activity—the resulting physical and psychoactive effects on humans."²⁰ This is a flawed approach because chemical structure alone cannot predict how a drug will affect the human brain.²¹ The relative potency of fentanyl and fentanyl analogues varies widely: "[s]ome analogues, like acetyl fentanyl, are less potent

¹⁶ See Report at "Highlights"; 20.

¹⁷ Report, App. I: at 28 n.27; *see also*, Report, App. IV at 50, 52–53 ("Although the timing of DEA's temporary order corresponds to a decrease in law enforcement reports of new and existing fentanyl analogues that are not individually scheduled, we are unable to draw conclusions about the extent to which the cause of the decrease is related to class-wide scheduling. This is because of the short time period that the order has been in effect and the numerous other factors that could affect law enforcement reports of these analogues, including fentanyl-related substances.").

¹⁸ Report, App. IV at 51 n.73 (emphasis added); *see also*, *id.* at 62 ("Overall seizures of fentanyl and its analogues entering at U.S. ports of entry increased substantially from fiscal year 2018 through fiscal year 2020.") (emphasis added).

¹⁹ *Id.* at 16.

²⁰ Report, App. II at 31.

²¹ See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 (Testimony of Dr. Sandra D. Comer, Professor of Neurobiology (in Psychiatry), Columbia University Irving Medical Center, New York State Psychiatric Institute) (Jan. 28, 2020), <https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf>.

than fentanyl; others, like carfentanyl, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive.”²² There are already examples of the class-wide control’s overbreadth: the Report identifies specific substances that meet the criteria for class-wide control that have “little to no pharmacological potential for abuse,”²³ as does recent scientific research.²⁴

Under the class-wide control, any offense involving a fentanyl-related substance is subject to federal criminal prosecution, even if the substance in question has no potential for abuse. This approach would result in convictions for substances that may not have a psychoactive effect similar to fentanyl.²⁵ The Report minimizes these concerns and repeats the Department’s assertions that it will not prosecute individuals for substances that are not harmful.²⁶ But a careful reading of the Report also shows that these assurances cannot be credited: as acknowledged (in a footnote), after 2018, the government prosecuted cases involving benzyl fentanyl,²⁷ a substance long known to have no potential for abuse.²⁸ If class-wide scheduling becomes permanent, prosecutors will have no incentive to determine whether or not a substance has abuse potential. Nor are prosecutors

²² Kemp Chester, Assoc. Dir., Nat’l Heroin Coordination Grp., Off. of Nat’l Drug Control Pol’y, Response to Questions for the Record Following Hearing Entitled, *The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary* (June 4, 2019) at 3, <https://www.judiciary.senate.gov/imo/media/doc/Chester%20Responses%20to%20QFRs1.pdf>.

²³ Report, App. III (“[S]mall changes can produce substances with little to no pharmacological potential for abuse—as was found for two fentanyl analogues cited by DEA in the temporary scheduling order for fentanyl-related substances.”).

²⁴ Dr. Sandra D. Comer et. al., *Potential unintended consequences of class-wide drug scheduling based on chemical structure: A cautionary tale for fentanyl-related compounds*, *Drug and Alcohol Dependence*, 3 (2021), <https://www.sciencedirect.com/science/article/pii/S0376871621000259>.

²⁵ Report, App. IV at 57.

²⁶ *Id.* at 57 n.88.

²⁷ In 1985, the DEA temporarily placed benzyl fentanyl on Schedule I based on its structure, but later removed it from control after “further research found no evidence of abuse potential.” *Drug Enf’t Admin. Correction of Code of Federal Regulations: Removal of Temporary Listing of Benzylfentanyl and Thienylfentanyl as Controlled Substances*, 21 C.F.R. § 1308 (2010).. In 2019, DEA classified benzyl fentanyl as a “List I” chemical, meaning that it is an ingredient that can be used to create fentanyl analogues. *See Drug Enf’t Admin., Designation of Benzylfentanyl and 4-Anilino piperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 Federal Register 73 at 20822-20829, (April 15, 2020), https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0415.htm. In contrast to Schedule I fentanyl analogues, the potential sentences for distribution of List I chemicals are largely capped at five years. *See* 21 U.S.C. § 841(f)(1) (“Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall, except to the extent that paragraph (12), (13), or (14) of section 842(a) of this title applies, be fined under title 18 or imprisoned not more than 5 years, or both.”)

²⁸ Report, App. IV at 57 n.89 (“[R]epresentatives provided [the GAO] examples of at least three cases where individuals were prosecuted for the substance benzyl fentanyl which has no pharmacological effect. They stated that, in one instance, prosecutors sought the mandatory minimum associated with the charge”). The USSC Report confirms this, finding that after the 2018 temporary control, the government prosecuted “several cases involving . . . benzyl fentanyl.” *See* USSC Report at 23.

equipped to make such assessments, particularly for substances under class-wide control, which would be scheduled without gathering and reviewing scientific evidence.²⁹

The Report should highlight the implications of criminalizing substances with no potential for abuse.

IV. The Report minimizes concerns that fentanyl and fentanyl-analogue prosecutions would continue to target minimally-involved individuals and street-level dealers, an enforcement approach that exacerbates racial disparities and does not deter drug trafficking organizations.

We urge the GAO to devote further discussion and analysis to the fact that prosecutions for fentanyl analogues disproportionately target minimally-involved individuals and street-level dealers.³⁰ The evidence compiled in the Report and in a recently-published report by the United States Sentencing Commission shows that most enforcement efforts have targeted low-level individuals.³¹ And there is overwhelming evidence that incapacitating low-level individuals does not disincentivize drug trafficking organizations.³² Class-wide scheduling needs to be understood, and should be framed in the Report, as another failed effort to fight the war on drugs by prosecuting low-level individuals and punishing them with disproportionately long sentences.³³

The Report presently cabins these systemic concerns to a few sentences,³⁴ but devotes significant discussion to uncritically highlighting statements from law enforcement that “one of the goals of class-wide scheduling was to disincentivize drug trafficking organizations to invent new fentanyl-related substances to evade DEA’s control,” and that law enforcement’s goal is to “dismantle the entire organization.”³⁵ The Report also includes a potentially misleading note that “out of the eight cases we reviewed that were prosecuted under class-wide scheduling, four involved a defendant who was part of a larger drug trafficking organization.”³⁶ This characterization omits the fact, included

²⁹ See Report at 16 (“If fentanyl-related substances are legislatively scheduled without an Eight-Factor Analysis being conducted, the Eight-Factor Analysis needed for administratively rescheduling these substances could involve more evidence than was required for the initial legislative scheduling.”).

³⁰ *Id.*, Report, App. IV at 59.

³¹ See *id.* at 54; USSC Report at 28.

³² Nat’l Resch. Council, The Growth of Incarceration in the United States: Exploring Causes and Consequences 146 (Jeremy Travis et al. eds., 2014), http://nap.edu/catalog.php?record_id=18613; Pew, *More Imprisonment Does Not Reduce State Drug Problems*, (March 8, 2018), <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems>; USSC, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* 131 (2004), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-projects-and-surveys/miscellaneous/15-year-study/15_year_study_full.pdf, see also Butler Test. at 12-14.

³³ Butler Test. at 7.

³⁴ See *id.* at 19, Report, App. IV at 59.

³⁵ See, e.g., Report, App. IV at 59.

³⁶ *Id.*

elsewhere in the Report, that each of those four individuals was a street-level dealer, and that the government has not used class-wide scheduling to prosecute even one high-level importer, supplier, or drug kingpin.³⁷ Targeting street-level dealers for prosecution disproportionately impacts people of color, particularly Black Americans, all while failing to reduce the supply of or demand for illegal drugs.³⁸

V. The Interagency Working Group's ("Interagency Group") proposal would not address the criminal justice implications of class-wide scheduling.

The Report suggests that "fentanyl-related substances could be legislatively scheduled with modifications"³⁹ to the class-wide control, and points to recommendations made by an "interagency workgroup convened by ONDCP . . . such as removing barriers to obtaining approval to conduct research and streamlining the process for removing from Schedule I . . . substances discovered to have low abuse potential."⁴⁰ We request GAO include both in the Highlights and in the Report Defenders' concerns that the Interagency Group's proposal would not remediate the flawed enforcement-first approach embraced by class-wide control, would lead to lengthy sentences for trace amounts of fentanyl-related substances, and would exacerbate racial disparities in federal sentencing. The Interagency Group's proposal also does not relieve concerns that class-wide scheduling would criminalize substances with no potential for abuse. Although it would attempt to "streamlin[e] the process for removing from Schedule I [] substances discovered to have low abuse potential," de-scheduling would not vacate sentences imposed for such substances.⁴¹

The shortcomings in the Interagency Group's proposal may be the result of its failure to seek the views of Federal Public and Community Defenders or of the civil rights and criminal justice community. Similarly, the GAO did not seek these perspectives on the Interagency Group's Proposal. The Report should note that these critical voices were neither present during the creation of the Interagency Group recommendations nor were we given an opportunity to comment on the proposal through the Report.

³⁷ *Id.* at 54.

³⁸ Pew, *More Imprisonment Does Not Reduce State Drug Problems* (March 8, 2018), <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems>.

³⁹ Report, Highlights.

⁴⁰ *Id.*

⁴¹ See 1 U.S.C. § 109 (providing that if a statute is changed or repealed after a crime is committed, "it shall not have the effect to release or extinguish any penalty, forfeiture, or liability incurred under such statute").

We hope that the GAO will modify the Report to reflect our comments. We remain available to discuss our perspectives and experience on this issue as needed.

Sincerely,

/s/

David Patton
Executive Director, Federal Defenders of New York
Co-Chair, Federal Defender Legislative Committee

/s/

Jon Sands
Federal Public Defender for the
District of Arizona
Co-Chair, Federal Defender Legislative Committee



DAVE YOST
OHIO ATTORNEY GENERAL

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April 14, 2021

Honorable Anna Eshoo
Chairwoman

United States House Committee on Energy
& Commerce, Subcommittee on Health
272 Cannon House Office Building
Washington, D.C. 20515

Honorable Brett Guthrie
Ranking Member

United States House Committee on Energy
& Commerce, Subcommittee on Health
2434 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Eshoo & Representative Guthrie,

I write today to offer my strong support for H.R. 1910 and S. 339, companion legislation entitled the Federal Initiative to Guarantee Health by Targeting (FIGHT) Fentanyl Acts. As you are likely aware, the Drug Enforcement Agency's (DEA) temporary order classifying fentanyl-related compounds as Schedule I drugs is set to expire on May 6, 2021. This temporary order is already an extension of a previous emergency order that would have lapsed in February 2020. The FIGHT Fentanyl Acts would codify this temporary order, extending it permanently.

In the most recent data available from the Centers for Disease Control and Prevention, there were 71,000 drug-related deaths in the United States in 2019. Of those deaths, roughly 50% involved fentanyl or a fentanyl-related compound. In November 2019, a collaboration of local, state, and federal agencies working with my office intercepted over 20 kilograms of fentanyl, 1.5 kilograms of methamphetamine, and a half kilogram of heroin in Ohio. Further testing revealed that the 20 kilograms of fentanyl were laced with carfentanil, which can be over 100 times more potent than fentanyl.

I commend Senator Portman and Representative Chabot for their leadership in bringing forward this important legislation. There are many difficult, even impossible choices before you. This is not one of them, and may be the easiest task of your unenviable list. I urge you to pass H.R. 1910 and/or S. 339 before the DEA's temporary order expires.

I am happy to speak with you or any members of the Subcommittee at your convenience.

Yours,

Dave Yost
Ohio Attorney General

Representative Anna Eshoo & Representative Brett Guthrie
Re: H.R. 1910 and S. 339
April 12, 2021

p | 2

cc:	Honorable Rob Portman	Honorable Steve Chabot
	United States Senate	United States House of Representatives
	448 Russell Senate Office Building	2408 Rayburn House Office Building
	Washington, D.C. 20510	Washington, D.C. 20515



**Statement for the Record
Submitted to
U.S. House Committee on Energy and Commerce Subcommittee on Health
April 14, 2021
On Behalf of the American Academy of PAs**

On behalf of the approximately 150,000 PAs (physician assistants) in the United States, the American Academy of PAs (AAPA) welcomes the opportunity to submit a statement regarding the April 14, 2021, hearing held by the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health titled “An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America.”

AAPA thanks Chairwoman Eshoo and Ranking Member Guthrie of the subcommittee, along with Chairman Pallone and Ranking Member McMorris Rodgers of the full committee, for holding this important legislative hearing, and for continuing to shine a spotlight on an issue that impacts far too many individuals and communities in the United States.

AAPA also thanks all members of the subcommittee and the Representatives whose legislation will be examined today for their hard work and commitment to finding solutions for an epidemic that is impacting millions of Americans.

Strong Support for H.R. 2482, the Mainstreaming Addiction Treatment Act

AAPA thanks Representatives Paul Tonko and Michael Turner for their leadership in reintroducing H.R. 1384, the Mainstreaming Addiction Treatment Act of 2021.

The Mainstreaming Addiction Treatment Act would eliminate the current buprenorphine waiver program, allowing providers who are already authorized to prescribe buprenorphine for non-MAT purposes to meet a growing and unmet need for OUD treatment. AAPA supports removing non-evidence-based restrictions on MAT so that more providers are able to deliver MAT to the patients who need it.

PAs are currently eligible to apply for a waiver from the Drug Enforcement Agency (DEA) to prescribe buprenorphine for the purpose of providing medication assisted treatment (MAT) medication for the treatment of opioid use disorder (OUD). To date, more than 3,900 PAs have obtained a waiver under this program. While the waiver program is making significant strides to improve access to treatment, it contains several requirements which are limiting its impact on alleviating the crisis, including the imposition of uneven educational requirements on different types of qualified providers. Under the existing program physicians are only required to complete 8 hours of training, while PAs and nurse practitioners (NPs) are required to complete 24 hours of training. This discrepancy is not based on science or best medical practice but was arbitrarily included at the creation of the waiver program. Unnecessary and excessive training requirements such as this are a barrier for many PAs working in areas facing a lack of access to addiction treatment, and needlessly restricts access to lifesaving treatment for OUD.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 authorized a five-year program for PAs and NPs to obtain a DEA waiver to prescribe buprenorphine for the purpose of providing MAT for the treatment of OUD. This waiver program was made permanent in 2018 with the passage of the SUPPORT Act, and further expanded the types of providers eligible to prescribe buprenorphine by creating a five-year authorization for certified nurse-midwives, clinical nurse specialists, and nurse anesthetists to receive a waiver.

AAPA worked with Representative Tonko, the leadership of the House Committee on Energy and Commerce, and other Congressional champions on the creation of this waiver program, and continues to work with Representatives Tonko and Turner, along with many others, in order to ensure that more patients who suffer from OUD are able to access this lifesaving treatment.

Views on H.R. 2067, the Medication Access and Training Expansion Act

AAPA appreciates the intent of H.R. 2067, ensuring that all prescribers of controlled medications are properly educated on the proper use of opioids and their potential for misuse and abuse. However, AAPA continues to have concerns with creating additional mandatory federal requirements for prescriber education and training given that PAs already face robust educational requirements to earn their degree and maintain their professional certification.

H.R. 2067 would require all healthcare providers to complete a one-time educational program in order to procure or renew a Drug Enforcement Administration (DEA) license authorizing them to prescribe controlled medications. Placing this additional burden on all PAs seeking to obtain or renew a DEA license to prescribe control substances, a requirement for many jobs, has the potential to create disruption for practitioners and patients.

Additionally, PAs currently receive a significant amount of education about prescribing controlled medication, both in their original education and training and because PAs are required to complete over 100 hours of continuing medical education (CME) every two years in order to maintain national certification. CME regarding proper prescribing practices for opioids, and how to recognize OUD, are widely available for PAs to utilize.

AAPA appreciates that Representative Trahan listened to concerns from non-MD/DO providers about this legislation in the 116th Congress and made the requirement the same for all providers, an improvement over requiring varying amounts of training for different health professions.

While AAPA strongly supports and encourages efforts to expand educational opportunities for prescribers, educational and training requirements have a history of being addressed at the state level. We urge policy makers to work to prevent practitioners from being required to navigate a confusing patchwork of state and federal requirements.

PA Background

PAs are one of three types of health care professionals, including physicians and advanced practice registered nurses, who are recognized by the Medicare program to provide primary medical care in the United States. PAs are state-licensed, nationally certified medical professionals. As highly educated and trained medical providers licensed in all 50 states, the District of Columbia, all US territories, and the

uniformed services, PAs diagnose illness, develop and manage treatment plans, often serve as a patient's principal healthcare provider, and prescribe medications.

PAs are authorized to prescribe controlled medications in all 50 states. Once granted, no state has ever rescinded PA authority to prescribe controlled medications. There has been no record of increased liability or malpractice claims due to PA prescribing of scheduled drugs, and professional liability insurers have not increased premiums when PAs have been granted authority to prescribe controlled medications.

PA education is modeled on the curriculum used in medical schools. The average length of PA education programs is 27 months, approximately three academic years, with at least 2,000 hours of supervised clinical practice by graduation. All PA educational programs have pharmacology courses; nationally, the average amount of formal classroom instruction in pharmacology is 75 hours. This does not include instruction in pharmacology that students receive during clinical medicine coursework and clinical rotations. National education accreditation standards require PA programs to include instruction in pharmacology and pharmacotherapeutics and their application in clinical practice. Knowledge of pharmacology and appropriate drug utilization are also areas of practice tested on the national certifying examination, which is required for licensure.

AAPA appreciates the important work being done in Congress, as well as all the relevant federal agencies, to combat the opioid epidemic in the United States. Far too many people in the United States are suffering from OUD and a lack of treatment options, on top of the ongoing COVID-19 pandemic. PAs play a vital role in ensuring that these patients are able to access treatment services.

AAPA is committed to working with Congress and all relevant federal agencies to improve access to healthcare in the United States. Thank you for the opportunity to submit a statement for the record on this important issue, and please do not hesitate to contact Tate Heuer, AAPA Vice President, Federal Advocacy, at (571) 319-4338 or theuer@aapa.org with any questions.



April 14, 2021

The Honorable Anna Eshoo
Chair
Health Subcommittee
House Committee on Energy & Commerce
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
Health Subcommittee
House Committee on Energy & Commerce
Washington, DC 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie:

I am writing on behalf of the American Psychological Association (APA) to express our support for your subcommittee's work in considering legislation to address the worsening drug overdose epidemic as part of its April 14th hearing entitled "An Epidemic within a Pandemic: Understanding Substance use and Misuse in America."

APA is the nation's largest scientific and professional nonprofit membership organization representing the discipline and profession of psychology. APA has more than 122,000 members and associates who are clinicians, researchers, educators, consultants, and students. Through the application of psychological science and practice, our association's mission is to make a positive impact on critical societal issues.

The CDC projects that there were more than 88,000 drug overdose deaths over the previous 12 months ending in August of 2020, an astounding 26.8% increase over the August 2019 figure.¹ The nation will likely have experienced a drug overdose death toll of more than 100,000 Americans over the course of 2020. The CDC's data shows that opioids, and especially fentanyl, continue to account for the bulk of overdose deaths. However, overdose deaths associated with the use of psychostimulants such as methamphetamine increased by 46% over the previous year. CDC's data also showed that overdose deaths attributable to the use of methamphetamine and other psychostimulants have been occurring in the American Indian/Alaska Native population at more than twice the rate of any other racial groups.² APA's latest *Stress in America* report³ found that nearly one in four adults reported drinking more alcohol to cope with their stress during the coronavirus pandemic.

We must respond aggressively to address this mounting crisis, and we applaud your committee and its members in considering legislation on multiple policy issues. We would like to express our particular support for several bills to be discussed in the hearing.

- H.R. 654, the "Drug Free Communities Pandemic Relief Act". Communities vary widely in the nature of the drug overdose and substance use problems they face. The Drug Free Communities program incentivizes and supports communities in establishing their own programs. In the current crisis, and with sharply rising drug overdose deaths, we support waiving the program's local matching requirement in order to maintain support for community-led programs.
- H.R. 955, the "Medicaid Reentry Act of 2021". APA has long supported this legislation and we are hopeful that it can be enacted this year. Providing health care services to inmates under Medicaid for the 30-day period prior to their release will improve the ability of inmates with substance use disorders to avoid relapse upon leaving prison.

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- H.R. 1384, the “Mainstreaming Addiction Treatment Act of 2021”. The current law requirement that prescribing providers obtain a waiver from the Drug Enforcement Agency (DEA) before prescribing buprenorphine for the treatment of substance use disorders is unnecessary and counterproductive, and serves as a barrier an important component of treatment for opioid use disorders.
- H.R. 2051, the “Methamphetamine Response Act of 2021”. As the CDC data referenced above shows, drug overdose deaths associated with methamphetamine use are rising sharply. Contingency management—a behavioral treatment developed by psychologists—is currently the only effective treatment for methamphetamine and cocaine use disorders, in addition to being an effective component of treatment for other substance use disorders. We strongly support the inclusion by the Office of National Drug Control Policy of initiatives to identify and address policy barriers related to contingency management interventions for stimulant use disorders, and to explore reimbursement for contingency management and digital treatments for substance use disorders, in its recent statement of drug policy priorities for this year.
- H.R. 2366, the “Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021”. This legislation includes a wide array of initiatives to combat the drug overdose epidemic. We particularly endorse its provisions to study overdose prevention centers and establish harm reduction programs, to eliminate the requirement that an individual be addicted for at least one year before being admitted for maintenance treatment by an opioid treatment program, and to develop and implement contingency management programs. These are long overdue changes in our nation’s drug policy, and are consistent with the public health approach—in which substance use disorders are treated as a health condition, not a personal failing—which is necessary to stem the tide of overdose deaths. The most recent data from the Centers for Disease Control and Prevention (CDC) shows stunning increases in drug overdose deaths. APA’s most recent *Stress in America* report, released in March, found that nearly one in four U.S. adults reported drinking more alcohol to cope with their stress during the coronavirus pandemic.

Thank you for your leadership in continuing to improve our nation’s substance use treatment system, and for the opportunity to share comments. We look forward to working with you and your committee’s members on this vitally important issue.

Sincerely,



Katherine McGuire
Chief Advocacy Officer

ⁱ Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021. Accessed at <https://cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

ⁱⁱ Volkow, N. National Institute on Drug Abuse, 2021. “U.S. Overdose Deaths Involving Psychostimulants (Mostly Amphetamine), by Race” [Powerpoint presentation]. Accessed at <https://www.apa.org/members/content/methamphetamine-addiction>

ⁱⁱⁱ <https://www.apa.org/news/press/releases/stress/2021/sia-pandemic-report.pdf>



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April 14, 2021

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House Committee on Education and Labor
Subcommittee on Health
(The Honorable Anna G. Eshoo, Chairwoman)

"An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America."

Testimony Submitted for the Hearing Record

Madame Chairwoman and members of the Subcommittee, it is an honor to present this written statement for this morning's necessary hearing. You are to be commended for scheduling today's proceedings.

Released this past Friday, the President's FY 2022 budget proposals include significant funds to address this crisis, in addition to the funds in the American Rescue Plan, which makes today's hearing even more timely.

Founded in 1994, SMART Recovery is a global community of well over 3,500 mutual support groups, more than 2,300 in the United States alone, with a substantial number online during the ongoing COVID-19 pandemic. Our website receives nearly 2 million unique visitors a year. SMART's mission is to help individuals overcome any addiction, and to support their families and friends. SMART Recovery is a 501(c)(3) nonprofit organization composed almost entirely of volunteers.

SMART, which stands for Self-Management and Recovery Training, provides this help at free weekly meetings. We use a self-empowering, evidence-based approach based on principles and practices from the cognitive and motivational therapies most widely used in treatment.

To the maximum extent we can, we provide support to the fast-growing number of people with opioid use disorder; SMART Recovery meetings provide stigma-free support to individuals undergoing medication-assisted treatment (MAT). Due to our scientific orientation, SMART has always accepted the use of medications prescribed to treat behavioral health concerns and assist in addiction recovery.



As we all know, the addiction crisis, including the opioid epidemic, is years away from being resolved, even with billions of dollars in appropriations and passage of well-intentioned authorizing legislation. The novel coronavirus pandemic has made this crisis much worse for many reasons, including isolation, increased mental health problems, and reduced access to healthcare. Living alone, people who overdose on opioids cannot be rescued by drugs such as naloxone, which must be administered within minutes after they lose consciousness.

In 2019, drug overdose deaths numbered 72,000, a near-record high, according to the CDC National Center for Health Statistics (<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>). The 12-month provisional count through May 2020 was already 82,000 and up to 88,000 through August. At this rate, the final figure for 2020 could have totaled as high as 100,000—a 38% spike in one year. Opioids cause two-thirds of overdose deaths.

The many causes of this healthcare crisis have created for the foreseeable future a grisly new normal for the many people who need help, including the more than 20 million Americans suffering from substance use disorders and the much larger number of family members and friends who care for them.

We witness this suffering firsthand at SMART Recovery meetings, including online meetings. It is disheartening, overwhelming, and unconscionable. In the addiction epidemic, we are not facing a healthcare crisis that lacks proven solutions. Serving on the Board of SMART Recovery International, I see that only the United States has an opioid crisis of this magnitude. Many other countries have prevented or ended such epidemics through the widespread use of medications such as methadone and buprenorphine that protect people from fatal overdoses while they recover with the help of therapy and mutual support groups.

Addiction is not Stage 4 cancer, advanced heart disease, or kidney failure, the severe illnesses that took my wife a few years ago. We know how to treat addictions with many medications, therapies, and support from mutual aid groups. People can recover with such treatment. Among the problems in this country are the shortage of treatment and resistance to life-saving medications in many areas.

The Federal government must expand access to affordable treatment across America significantly and ensure that providers use proven measures. Existing and even proposed funding levels are well below what is needed. We are not giving nearly enough attention to ensure that everyone in need receives the best care, including ready access to needed medications, high-quality behavioral healthcare, and ongoing peer support and mutual aid meetings that expressly endorse (rather than work at cross-purposes with) medication-assisted treatment.

This Subcommittee has been among the leaders in the fight to address this public health crisis. This Subcommittee has developed many important laws and supported their implementation. However, we urge Congress to take more aggressive action to reverse the course of this epidemic so we may begin to end it. The bills on the agenda for today's hearing are examples of what can be enacted. We want to call your attention to (and recommend) the following:

H.R. 1384 (the Mainstreaming Addiction Treatment Act of 2021) and H.R. 2067 (the Medication Access and Training Expansion Act of 2021), which must be enacted in tandem to make life-saving medication-assisted treatment widely available,

H.R. 955 (the Medicaid Reentry Act),

H.R. 2366 (the Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021),

SMART Recovery USA, Inc.
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H.R. 2051 (the Methamphetamine Response Act),

and

H.R. 2379 (the State Opioid Response Grant Authorization Act of 2021, about which I will share some observations shortly.

Medication-assisted treatment combined with psychosocial therapies and community-based mutual support groups is the “gold standard” for treating people with opioid use disorders. This standard is recognized by every major health organization, including SAMHSA, the U.S. Surgeon General, and World Health Organization.

SMART is the largest community-based recovery support program that expressly and affirmatively supports MAT and behavioral healthcare. Better known support organizations have not expressed support, and people undergoing such treatment often cannot find the help they need.

Among all of the important bills supported by the Subcommittee on this morning’s agenda, I call your attention to H.R. 2379, the proposed State Opioid Response Grant Reauthorization Act, and, as stated above, a bill whose enactment we strongly recommend.

When the bill is marked up, the text should be refined slightly in ways that all could strongly endorse. We respectfully recommend that any funds provided under this program be made pursuant to requirements that grantees use best practices and evidence-based approaches for prevention, treatment, and care.

To that end, language should be added where appropriate to require (among whatever other activities or services for which grant funds are used) that States, Indian Tribes, and populations served by Tribal organizations and Urban Indian organizations take steps to:

- 1) make medication-assisted treatment widely available,
- 2) make behavioral health care widely available; and
- 3) ensure that provision is made for evidence-based, self-empowering, mutual aid recovery support meetings that expressly support medication-assisted treatment.

The only peer support available in numerous communities is meetings whose attendees are told that MAT is “a poor choice,” that prescribers are misguided, and that people on MAT cannot participate and must stop taking these medications to become “clean,” advice that, if followed, could kill them if they relapse. The failure to provide this component of the “gold standard” increases the risk of relapse and overdose, which results in still higher-cost care. The budgetary outlays required to address the opioid crisis (and to help the large number of individuals with stimulant-use disorders) would be even higher if grant recipients were not required to ensure the availability of peer support meetings that work synergistically with MAT and behavioral health therapies.

As you know, under current grant programs, recipients can use some of their funds to foster the development of such meetings. Thus far, the States of Connecticut and Ohio have done so, and the Joint Explanatory Statement of the Managers accompanying the FY 2020 and FY 2021 Labor, HHS, Education and Related Agencies Appropriations legislation included the following language:

Treatment Assistance for Localities. The agreement recognizes the use of peer recovery specialists and mutual aid recovery programs that support MAT and encourages SAMHSA to support these activities as applicable in its current grant programs.



When H.R. 2379 is back before the Energy and Commerce Committee, including legislative language along the lines mentioned above would lessen the need for such report language through the appropriations process every year.

As we read the text of H.R. 2379, the list of eligible activities is wholly discretionary, and we do recognize that State governments and other eligible grantees should be given flexibility, in large part because they are closer to seeing how the crisis affects their communities. However, given that the funds available under this program (like any other Federal block grant program) are limited, it should not be controversial to ask that grantees use the funds consistent with best practices and in ways that ensure people receive the best possible care.

Thank you again for the opportunity to submit this statement. At SMART Recovery, we stand ready to help you address this crisis in every way we can. We look forward to answering any questions and provide any additional information.

Dear Subcommittee on Health of the Committee on Energy and Commerce,,

I write to submit t a statement for the record concerning the Subcommittee on Health of the Committee on Energy and Commerce legislative hearing on April 14, 2021, entitled "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America." Thank you for holding such an important hearling

On march 8th of 2021 marked 3 years since I was standing on Elliot Street in Brattleboro and I received a phone call from my nephew, Kaya Siegel's boss at work, letting me know that he had been found dead in the bathroom at work after an overdose. It marked 3 years since I fell to the pavement in a snow storm and experienced the cruelest loss of a child who's upbringing I was a part of. It marked 3 years since I had to call his mama and tell her that her baby had died after a year in recovery. And this was just over 20 years after his papa and my brother, Johnathon Siegel, died also while using Heroin when I was 19 years old. Three years ago on March 7th of 2018, I decided for sure that I would run for Governor of Vermont and the very next day on March 8th of 2018, my family had our world turned upside down by the preventable death of my nephew.

Throughout Kaya's life there were enormous barriers to accessing treatment in Vermont. Providers have to jump hoops to prescribe the life saving medication Buprenorphine and therefore those providers are few and far between. Syringe services are not available in all rural communities and therefor infection and Hepatitis C and HIV grow in our communities. Insurance does not cover all in or out patient treatment and therefor treatment is not always available or accessible. There are more barriers then I can name. Families and individuals struggling are left without the tools that they need to save their loved ones.

Right now Vermont is reaching 3 in 10 people, which means that 70% of people are falling through the cracks in my home state. We saw the depth of the problem in 2020 our preliminary numbers show that deaths increased 38% in Vermont. The numbers will only increase when the number of deaths are finalized. Our neighbors and community members who suffer from Substance Use Disorder make up one of the most vulnerable populations in our country, and they were not meaningfully included in the COVID response. We also saw this with people suffering from Mental Illness. We are in a Pandemic and there is a population whom we had not supported enough over the years and who were not provided the resources to weather this storm. In June of 2020, we learned that there had been a 30% increase in overdose deaths in Vermont, compared to the

previous year. We knew across the country that this crisis, the overdose crisis, was getting worse, we did not act in a way that would have meaningful impact. In 2020 in Vermont more people died due to an Opioid related death, than COVID, yet public health measures for this population were not taken. There are federal actions needed for our states to be able to take those measures.

Among the people who have lost their life since the start of the pandemic, included my life long family friend, Roy Krause, and so many others. Roy Krause had also been in recovery for some time and like so many in this last year, suffered a recurrence and died as a result. It is not a fluke that our loved ones are dying all around us, this is a population who needed more tools to survive and we did not give them to them. Our deaths in 2020 were astronomical across the country. Every life lost is another preventable death. Another family experiencing trauma that they did not have to. Another human being who died because our system failed them. Our system is people made and it can be people fixed.

We have to put harm reduction first. Harm reduction IS COVID relief. It should be included in COVID relief. Harm reduction is what is needed in this moment more than ever. We must have treatment on demand, including medically assisted treatment on demand, dual diagnosis support and criminal justice reform.

It is time to take aim at the systemic barriers to saving lives, meticulously using the science and information available from Lived Experience Experts to restructure how our country responds to this crisis. Federally there is some legislation that will help support this work to heal the crisis. We need to end the ban on federal funds to purchase syringes and other supplies. We must lean away from extending mandatory minimums for Fentanyl and remove the X Waiver.

The MAT act is a bipartisan solution that will which eliminate the redundant and outdated requirement that practitioners apply for a separate waiver through the Drug Enforcement Administration (DEA) to prescribe buprenorphine as well as participate in outdated training. Training that PCPs do not need to prescribe an Opioid like Oxycontin. This barrier means that our children, when they are struggling can not easily access the medication necessary to save their lives. In Vermont some people have to make a three hour round trip every single day to receive treatment. That means if they have children, a job, lack of transportation or a number of other barriers, then they will not be able to get the treatment that

they need. The MAT act puts the decisions about treatment and health care back into the doctor and the patient. It will support more sustained recovery and will make our communities stronger. Most importantly it will save lives.

Additionally, while I understand that it can be tempting to lean in to a mandatory minimum for Fentanyl, it is really harming the same people that you are trying to help. Most often those impacted by this are People Of Color and low income folks that really are struggling with Opioid Use Disorder. They may be being trafficked or left without any tools to access the treatment that they need. The mandatory minimums in fact further criminalizes this health care issue as oppose to moving away from the drug war and toward what science and Lived Experience Experts tell us about this disease.

Finally, I am grateful to see you taking up this important issue. It has been painful as a family member who has lost two loved ones to watch years upon years go by without meaningful legislation that will support the healing of our communities. You have an excellent piece of legislation before you in the MAT Act, that will save lives. That is exactly the right course correction that is needed right now as across the country we see deaths rise so astoundingly. I write you asking you to take action now on this disease because once our family members die, we do not get them back.



April 14, 2021

The Honorable Anna Eshoo
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee on Health:

My name is Jeffrey A. Singer. I am a Senior Fellow in Health Policy Studies at the Cato Institute. I am also a medical doctor specializing in general surgery and have been practicing that specialty in Phoenix, Arizona for over 35 years. I would like to thank the Subcommittee on Health for convening a hearing on Wednesday, April 14, 2021 on "An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America." I appreciate this opportunity to provide my perspective, as a health care practitioner and policy analyst, to assist this committee with its assessment of the current state of substance use and misuse in the United States.

The COVID-19 pandemic has diverted the nation's attention away from an overdose epidemic that was raging long before the appearance of the deadly virus and has accelerated during the viral pandemic. The Centers for Disease Control and Prevention reported last December that, after a brief pause in 2018, the overdose rate increased during 2019 by more than 5 percent to a total of 70,630. Overdose deaths due to opioids of any kind increased from roughly 47,000 to over 50,000, representing an increase of more than 6 percent. But illicit fentanyl and its analogs comprised more than 36,000 of all opioid overdose deaths, an increase of nearly 16 percent over one year, while heroin was responsible for approximately 14,000 (a roughly 7 percent decrease) and prescription opioids were found in just under 12,000 overdose deaths, representing a decrease of more than 7 percent. Methadone was found in a little more than 2,700 overdoses, a decrease of more than 10 percent. Perhaps even more alarming was that deaths due to psychostimulants such as methamphetamine and cocaine increased to historically high levels of more than 16,000, representing a nearly 24 percent jump in just one year.¹

Now a study from the Commonwealth Fund suggests that overdose deaths may have increased by more than 27 percent in 2020, the year of the pandemic, to roughly 90,000 with opioids comprising 75 percent of overdose deaths and fentanyl and its analogs involved in 80 percent of opioid overdoses.²

All of this is occurring in the presence of a “war on drugs” that was declared by President Richard Nixon over 50 years ago and a “cold war” on prescription opioids that commenced over a decade ago.

Unfortunately, much of the nation’s current policy rests on the mistaken narrative that the overdose crisis is largely the result of doctors overprescribing pain medications to their patients, creating a population of opioid addicts.

However, data provided by the CDC and the National Survey on Drug Use and Health, and reported in the peer-reviewed literature, clearly show there is no correlation between number of opioid prescriptions and the non-medical use of prescription opioids or opioid use disorder among persons age 12 and over. During a 12-year period when prescription volume doubled, non-medical use and opioid use disorder rates remained essentially unchanged.³ A study published in 2018 by public health researchers at Johns Hopkins and Harvard Universities reported on 568,000 “opioid naïve” patients prescribed prescription opioids for postoperative pain between 2008 and 2016 and found a total opioid misuse rate of 0.6 percent.⁴ A study reported in the November 2019 *Annals of Emergency Medicine* found that only 1 percent of emergency department patients prescribed opioids for pain had “persistent use” of opioids six months later, and 80 percent of those were still suffering from their painful condition at the time.⁵ And a study reported last month by researchers at Case Western Reserve University, University of Alabama at Birmingham, and American University of Antigua College of Medicine found that opioid morphine equivalent doses “did not show a statistically significant relationship with injury-related mortality, including with any subgroups of unintentional deaths, suicides, and homicides” in trauma patients.⁶

To be sure, the stress and isolation associated with the COVID-19 pandemic has increased substance use in general, and has made overcoming addiction more difficult, as evidence suggests that connectedness is crucial in the treatment of substance use disorder. Furthermore, interruptions or disruptions in rehabilitation programs and access to Medication Assisted Treatment for opioid use disorder have likely contributed to the rise in overdoses in 2020.

But in fact, as researchers at the University of Pittsburgh School of Public Health pointed out in 2018, the overdose crisis has been on a steady, exponential increase since at least the late 1970s, with different drugs dominating at any particular point in time.⁷ An NBC News reporter covering the study stated, “It [the overdose crisis] started before the availability of synthetic opioids and may have only a little to do with the prescribing habits of doctors or the pushy habits of drugmakers, the team at the University of Pittsburgh found.”⁸ The researchers suggested that the overdose crisis may be driven by “an ongoing longer-term process” which may involve sociocultural dynamics. This suggestion helps explain why Cicero, et al of Washington University in St. Louis reported in November 2017 that more than 33 percent of heroin addicts entering rehab programs stated that their gateway drug—the drug with which they initiated drug use—was heroin, as opposed to just under 9 percent who initiated with heroin ten years earlier.⁹

Despite these findings, the bulk of public policy is aimed at reducing the number of opioids that physicians prescribe for their patients in pain. The CDC reports that total opioids prescribed per 100 persons peaked in the year 2012 and has decreased by 43 percent between 2012 and 2019 to a 14-year low.¹⁰ Reports of chronic pain patients being cut off abruptly from their prescription opioids and desperately turning to the black market for relief or, even worse, to suicide, abound in the press.¹¹ Meanwhile, as the black market supply of diverted prescription opioids diminished starting around 2010, the proportion of overdose deaths attributable to diverted prescription opioids stabilized and then decreased while deaths due to, first, heroin, and later fentanyl began to rise as these drugs filled the void. And the overdose epidemic continues apace.

The ascendancy of fentanyl and the resurgence of methamphetamine-related deaths 15 years after Congress passed the Combat Methamphetamine Epidemic Act of 2005 should come as no surprise to those familiar with what has come to be called “The Iron Law of Prohibition,” an application of what economists call the Alchian-Allen Effect.¹² Put simply, as law enforcement increases, the potency of the drug increases. As the term’s author, Richard Cowan puts it, “the harder the enforcement, the harder the drugs.”¹³ When drugs are prohibited, they will be produced in more concentrated forms because they offer better efficiency by taking up less room in storage, less weight in transportation, and can be subdivided into smaller portions to generate more money. During alcohol prohibition, whiskey and other potent liquors were smuggled rather than beer or wine. Likewise, when people “tailgate” at football games, they drink beer or wine—but when they enter the stadium where it is not permitted to bring in alcohol, they tend to sneak in the “hard stuff.”

The Iron Law of Prohibition explains the popularity that fentanyl and its analogs have with drug dealers: it is easily made in clandestine labs and mixed with heroin to increase its potency and reduce the size and weight needed to smuggle heroin across the border. Fentanyl is also smuggled across the border where it can be mixed with cocaine or methamphetamine (a preferred combination of people who like to “speedball”) or pressed into counterfeit prescription pain pills. Restrictions to movement and travel arising from the COVID-19 pandemic have disrupted the supply chain for heroin. This has increased the utility of fentanyl and may be contributing to its predominance among the drugs causing overdose deaths.¹⁴

The Iron Law of Prohibition also explains why drug cartels have found more efficient means of producing more concentrated forms of methamphetamine, using substrates such as phenyl-2-propanone (“P2P”) instead of relying on diverted over-the-counter Sudafed. Meanwhile, nasal congestion and allergy sufferers find it more difficult and inconvenient to obtain Sudafed, a very effective decongestant, which is behind-the-counter and controlled in most states, and prescription-only in Oregon and Mississippi.

I implore this Subcommittee to avoid attempts to “double down” on the policies that are clearly not reducing overdose deaths but are causing harm to innocent patients suffering from pain while making non-medical drug use even more dangerous and deadly.

Policy should avoid further attempts to codify the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain*.¹⁵ It must be stressed that the guidelines were never intended to be prescriptive, but rather suggestive. In fact, the authors of the guideline made clear that most of the recommendations were based on “Type 4 evidence,” which was defined as evidence “in which one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect.”

The misinterpretation and misapplication of the 2016 CDC guidelines by lawmakers, insurance plans, pharmacies, and some practitioners caused the CDC to issue an advisory letter in 2019, urging against the guideline’s misinterpretation and misapplication.¹⁶ The guideline has come under criticism from multiple addiction and pain management specialists.¹⁷ In June of 2020, Dr. James L. Madara of the American Medical Association wrote Dr. Deborah Dowell, the Chief Medical Officer of the CDC, stating that “patients experiencing pain should be treated as individuals, not according to one-size-fits-all algorithms and policies that do not take individual patient’s needs into account.” The letter went on: “Early on, the AMA feared that the arbitrary opioid analgesic dosage and quantity thresholds appearing in the CDC Guideline would cause unintended consequences when used to severely limit individual treatment decisions made by physicians...”¹⁸

The heavy reliance on Morphine Milligram Equivalent (MME) dosage to regulate prescribing has also come under heavy criticism from pharmacologists and pain specialists.¹⁹ This reliance ignores the substantial genetic differences in drug metabolism between individuals. For example, the levels of the two primary enzymes that metabolize opioids can differ by 100-fold from one person to another, so the same dose of an opioid can be too low for a 100-pound woman and too high for a 250-pound man.²⁰

We have seen during this pandemic how quickly our state of knowledge changes as more information about transmission, replication, and how to protect against the COVID-19 virus evolves. This applies as well to the state of knowledge that existed about the overdose epidemic when the CDC published its guideline in 2016. It would be unwise to codify a guideline that, at the time was admittedly based largely on Type 4 evidence, and is now 5 years old.

The 2016 Guideline recognized that one size does not fit all, and that individual context matters—which is why it was offered for consideration as a “rule of thumb” as opposed to absolute instructions. Codifying guidelines has the effect of casting them in stone. It makes nuance impossible. It incentivizes law enforcement agencies to view any deviation from the guidelines as a legal transgression and, as a result, frightens practitioners into abiding by guidelines at the expense of their best medical judgment.

I urge this Subcommittee to focus its efforts on harm reduction rather than on further punitive and restrictive measures.²¹ One measure to consider is to require the Food and Drug Administration to reclassify the opioid antidote naloxone as over-the-counter.²² The FDA has expressed a willingness to do so, but has been too deferential to the naloxone manufacturers, who may benefit financially by being able to charge higher prices to third-party payers because of naloxone’s prescription requirement.²³

Medication Assisted Treatment (MAT) with methadone or buprenorphine has been shown to be the only form of addiction rehabilitation to be associated with reduced overdose and opioid-related morbidity, when compared to opioid antagonist therapy (naltrexone), inpatient treatment, and intensive outpatient behavioral therapies, according to recent research reported in the *Journal of the American Medical Association*.²⁴ Yet because of the onerous requirement that practitioners get an “X-waiver” on their narcotics license from the Drug Enforcement Administration, only about 7 percent of practitioners are prescribing buprenorphine MAT. Furthermore, restrictions on the number of patients a practitioner may treat at any given time, along with restrictions on non-physicians engaging in buprenorphine MAT make matters worse. Congress should remove the X-waiver requirement. In the previous Congress this idea had bipartisan support.²⁵

In addition, Congress should consider legislation to deregulate methadone treatment programs in order to allow outpatient prescription by primary care providers in an ambulatory setting. Methadone has been prescribed by primary care providers to treat addiction in Canada since 1963, in the U.K. since 1968, and in Australia since 1970.²⁶ A pilot program was undertaken with success by researchers at Boston University in conjunction with the Massachusetts Department of Public Health and reported in the *New England Journal of Medicine*.²⁷ A report last year by the National Academy of Sciences, Engineering, and Medicine also argued for allowing methadone treatment to be prescribed in primary care settings.²⁸

Ordinarily, patients enrolled in methadone treatment programs must take the methadone—usually in liquid form—in the presence of treatment clinic staff. This implies distrust and reinforces the stigma attached to substance use disorder patients. It also makes compliance difficult. As an emergency measure to address the needs for isolation during the pandemic, the Substance Abuse and Mental Health Services Administration announced it will allow methadone clinics to dispense up to 28 days of take-home medication to patients.²⁹ Codifying that temporary administrative decision would be a step in the right direction.³⁰

Congress should repeal the so-called “Crack House Statute,” which stands in the way of cities that wish to establish Safe Consumption Sites, operating in over 120 locations in the developed world, including neighboring Canada, and proven since the early 1990s to be effective in reducing overdose deaths, blood-borne infectious diseases, and in bringing more people who suffer from substance use disorder into treatment.³¹

The previous administration encouraged the proliferation of syringe services programs, also known as “needle exchange programs,” and this should continue. Unfortunately, many states have drug paraphernalia laws that stand in the way of the development of this federally legal and highly effective means of harm reduction. These same laws prevent the distribution of fentanyl test strips to opioid and psychostimulant users as well as operation of anonymous drug testing drop-off sites by harm reduction organizations.³²

Finally, Congress should de-schedule marijuana. Among other benefits, this will facilitate research into the potential benefits of cannabis as a substitute for opioids in the treatment of pain as well as a potential adjunct in Medication Assisted Treatment.³³

If Congress wishes to prevent a gathering tsunami of drug overdose deaths, it should end its focus on the number of pain pills practitioners prescribe to their patients. Instead, Congress should pivot to measures aimed at reducing harm to non-medical users who access increasingly dangerous drugs on the black market fueled by drug prohibition.

Respectfully submitted,

/s/

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¹ <https://www.cdc.gov/nchs/products/databriefs/db394.htm>

² https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward?utm_campaign=wp_the_health_202&utm_medium=email&utm_source=newsletter&wpisrc=nl_health202

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/>

⁴ <https://www.bmj.com/content/360/bmj.j5790>

⁵ <https://www.bmj.com/content/360/bmj.j5790>

⁶ <https://pubmed.ncbi.nlm.nih.gov/33814132/>

⁷ <http://science.sciencemag.org/content/361/6408/eaau1184>

⁸ <https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-crisis-started-40-years-ago-report-argues-n911456>

⁹ <https://pubmed.ncbi.nlm.nih.gov/28582659/>

- ¹⁰ <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>
- ¹¹ <https://www.cincinnati.com/story/news/2019/10/24/opioid-crisis-doctors-pain-pill-subscription-report/4012269002/> ; see also <https://www.foxnews.com/health/as-opioids-become-taboo-doctors-taper-down-or-abandon-pain-patients-driving-many-to-suicide>
- ¹² <https://web.archive.org/web/20131229232307/http://www.cato.org/pubs/pas/pa-157.html> ; see also <https://journals.sagepub.com/doi/10.1177/002204269802800309>
- ¹³ Cowan, Richard (December 5, 1986). "How the Narcs Created Crack: A War Against Ourselves." *National Review*. **38** (23): 26-34
- ¹⁴ <https://www.unodc.org/documents/data-and-analysis/covid/Covid-19-and-drug-supply-chain-Mai2020.pdf>
- ¹⁵ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>
- ¹⁶ <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>
- ¹⁷ <https://www.cato.org/blog/multiple-distinguished-health-care-practitioners-speak-out-against-our-misguided-opioid-policy>
- ¹⁸ <https://searchf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-6-16-Letter-to-Dowell-re-Opioid-Rx-Guideline.pdf>
- ¹⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5739114/>
- ²⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3580761/>
- ²¹ <https://www.cato.org/policy-analysis/harm-reduction-shifting-war-drugs-war-drug-related-deaths>
- ²² <https://reason.com/2018/04/27/to-combat-opioid-abuse-the-surgeon-general/>
- ²³ <https://www.cato.org/blog/fda-bends-over-backwards-get-drug-makers-ask-them-make-naloxone-etc?queryID=5e8d90a53cd4146cbfeb21c6aa86396f>
- ²⁴ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032>
- ²⁵ <https://www.cato.org/blog/will-congress-finally-x-out-x-waiver?queryID=862b69beb93afdd8be23b6799ddeb8ee>
- ²⁶ <https://www.cato.org/blog/methadone-mixed-messages?queryID=37d266940cdf49bd3fc7293c474181e9>
- ²⁷ <https://www.nejm.org/doi/full/10.1056/NEJMp1803982>
- ²⁸ <https://www.cato.org/blog/nasem-makes-major-plca-harm-reduction-drug-policy?queryID=2d958d5b2acc6b124fa74f166c5de827> ; see also <https://www.nap.edu/resource/25626/ODU-infectious-disease-services-recommendations.pdf>
- ²⁹ <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>
- ³⁰ <https://www.cato.org/blog/mat-regulations-relaxed-during-covid-19-pandemic-should-catalyze-further-reform?queryID=148915a5c7c82317219d83ce3d3c24e7>
- ³¹ <https://www.inquirer.com/opinion/commentary/philadelphia-safehouse-ruling-supervised-injection-site-department-of-justice-20191008.html>
- ³² <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-020-00373-4>
- ³³ <https://pubmed.ncbi.nlm.nih.gov/31109198/> ; see also <https://www.cato.org/blog/yet-another-study-points-potential-cannabis-reducing-opioid-use?queryID=776a5aa470b889f0b8f2ffe884484f7c>



April 8, 2021

Chairman Richard Durbin
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

Senator Charles Grassley, Ranking Member
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

Chairman Jerrold Nadler
House Judiciary Committee
2138 Rayburn House Office Building
Washington, D.C. 20515

Rep. Jim Jordan, Ranking Member
House Judiciary Committee
2138 Rayburn House Office Building
Washington, D.C. 20515

CC: Chairwoman Patty Murray, Senate HELP Committee; Ranking Member Richard Burr, Senate HELP Committee; Chairman Frank Pallone, House Energy and Commerce Committee; Ranking Member Cathy McMorris Rodgers, House Energy and Commerce Committee

Dear Chairman Durbin, Chairman Nadler, Ranking Member Grassley and Ranking Member Jordan:

The more than 100 undersigned organizations write to urge Congress and the Biden administration to let the Trump administration temporary “class-wide” emergency scheduling of fentanyl-related substances expire in May 2021. Class-wide scheduling would exacerbate pretrial detention, mass incarceration and racial disparities in the prison system, doubling down on a fear-based, enforcement-first response to a public health challenge. As we approach the 50-year milestone of President Nixon’s announcement of the War on Drugs, there is ample evidence that these unscientific policies destroy communities, entrench racial disparities, and do nothing to reduce drug supply or demand. Lawmakers should instead support legislation grounded in public health and evidence-based approaches to illicit fentanyl-related overdose deaths.

We must learn from the lessons of the past: It is time for Congress and the Biden administration to embrace a public health approach to drug use. The United States is in the midst of a deadly

overdose crisis that claims tens of thousands of lives each year.¹ In the past few years, synthetic drugs such as fentanyl and its analogues have been responsible for overdose deaths in many parts of the country.² These overdose deaths form a part of a broader wave of mortality associated with unemployment, alcohol poisoning and suicide, circumstances related to working class economic decline and mental health challenges.³ Focusing on drug interdiction does not address the root cause of these overdoses. Skyrocketing prosecutions and criminal penalties have done nothing to stem the tide of these deaths, or to reduce the supply of harmful substances in our country.⁴ Relying on jails to force individuals into painful, involuntary, and often unsafe withdrawal is not the solution. Now, more than ever, policymakers must turn to evidence and science, not fear, to find answers.

Our country is repeating past missteps when it comes to policy responses to fentanyl and its analogues. In the 1980s, policymakers enacted severe mandatory minimums for small amounts of crack cocaine in response to media headlines and law enforcement warnings that perpetuated mythology and fear. In the ensuing decades, people of color have been disproportionately incarcerated and sentenced to mandatory minimum sentences for small amounts of crack cocaine. The emergence of fentanyl-related substances in recent years has fueled similar waves of alarmist media and law enforcement headlines that are informed by mythology rather than science.⁵ Any further extension of the Trump administration's class-wide scheduling policy threatens to repeat past missteps with crack cocaine that policymakers are still working to rectify.

In 2018, the Trump administration chose to implement a hardline anti-science policy of class-wide scheduling of fentanyl analogues rather than pursue evidence and health-based approaches to fentanyl-related overdose deaths. This policy placed on Schedule I of the federal Controlled

¹ See <https://science.sciencemag.org/content/sci/361/6408/eaau1184/F2.large.jpg> from Source: Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016 Hawre Jalal, Jeanine M. Buchanich, Mark S. Roberts, Lauren C. Balmert, Kun Zhang, Donald S. Burke *Science* 21 Sep 2018: Vol. 361, Issue 6408, eaau1184

² Nat'l Inst. of Drug Abuse, *Overdose Death Rates* (last updated Jan. 29, 2021), <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>.

³ Carol Graham, *America's crisis of despair: A federal task force for economic recovery and societal well-being*, Brookings, (Feb. 10, 2021), <https://www.brookings.edu/research/americas-crisis-of-despair-a-federal-task-force-for-economic-recovery-and-societal-well-being/>.

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Provisional Drug Overdose Death Counts, 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class January 2015 through July 2020, Synthetic opioids excluding methadone (T40.4), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>; Drug Alcohol Depend. 2020 Nov 1; 216: 108314,

Steep increases in fentanyl-related mortality west of the Mississippi River: Recent evidence from county and state surveillance, Chelsea L. Shover, Titilola O. Falasinnu, Candice L. Dwyer, Nayelic Benitez Santos, Nicole J. Cunningham, Rohan B. Freedman, Noel A. Vest, and Keith Humphreys,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7521591> ; National Public Radio, "We Are Shipping To The U.S.": Inside China's Online Synthetic Drug Networks," Emily Fang, November 17, 2020,

<https://www.npr.org/2020/11/17/916890880/we-are-shipping-to-the-u-s-china-s-fentanyl-sellers-find-new-routes-to-drug-user>

⁵ Int J Drug Policy. 2020 Dec; 86: 102951. Fentanyl panic goes viral: The spread of misinformation about overdose risk from casual contact with fentanyl in mainstream and social media

Leo Beletsky, Sarah Seymour, Sunyou Kang, Zachary Siegel, Michael S. Sinha, Ryan Marino, Aashka Dave, and Clark Freifeld; "You Can't Overdose on Fentanyl by Touching It," Vice, March 21, 2018, Maia Szalavitz;

American College of Medical Toxicology, "Fentanyl Exposure in the News (Website),"

https://www.acmt.net/Fentanyl_Exposure_in_the_News.html

Substances Act an entire class of substances that has chemical properties similar to fentanyl. This move expands the application of existing severe mandatory minimum sentencing laws enacted by Congress in the 1980s to a newly scheduled class of fentanyl-related compounds. For example, just a *trace amount* of a fentanyl analogue in a mixture with a combined weight of 10 grams—10 paper clips—can translate into a five-year mandatory minimum, with no evidence needed that the seller even knew it contained fentanyl. In addition, current laws impose a statutory maximum sentence of 20 years for just a trace amount of a fentanyl analogue in a mixture with a combined weight of *less than* 10 grams.⁶

Between 2015 and 2019, prosecutions for federal fentanyl offenses increased by nearly 4,000%, and fentanyl-analogue prosecutions increased a stunning 5,000%.⁷ There are significant racial disparities in these prosecutions, with people of color comprising almost 75% of those sentenced in fentanyl cases in 2019.⁸ This holds true for fentanyl analogues, for which 68% of those sentenced were people of color.⁹ In addition, more than half of all federal fentanyl-analogue prosecutions in 2019 involved a street-level seller or other minor role; only 10.3% of these cases involved the most serious functions.¹⁰ Congress and the Biden administration should be wary of expanding the reach of these penalties by adopting a policy explicitly designed to expedite drug prosecutions and increase penalties.¹¹

Class-wide scheduling excises public health and science from drug control and will lead to over-criminalization. Under the class-wide control, any offense involving a fentanyl-related substance is subject to federal criminal prosecution, *even if the substance in question has no potential for abuse*. In February of 2018, the DEA used its emergency scheduling authority to preemptively place an unknown number of fentanyl-related substances—*whether in existence or not*¹²—onto Schedule I.¹³ That scheduling action placed any substance with a certain chemical

⁶ See generally Brian T. Yeh, Cong. Research Serv., RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws* (Jan. 20, 2015), <https://fas.org/srg/crs/misc/RL30722.pdf>.

⁷ U.S. Sent. Comm'n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* (Jan. 2021), at 24 (hereinafter "USSC Fentanyl Report"), https://www.uscc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf.

⁸ See U.S. Sent. Comm'n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* (Jan. 2021), at 24 (hereinafter "USSC Fentanyl Report"), https://www.uscc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf.

⁹ *Id.*

¹⁰ U.S. Sent. Comm'n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* (Jan. 2021), at 28 (Summation of Street-Level Dealer, Courier/Mule, Renter/Storer, Enabler, and User Offender Functions at 51.5%; Summation of most serious functions, importer/high-level distributor and leader/organizer at 10.3%) (hereinafter "USSC Fentanyl Report"), https://www.uscc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf.

¹¹ See Dep't of Justice, *U.S. Attorney Scott Brady Statement on Expiration of Fentanyl Analogue Emergency Scheduling*, (Jan. 29, 2020) ("The emergency scheduling—limited to a two-year period—also made the fentanyl analogues subject to still statutory mandatory minimum sentences."), <https://www.justice.gov/usao-wdpa/pr-us-attorney-scott-brady-statement-expiration-fentanyl-analogue-emergency-scheduling>

¹² See Temporary Scheduling Order ("It bears emphasis, however, that even in the absence of a future publication by DEA specifically identifying such a substance, the substance is controlled by virtue of this temporary scheduling order if it falls within the definition of fentanyl-related substance.").

¹³ Drug Enforcement Admin., Press Releases, *U.S. Drug Enforcement Agency Emergency Schedules All Illicit Fentanyl In An Effort to Reduce Overdose Deaths* (Feb. 7, 2018), <https://www.dea.gov/press-releases/2018/02/07/us-drug-enforcement-administration-emergency-schedules-all-illicit>.

structure on Schedule I.¹⁴ But chemical structure alone cannot predict how a drug will affect the human brain,¹⁵ and not all fentanyl analogues are harmful. “Some analogues, like acetyl fentanyl, are less potent than fentanyl; others, like carfentanil, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive.”¹⁶ However, the same severe penalties apply, including the harsh mandatory minimums, regardless of the potency and purity of a particular fentanyl-related substance.

Customarily, the Attorney General consults with the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA),¹⁷ to confirm a substance’s potential for abuse—and lack of therapeutic potential—before it is permanently placed in Schedule I.¹⁸ But, in the case of the 2018 temporary scheduling order on fentanyl-related substances, rather than allow for the completion of scientifically and medically-based proceedings, the DEA and the Trump administration persuaded Congress to create an exception to the ordinary rule by enacting a bill to extend the temporary scheduling of fentanyl-related substances until May 6, 2021.¹⁹ And now, proponents of the class-wide approach are once again asking Congress to grant DEA the authority to schedule all fentanyl-related substances *permanently*. We oppose any initiatives that would continue to extend class-wide scheduling, whether temporarily or permanently.

Excising science and public health from the drug control process would set a harmful precedent for the criminal legal system and public health. There is simply no scientific basis for this approach, and no precedent for its sweeping, permanent grant of authority. DEA is not equipped to assess the abuse potential or the therapeutic value of substances, particularly when it comes to emerging substances unknown to science. Our communities will have to bear the consequences of such a process, including the application of mandatory minimum sentences, for persons who play bit roles in distribution of even trace amounts of a fentanyl-related substance.²⁰ Giving the DEA broad authority over scheduling would also unduly water down the evidence required for a conviction, depriving accused persons of the opportunity to mount a meaningful defense, and undercutting the goals of criminal legal reform.

An extension of the ban is unnecessary because harmful fentanyl analogues are illegal with or without classwide scheduling. DOJ spokespersons repeatedly, erroneously, have claimed that failure to enact class-wide scheduling would “legalize” harmful fentanyl analogues. On

¹⁴ See Dep’t of Justice, Drug Enforcement Admin., *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I*, 83 Fed. Reg. 25, 5,188 (Feb. 6, 2018) (codified at 21 CFR Part 1308) (hereinafter “2018 Temporary Scheduling Order”).

¹⁵ See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 (Testimony of Dr. Sandra D. Comer, Professor of Neurobiology (in Psychiatry), Columbia University Irving Medical Center, New York State Psychiatric Institute) (Jan. 28, 2020), <https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf>.

¹⁶ Kemp Chester, Assoc. Dir., Nat’l Heroin Coordination Grp., Off. of Nat’l Drug Control Pol’y, Response to Questions for the Record Following Hearing Entitled, The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary (June 4, 2019) at 3, <https://www.judiciary.senate.gov/imo/media/doc/Chester%20Responses%20to%20QFRs1.pdf>.

¹⁷ See 21 U.S.C. 811(b).

¹⁸ See 21 U.S.C. 811(h).

¹⁹ See Pub. L. No. 116-114, 134 Stat. 103 (2020).

²⁰ Cite 841, Scott Brady.

April 2019, a DEA spokesperson stated that “...any fentanyl substances not already permanently placed in Schedule I or II would fall off the list and technically not be an illegal substance.”²¹ Later, in January of 2020, then-Attorney General William P. Barr authored an op-ed in the Washington Post in which he repeated the misinformation that, if fentanyl-related substances were not scheduled or the emergency scheduling order was allowed to expire, the drugs would become legal.²² To be clear, these statements were then—and are still now—false. In fact, the 2018 emergency scheduling order itself correctly noted that trafficking of fentanyl analogues is “actually illegal as persons who do so can be prosecuted using the controlled substance analogue provisions of the CSA.”²³

In addition, the Department of Justice and DEA have claimed that the Analogue Act is unduly complex and burdensome. But the Analogue Act appropriately requires the government—when it brings the force of federal criminal penalties against an individual—to prove that a novel substance is actually harmful or was intended to be harmful. If the substance involved is harmful, that should not be a difficult burden for the government to meet. Nor do those burdens obstruct DOJ’s efforts to prosecute individuals: DOJ has acknowledged its “very good track record in Analogue Act prosecutions.”²⁴ Science matters, and due process is not a mere inconvenience to sweep aside. Overcoming an individual’s presumption of innocence is not intended to be convenient for the government. The Analogue Act requires the government to prove that a novel substance meets the Controlled Substance Act’s definition of “controlled substance analogue” before that person can be convicted and punished. Congress carefully designed the elements of

²¹ See Erin Durkin, *DEA’s Plea to Congress: Permanently Ban Fentanyl Substances*, Nat’l J. Daily Extra (Apr. 21, 2019).

²² See William P. Barr, *William Barr: Fentanyl Could Flood the Country Unless Congress Passes this Bill*, Wash. Post, (Jan. 10, 2020), https://www.washingtonpost.com/opinions/william-barr-congress-pass-this-bill-so-we-can-attack-the-onslaught-of-illegal-fentanyl/2020/01/10/cbb8ccdc-33cb-11ea-a053-dc6d944ba776_story.html. See also: Statement of the U.S. Department of Justice, Amanda Liskamm, Director, Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General, and, Greg Cherundolo, Chief of Operations, Office of Global Enforcement, Drug Enforcement Administration, Before the Committee on the Judiciary, For a Hearing Entitled “The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order,” June 4, 2019, p. 2, <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-Cherundolo%20Joint%20Testimony.pdf>; Statement of the U.S. Department of Justice, Amanda Liskamm, Director, Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General, and, Tim McDermott, Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, Before the Committee on the Judiciary, United States Senate, For a Hearing Entitled “Tackling the Opioid Crisis: A Whole-of-Government Approach,” December 17, 2019, p. 8, <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-McDermott%20Testimony.pdf>; Statement of the U.S. Department of Justice, Amanda Liskamm, Director, Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General, Before the Committee on the Judiciary, Subcommittee on Crime, Terrorism, and Homeland Security, United States House of Representatives, For a Hearing Entitled “Fentanyl Analogues: Perspectives on Classwide Scheduling,” January 28, 2020, p. 2, <https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-LiskammA-20200128.pdf>

²³ 83 FR 5188, Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule, *Drug Enforcement Administration*, February 6, 2018, see <https://www.federalregister.gov/d/2018-02319/p-14>

²⁴ Statement of the U.S. Department of Justice, Amanda Liskamm, Director, Opioid Enforcement and Prevention Efforts, Office of the Deputy Attorney General, and, Greg Cherundolo, Chief of Operations, Office of Global Enforcement, Drug Enforcement Administration, Before the Committee on the Judiciary, For a Hearing Entitled “The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order,” June 4, 2019, p. 5, <https://www.judiciary.senate.gov/imo/media/doc/Liskamm-Cherundolo%20Joint%20Testimony.pdf>

that definition to secure convictions for dangerous novel substances while shielding harmless conduct from criminal sanctions.²⁵

Class-wide scheduling hurts public health and scientific research. Giving the DEA broad, “class-wide” powers to schedule fentanyl analogues without HHS oversight could also undermine scientific research critical to finding solutions to the overdose crisis. In a July 2019 letter to HHS, bipartisan members of the Senate Judiciary Committee warned that the same barriers to research that scientists encounter when attempting to study Schedule I drugs would apply to substances added by a class-wide ban.²⁶ Senate Judiciary Committee members further warned that “the failure to engage necessary health experts vests far too much authority to a law-enforcement agency and may result in action that will deter valid, critical medical research aimed at responses to the opioid crisis, including efforts to identify antidotes to fentanyl-analogue overdoses and improved treatment outcomes.”²⁷ Similarly, in her January 2020 statement before the Subcommittee on Crime, Terrorism, and Homeland Security of the House Judiciary Committee, Dr. Sandra Comer, the public policy officer for the College on Problems of Drug Dependence, strongly recommended that any legislation on scheduling synthetic opioids should involve HHS’s science-based agencies, specifically the National Institute on Drug Abuse and the FDA.²⁸ We are gravely concerned that efforts encouraged by the DEA would take away HHS oversight essential to excluding substances that should not be scheduled. Substances that have no psychoactive value but are important to research could be inadvertently added to Schedule I without proper HHS input, needlessly increasing both the burdens to research and the effects of criminalization.

The expiration of class-wide scheduling is an opportunity for the Biden administration and Congress to make good on a commitment to end mandatory minimums and embrace a public health approach.²⁹ The classwide scheduling discussion allows Congress and this administration the opportunity to choose a new path on drug policy. The Biden administration has expressed support for ending mandatory minimums. Allowing this policy to expire aligns with Biden’s stated support of ending mandatory minimums and treating drugs as a public health issue. Lawmakers should instead support legislation grounded in public health and harm reduction. Some health-centered policy provisions lawmakers should prioritize include the following: supporting harm reduction interventions such as syringe service programs; enacting a federal Good Samaritan statute; removing cost and access barriers to naloxone and effective

²⁵ Butler Test. at 9-10 (summarizing legislative history of the Analogue Act, including consideration by Congress of testimony from the American Chemical Society).

²⁶ See Letter from Senators Richard J. Durbin, Michael S. Lee, Sheldon Whitehouse, Amy Klobuchar, Christopher A. Coons, Mazie Hirono, Cory A. Booker, Kamala D. Harris to The Hon. Alex M. Azar II, Secretary, U.S. Dep’t of Health and Human Services (Jul. 10, 2019), <https://www.durbin.senate.gov/imo/media/doc/Letter%20to%20DOJ%20HHS%207.10.pdf>.

²⁷ *Id.*

²⁸ See Statement of Sandra D. Comer, Ph.D., Before the Subcomm. on Crime, Terrorism, and Homeland Security of the House Comm. on the Judiciary, Washington, D.C. (Jan. 28, 2020). See also: Letter from the American Society for Pharmacology and Experimental Therapeutics (ASPET) to House Judiciary Committee dated February 4, 2020 regarding classwide scheduling of fentanyl analogues, https://www.aspet.org/docs/default-source/advocacy-files/aspet-fentanyl-classwide-scheduling-letter.pdf?sfvrsn=4db79cd2_0

²⁹ See <https://joebiden.com/opioidcrisis/> and <https://joebiden.com/justice/>

forms of opioid use disorder treatment such as buprenorphine and methadone³⁰; and improving public health surveillance of fentanyl analogues and overdose cases.

We share your concern about fentanyl-related deaths and support effective health-based approaches to mitigating this public health crisis, but class-wide scheduling merely repeats the mistakes of the past by exacerbating our incarceration problem. We welcome continued dialogue with you and your staff about how to move forward on this important topic. However, we must reiterate our firm opposition to “class-wide” emergency scheduling, whether temporary or permanent. Thank you for your time and attention to this matter. Please contact Grant Smith, Deputy Director, DPA at gsmith@drugpolicy.org or Patricia Richman, National Sentencing Resource Counsel, Federal Public and Community Defenders at Patricia_Richman@fd.org; for questions or concerns.

Sincerely,

A Little Piece Of Light (NY)
 AIDS Alabama (AL)
 AIDS United
 Alliance for Living (CT)
 American Civil Liberties Union
 Any Positive Change, Inc. (CA)
 Asian American Drug Abuse Program, Inc. (CA)
 AMERSA (RI)
 Autistic Self Advocacy Network
 The Bail Project
 Baltimore Harm Reduction Coalition (MD)
 Being Alive LA (CA)
 Bend the Arc: Jewish Action
 Black and Pink Massachusetts (MA)
 Brennan Center for Justice
 Bridge To The Mountains (PA)
 Center For Employment Opportunities
 Center for Health and Justice Transformation (RI)
 Center for Justice Research at Texas Southern University (TX)
 Center for Popular Democracy
 Chicago Drug Users' Union (IL)
 College and Community Fellowship (NY)
 Community Alliance on Prisons (HI)
 Community Health Project Los Angeles (CA)
 Congregation of Our Lady of Charity of the Good Shepherd, US Provinces (MD)
 Church of Scientology National Affairs Office

³⁰ See Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021: <https://www.congress.gov/bill/117th-congress/house-bill/2366>; Mainstreaming Addiction Treatment Act (H.R. 1384/S.445) <https://www.congress.gov/bill/117th-congress/house-bill/1384> and <https://www.congress.gov/bill/117th-congress/senate-bill/445>; TREATS Act (S. 340) <https://www.congress.gov/bill/117th-congress/senate-bill/340>

CURE (Citizens United for Rehabilitation of Errants)
 Desiree Alliance (AZ)
 Down Home NC (NC)
 Dream Corps JUSTICE
 Drug Policy Alliance
 Due Process Institute
 Fair and Just Prosecution
 FAMM
 Family and Medical Counseling Services, Inc. (DC)
 Federal Public and Community Defenders
 Friends Committee on National Legislation
 GLIDE (CA)
 GoodWorks: North Alabama Harm Reduction (AL)
 Harm Reduction Action Center (CO)
 Harm Reduction Michigan (MI)
 Harm Reduction Services (CA)
 Harm Reduction Sisters (NC)
 Hawaii Health and Harm Reduction Center (HI)
 Health in Justice Action Lab (MA)
 Health Policy Network, LLC (PA)
 HealthRight360 (CA)
 Hep Free Hawaii (HI)
 HEPPAC (CA)
 HIPS (DC)
 HIV Education and Prevention Project of Alameda County HEPPAC (CA)
 HIV/HCV Resource Center (NC)
 Human Rights Watch
 Interfaith Action for Human Rights
 Justice Roundtable
 Justice Strategies
 Latino Justice PRLDEF
 Law Enforcement Action Partnership
 The Levenson Foundation (TX)
 Live4Lali (IL)
 LSF Services (NY)
 The Leadership Conference on Civil and Human Rights
 Legal Action Center
 Maine Access Points (ME)
 Maine People's Alliance (ME)
 The Mountain Center (NM)
 NAACP
 National Action Network
 National Advocacy Center of the Sisters of the Good Shepherd
 National Alliance of State and Territorial AIDS Directors (NASTAD)
 National Association of Criminal Defense Lawyers
 National Association of Social Workers

National Center for Advocacy and Recovery for Behavioral Health
 National Center for Lesbian Rights
 NCADD-MD (MD)
 National Council of Churches
 National Harm Reduction Coalition
 National Health Care for the Homeless Council
 National Juvenile Justice Network
 National Organization for Women
 National Viral Hepatitis Roundtable
 NEXT Harm Reduction (NY)
 NETWORK Lobby for Catholic Social Justice
 Opioid Network (NY)
 People's Action
 Philadelphia Overdose Prevention Initiative (PA)
 Prevention Point Pittsburgh (PA)
 QC Harm Reduction (IL)
 Rights & Democracy (VT)
 River Valley Organizing (OH)
 St. James Infirmary (CA)
 The Sentencing Project
 Showing Up for Racial Justice Ohio (NY)
 SOAR WV (WV)
 Stopthedrugwar.org
 Students for Sensible Drug Policy
 Texas Drug User Health Alliance (TX)
 TN State Conference NAACP (TN)
 Transitions Clinic Network (CA)
 Treatment Action Group
 Treatment Communities of America
 Truth Pharm (NY)
 Tzedek Association
 Unlimited Sciences (CO)
 Urban Survivors Union (IN)
 Vera Institute of Justice
 VOCAL-NY (NY)
 Washington Office on Latin America
 Witness to Mass Incarceration, Inc.

U.S. House of Representatives
Committee on Energy and Commerce

**“An Epidemic within a Pandemic: Understanding Substance Use
and Misuse in America”**

14 April 2021

Testimony submitted by

Sandra D. Comer, Ph.D.

Professor of Neurobiology (in Psychiatry)
Columbia University Irving Medical Center
New York State Psychiatric Institute

Public Policy Officer
The College on Problems of Drug Dependence

Introduction

We share the concerns of the Committee about the opioid crisis and thank you for holding today's hearing on class-wide scheduling of synthetic fentanyl and for inviting me to provide this testimony. My name is Dr. Sandra Comer and I am the Public Policy Officer of the College on Problems of Drug Dependence (CPDD), a membership organization with over 1000 members that has been in existence since 1929. It is the longest standing organization in the United States (U.S.) and the world addressing problems of drug dependence and abuse. The organization serves as an interface among government, industry, and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the field of substance use disorders (SUDs).

I am also a Professor of Neurobiology in the Department of Psychiatry at the Columbia University Irving Medical Center, and a Research Scientist at the New York State Psychiatric Institute. My research focus for over 2 decades has been on the development and testing of new approaches to the treatment of opioid use disorder (OUD).

Scope of the Problem

Approximately 36 million people worldwide have a substance use disorder related to controlled substances, but across all of the illicit drug classes, non-therapeutic use of opioids is associated with the most harm: 80% of "healthy" lives lost as a consequence of disability and premature deaths associated with SUDs have been attributed to opioids¹. The U.S. in particular is experiencing an unprecedented increase in illicit use of opioids and its associated morbidity and mortality. In 2017, opioid overdoses (OD) claimed more than 47,000 lives in the U.S., more than 28,000 of which were attributed to synthetic opioids other than methadone². OD deaths are the tip of the iceberg as research suggests 20-30 non-fatal ODs occur for every OD death³. In addition, the majority of people who use opioids either have experienced a non-fatal OD or have witnessed an OD during their lifetime⁴⁻⁶. These numbers are likely to be underestimates because the data on non-fatal overdoses were collected prior to the introduction of illicitly manufactured fentanyl. ***Of great concern to the research community is that our tools for treating OUD and reversing opioid OD were developed before the emergence of highly potent illicit fentanyl so new approaches may be needed to address this challenge.***

Research Gaps

Fortunately, several medications are available and have been used successfully for treating OUD, including methadone, buprenorphine⁷⁻⁹, and naltrexone¹⁰⁻¹⁵. Despite the clear clinical utility of these medications, approximately half of the patients who initiate medication relapse and/or drop out of treatment within 6 months^{11,15,16}. Thus, there is a substantial need for improving the effectiveness of these medications, given the high relapse rates.

The introduction of fentanyl and its analogues to the street supply of illicit opioids complicates an already difficult-to-treat disorder because it is not clear whether the approved treatment medications can reduce use of these drugs as effectively as they

reduce the use of heroin and prescription opioids such as oxycodone. A number of preclinical studies have demonstrated that fentanyl is a highly potent opioid with a receptor pharmacology that differs from other opioids¹⁷. Multiple studies conducted in several different species have demonstrated that opioid agonist maintenance or irreversible antagonist administration was less effective in blocking the effects of higher efficacy agonists, like fentanyl, compared to intermediate efficacy agonists, like heroin or morphine¹⁸⁻²⁹. ***Further research on the ability of the approved medications for treating OUD in patients who are predominantly using fentanyl is clearly needed. The development of alternative medication approaches is also critically needed to address the shift in the illicit opioid supply toward fentanyl.***

Naloxone is a potent, short-acting medication that blocks opioid receptors. While it binds to opioid receptors, it does not activate them (that is, it doesn't produce a "high" or other desirable effect), so the risk of abusing the medication is non-existent. Naloxone is effective in both preventing and reversing the effects of heroin and other opioids, including respiratory depression, which is the primary cause of death due to opioid overdose³⁰. The antagonist effects of naloxone are evident within 5 minutes following administration and its effectiveness at commonly prescribed doses (0.4-0.8 mg) can last 45 to 90 minutes. It is relatively ineffective orally, so it is typically administered intravenously or intramuscularly and more recently, intranasally³¹⁻³³. Originally approved by the Food and Drug Administration (FDA) in 1971 for treating opioid overdose, naloxone is traditionally used in both emergency room and non-hospital settings, where it is administered by medically trained personnel.

Non-fatal and fatal opioid overdoses have increased substantially over recent decades. Naloxone is now being used by individuals with little or no medical training in order to broaden our ability to address the opioid overdose crisis. Recent reports suggest that fentanyl and its analogues have contributed to the sharp increase overdose deaths and that higher and/or repeated dosing with naloxone may be required to reverse fentanyl-induced respiratory depression³⁴⁻³⁶. ***The reason that higher doses of naloxone may be required for fentanyl overdoses is not entirely clear.*** Possibilities are that a large dose of naloxone is needed simply because a large dose of fentanyl was used, a fentanyl analogue was used that is not sensitive to naloxone, or a post-receptor or non-opioid-receptor cascade of effects is initiated that is not sensitive to reversal by naloxone. Another possible explanation for the apparent lack of effectiveness of naloxone in some overdose situations is that fentanyl and naloxone may share a site that allows drug entry into the brain and when high doses of fentanyl are used, the ability of naloxone to pass into the brain is impeded^{35,37}. Emerging preclinical research suggests that naloxone may not be as effective against carfentanil, a highly potent fentanyl analog³⁸, and other opioid antagonists may be more effective than naloxone in reversing fentanyl over-intoxication³⁹. ***Clearly, additional studies are needed to understand the mechanisms by which fentanyl and its analogues produce severe respiratory depression. Furthermore, studies are needed to assess the effectiveness of naloxone and other opioid antagonists in reversing fentanyl-related OD because naloxone may not be the ideal compound for reversing the respiratory depressant effects of fentanyl-like drugs.***

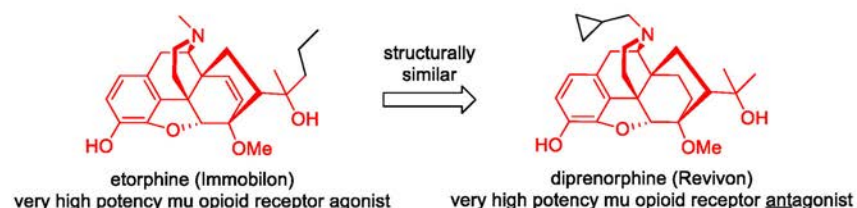
Class-wide Scheduling of Fentanyl Analogues from a Research Perspective

Fentanyl and related analogues are exceptionally potent, inexpensive, and easy to synthesize. Small modifications in these molecules can have profound effects on their activity, changing an inactive compound to a potent opioid with high abuse potential. **A critical point is that similarity in chemical structure does not necessarily translate into similarity in abuse liability.** Below is an example of how small modifications to a core chemical structure can result in large differences in pharmacological activity.



Oxymorphone is a potent mu opioid receptor agonist with high abuse potential, while naltrexone and naloxone are opioid antagonists that have saved thousands of lives. Naltrexone is approved for treating both alcohol and opioid use disorder and naloxone is approved for treating opioid overdose. All three of these medications share the same core chemical structure (shown in red).

Another example of compounds that share similar structures but not pharmacological activity is etorphine and diprenorphine (below):



Etorphine is a very potent opioid used in veterinary medicine to tranquilize large animals and diprenorphine is an antagonist used as an antidote for etorphine. These examples illustrate how **the antidote to a toxic substance and the toxic substance itself can share core chemical structures. However, the chemical structure of a compound alone cannot tell us whether it will have agonist or antagonist activity. Basic pharmacological studies must be performed in order to make this determination.**

- Science-based agencies, specifically the FDA and the National Institute on Drug Abuse (NIDA) at the Department of Health and Human Services (HHS), should review the pharmacological activity, not just the chemical structures, of these compounds.

- The role of HHS need not be as robust as the 8-factor analysis currently mandated by the Controlled Substances Act. Instead, ***the Committee should consider adding a role for HHS in subjecting compounds to more limited tests of pharmacological activity through animal models using a rapid process that could be undertaken by NIDA and a designated, pre-screened team of extramural scientists.*** In fact, NIDA, FDA, and the Drug Enforcement Administration (DEA) currently participate on the Interagency Committee for Drug Control, which reviews and prioritizes compounds that need analysis. NIDA issues grants and contracts for such analyses, as does the DEA.

The current fentanyl crisis poses a formidable challenge to Congress and the DEA since there are literally thousands of (existing or potential) fentanyl analogues, some of which have high abuse and dependence potential. ***CPDD supports efforts to control the distribution, sales, and use of these synthetic fentanyls.*** In the face of the opioid crisis, it is tempting to globally put all compounds that are chemically similar to fentanyl in Schedule 1; however, such an action is likely to severely limit biomedical research and, in the long term, adversely impact public health. The opioid crisis is a very challenging public health issue and, arguably, we have yet to significantly turn the tide in this battle despite our current efforts. To restrict research by limiting access to potentially important compounds, based solely on chemical structure, is not likely to facilitate progress in this arena.

For a research scientist, obtaining a DEA Schedule 1 registration is complicated, burdensome, and can take a long time (e.g., more than a year), disincentivizing researchers in general and particularly young researchers (e.g., graduate students and postdoctoral fellows) who often need to complete their studies on strict academic schedules.

- The additional security that is necessary for handling Schedule 1 substances can be prohibitively expensive, particularly for young investigators in the current climate when securing NIH funding is very challenging and those from small or historically Black colleges and universities that may not have the resources to comply with the regulations outlined in the Controlled Substances Act. Specialized safes, locking refrigerators and freezers, video surveillance, and renovations can be expensive, and institutions often are not willing to pay these costs.
- Each additional Schedule 1 compound that might be of interest to study requires a protocol review that can take many months. Even for seasoned investigators who have been conducting research in this area for many years and who have efficient, well-funded laboratories, the delay in obtaining Schedule 1 compounds for experiments is prohibitively long and significantly impedes progress. For example, one investigator reported that despite having a DEA Schedule 1 registration, importation from outside the U.S. of a Schedule 1 compound that proved to have significant therapeutic value and no abuse liability required nearly two years.
- Part of the difficulties in obtaining licenses to study Schedule 1 compounds stems from differing interpretations of registration requirements at both the state and federal levels, as well as at the academic administrative level.

Some suggestions for streamlining the process for obtaining a DEA registration to study fentanyl analogues are to:

1. Permit researchers holding a Schedule 2 license to conduct research on all Schedule 1 drugs. Specifically, treat the process for obtaining and modifying a Schedule 1 research registration the same as is currently in place for Schedule 2 (e.g., the DEA currently does not require FDA review of Schedule 2 substances for the purpose of obtaining a license.) NOTE: 1) FDA review will still be required for clinical studies of these substances during the Investigational New Drug application process, and 2) the security requirements are the same for Schedule 1 and 2 drugs so there are no implications for diversion.
2. Clarify that it is permissible for one individual to hold a Schedule 1 registration under which colleagues from the same institution may work even if those colleagues do not work directly for the registrant.
3. Eliminate the requirement to store each substance in a separate cabinet and for each individual researcher to have their own storage cabinet.
4. Allow registered researchers to store, administer, and otherwise work with any substances for which they hold a research registration at multiple practice sites on a single campus so long as the registrant notifies the Attorney General prior to conducting research at those sites.
5. Clarify that it is permissible for researchers to make limited modifications to the substances they are researching, such as processing them into extracts, solutions, or derivatives, without having to obtain a separate manufacturing license.
6. Allow individuals conducting research with a substance subsequently placed into Schedule 1 who hold a registration to conduct research with any other Schedule 1 or Schedule 2 substance to continue work on the newly scheduled substance until their new or amended registration application is approved or denied. These individuals will have to submit their new or amended registration application within 120 days of the substance being added to Schedule 1.

Investigators have dedicated their careers to research in this area because we want to make a difference in protecting individuals from the devastation caused by drug abuse. But we believe that more information, not less, is the most likely way we can achieve that goal. I encourage you and your colleagues to consider alternative approaches so that the potential benefits and risks of new chemical entities can be characterized before decisions are rendered regarding DEA scheduling.

Summary

We share the concerns of the Committee about the opioid epidemic and its devastating consequence to millions of Americans, their families, and their communities. One of the main reasons for the dramatic and disturbing increase in illicit opioid use is the spread of fentanyl, a synthetic opioid that is inexpensive and potent, as well as its analogues. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

CPDD supports efforts to give the DEA authority to control the importation and distribution of synthetic fentanyl, but we also believe that any legislation to address this issue should include language reducing some of the barriers to research currently imposed by Schedule 1 licensing requirements and must address the unintended consequences of including such a broad range of substances in the scheduling language.

We strongly recommend that any legislation on scheduling synthetic opioids – either by extending the current temporary scheduling order, making permanent scheduling of these compounds, or requiring rapid tests of their pharmacological activity – should involve the Department of Health and Human Services' science-based agencies, specifically NIDA and the FDA.

We thank you for considering our position on how these decisions may have a potentially negative impact on our shared efforts to address this serious public health issue.

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April 14, 2021



The Honorable Anna Eshoo
Chairwoman
House Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie,

I am writing to share additional information for the record of today's hearing before the Subcommittee on Health entitled "An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America." The following serves as an addendum to the accompanying [letter](#) submitted for the record of this hearing that has been signed by over 100 civil rights, criminal justice and public health organizations in opposition to any extension of the Trump Administration class-wide scheduling of fentanyl analogues policy, which is currently set to expire on May 6, 2021.

The United States is facing an urgent drug overdose crisis that is estimated to have surpassed 100,000 opioid overdose deaths in 2020, a 41% increase over 2019 (which already was a record year with 70,980 deaths). The infectious diseases associated with opioid and use of other drugs also have dramatically increased. The number of new hepatitis C infections has more than tripled since 2010, with an estimated 44,000 people newly infected and 17,253 associated deaths in 2017. Since 2014, new hepatitis B infections have increased, with 32 states reporting increases in acute infections in adults over 40 years old in 2017. Outbreaks or significant spikes in infections of viral hepatitis as well as HIV among people who inject drugs continue to occur throughout the country.

The passage in recent years of legislative initiatives such as the Comprehensive Addiction and Recovery Act and the SUPPORT Patients and Communities Act helped apply a public health approach to substance use disorder and harms associated with drugs. Despite these federal initiatives, access to evidence-based treatment, harm reduction and recovery support services remains severely inadequate in many communities. These deficiencies are well documented in research and expert testimony before Congress, yet federal budgets and drug policy continue to prioritize enforcement-first approaches to illicit drugs. Despite allocating billions of dollars, drug enforcement tactics, programs and policies have failed to reduce illicit drug supply or demand. And rather than mitigate harms associated with illicit drugs, law enforcement activities including interdiction, prosecutions and incarceration have actually contributed to the

steadily worsening public health measures of the overdose crisis, including increasing measures of potency in the illicit supply of opioid drugs.

The growing saturation of illicit fentanyl in the drug supply, and emergence of novel fentanyl analogues, as well as other novel classes of drugs, reflects efforts to adapt to law enforcement tactics. Resulting outcomes for public health have worsened as law enforcement activities have intensified. Illicit opioid substances have become more potent, varied and novel, and remained widely available during the course of the Trump Administration, and despite a massive scale up by the Trump Administration in drug enforcement and prosecutions targeting synthetic opioids, which included the introduction of class-wide scheduling of fentanyl analogues.

Between June 2019 and July 2020, as class-wide scheduling of fentanyl analogues was in full effect, the Centers for Disease Control and Prevention reported that 37 of the 38 U.S. jurisdictions with available synthetic opioid data reported increases in synthetic opioid-involved overdose deaths, 18 of these jurisdictions reported increases greater than 50 percent, and 10 western states reported over a 98 percent increase in synthetic opioid-involved deaths.¹ These statistics mirror continued increases in overdose deaths from fentanyl-related substances since 2013.

At a time when the coronavirus pandemic and economic downturn is further exacerbating the overdose crisis, it is crucial that policymakers prioritize health and science-based approaches to reducing overdose deaths from illicit fentanyl-related substances and other drugs rather than double down on enforcement-first approaches like class-wide scheduling of fentanyl analogues that will continue to fail to address the root causes of the crisis.

On April 12th, the Biden Administration confirmed to the press that it supports a 7-month extension of this Trump Administration policy. As [this piece from *The Intercept*](#) entitled "*Biden Looks to Extend Trump's Bolstered Mandatory Minimum Drug Sentencing*" points out, "Advocates wonder why the Biden administration would go out of its way to extend a policy that would mark a return to the harsh drug sentencing laws from which the president has tried to distance himself, and even in some cases, [apologized for pursuing](#)." ²

The Biden Administration claims it needs more time to review the implications of this draconian Trump-era policy, despite three decades of evidence that enforcement first policies fail. Moreover, Congress already requested from the Government Accountability Office (GAO) a report to evaluate the utility of class-wide scheduling when it temporarily extended this policy in January 2020 for 15 months.

In its report publicly released on April 12th, [GAO found](#)³ that:

- The Trump Administration rarely used the additional sentencing authorities provided by class-wide scheduling, and when it did the target was low-level drug offenders. (p. 58)

- Despite assertions by the Trump Administration that class-wide scheduling would reduce the availability of fentanyl analogues in the U.S., Drug Enforcement Administration laboratory information system reports of seized fentanyl analogues increased in the two years since the implementation of the policy. (pp. 54, 65, 67). Further, the GAO did not substantiate claims that the classwide ban has reduced the number of novel fentanyl-related substances in the United States. (22, 54).
- Law enforcement representatives confirmed that they are seeking the classwide ban to **enhance already harsh penalties**, telling GAO that the ban would “facilitate . . . prosecutions,” and that failure to enact the ban “may result in . . . **lighter sentences**” for individuals prosecuted for drugs. (60).
- This Trump-era policy sidelined HHS and the scientific community’s customary role of properly evaluating the suitability of placing on Schedule I *thousands* of unique fentanyl-related compounds, including substances that could become potential new vaccines and treatments against opioid misuse and overdose. In turn, the Schedule I classification could be an obstacle in the development of life-saving drugs and substances were inappropriately included on Schedule I. (pp. 38, 41).

In addition, any extension of this Trump-era policy threatens to exacerbate disturbing federal sentencing trends involving fentanyl analogues. Between 2015 and 2019, prosecutions for fentanyl-analogue prosecutions [increased a stunning 5,000%](#). There are significant racial disparities in these prosecutions, with people of color comprising [68% of those sentenced](#) in fentanyl analogue cases in 2019. In addition, *more than half* of all federal fentanyl-analogue prosecutions in 2019 [involved a street-level seller or other minor role](#); only 10.3% of these cases involved the most serious functions.

The Biden Administration’s decision to be at odds with the civil rights, criminal justice and public health communities on this issue comes at a time when policymakers have been making progress undoing the harms of mandatory minimum sentencing brought about during the fear-driven, sensationalist panic around crack-cocaine in the 1980s. The emergence of fentanyl-related substances in recent years has fueled similar waves of alarmist media and law enforcement headlines that are informed by mythology rather than science.

Last month, the [Drug Enforcement and Policy Center](#) at The Ohio State University Moritz College of Law hosted a multi-panel virtual symposium, titled “[Prioritizing Science Over Fear: An Interdisciplinary Response to Fentanyl Analogues](#),” which explored the harms of approving any further extensions of this Trump-era policy. A [transcript](#) and [captioned recordings](#) of each panel from this event are now available. For more background on this event please see [here](#).

Rather than extend anti-science Trump-era policies that will exacerbate mass incarceration and racial disparities in drug policy, Congress and the Biden Administration should prioritize public health legislation that applies evidence-based approaches to illicit fentanyl and fentanyl analogues, including:

- **Mainstreaming Addiction Treatment (MAT) Act:** This legislation eliminates the redundant, outdated and stigmatizing DATA 2000 WAIVER requirement that practitioners must apply for a separate waiver through the DEA to prescribe buprenorphine for the treatment of opioid use disorder. This additional requirement discourages practitioners from integrating evidence-based treatment in their practices and perpetuates stigma in the medical community against patients who would benefit from buprenorphine treatment. Buprenorphine is one of three medications approved by the FDA to treat opioid use disorder, is highly effective at alleviating the painful symptoms associated with opioid use disorder and reduces mortality by up to 50 percent.⁴
- **Support, Treatment, and Overdose Prevention (S.T.O.P.) of Fentanyl Act of 2021:** This legislation provides for a comprehensive health- and evidence-based approach to addressing illicit fentanyl and fentanyl analogues without relying on policing and incarceration by putting forward policies and initiatives that bolster public health surveillance and research, deploy health resources to combat overdose deaths, connect individuals with treatment programs, and support on-going prevention and education activities. The legislation helps address overdose deaths and harm associated with illicit fentanyl-related substances by removing barriers and expanding telehealth and other forms of access to Medication Assisted Treatment (MAT), helping state and community-based organizations address the harms of drug misuse, and funding education for stakeholders on evidence-based treatment for opioid and fentanyl misuse.
- **The Medicaid Reentry Act of 2021:** This legislation permits Medicaid to provide essential health care for people in incarcerated settings 30 days prior to their release. Ninety-five percent of the more than 2 million adults who are incarcerated in the United States will be released and face a variety of reentry challenges.⁵ Transition into the community following a period of incarceration is a particularly crucial period for those with mental illness and substance use disorder because it is associated with significant stress and high risk of recidivism, relapse, or crisis. Most of these individuals lack health insurance and will face barriers navigating and gaining access to public health care programs. According to one study, risk of a fatal drug overdose is 129 times as high as it is for the general population during the two weeks after release.⁶ This legislation enables incarcerated individuals to secure a warm handoff to lifesaving community-based mental health and substance use disorder services, medications, and other supports.
- **The State Opioid Response Grant Reauthorization Act:** This legislation authorizes State Opioid Response (SOR) Grants and Tribal Opioid Response

(TOR) Grants for five years. As the current authorization for SOR and TOR Grants is set to expire, this legislation ensures continuity of this funding support by extending the authorization an additional five years. SOR and TOR Grants help states, tribal organizations and community-based stakeholders implement health and evidence-based responses to the overdose crisis, including overdoses involving illicit fentanyl and fentanyl analogues. SOR and TOR grants help support increasing access to FDA-approved medication-assisted forms of treatment, and reducing opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder.

Please contact me if you would like more information about the views or legislation outlined above or with any questions. Thank you.

Sincerely,



Grant Smith
Deputy Director, National Affairs
Drug Policy Alliance

¹ JAMA Network, "CDC Warns of Surge in Drug Overdose Deaths During COVID-19,"

Joan Stephenson, PhD, January 5, 2021

² The Intercept, "Biden Looks to Extend Trump's Bolstered Mandatory Minimum Drug Sentencing," April 12, 2021, Akela Lacy, <https://theintercept.com/2021/04/12/fentanyl-drug-sentencing-biden/>

³ U.S. Government Accountability Office, "SYNTHETIC OPIOIDS: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances," April 2021, GAO-21-499, <https://www.gao.gov/assets/gao-21-499.pdf>

⁴ National Academies of Sciences, Engineering, and Medicine. 2019. *Medications for opioid use disorder save lives*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/25310>.

⁵ See Lakeesha Woods et. al., *The role of prevention in promoting continuity of health care in prisoner reentry initiatives*, American journal of public health, vol. 103,5 (2013), 830-8, doi:10.2105/AJPH.2012.300961

⁶ Ingrid Binswanger et al. *Release from prison--a high risk of death for former inmates*, The New England Journal of Medicine, 356, no. 2 (Jan 2007), 157-65, DOI: 10.1056/NEJMsa064115

Statement for the Record
American Nurses Association
“An Epidemic Within a Pandemic: Understanding Substance
Use and Misuse in America”
House Energy and Commerce Health Subcommittee
April 14, 2021

The American Nurses Association (ANA), representing the interests of the nation’s 4.2 million registered nurses, commends the House Energy and Commerce Health Subcommittee for convening this hearing on “An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America,” and appreciate the opportunity to submit this statement for the record.

ANA is committed to advancing the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA is at the forefront of improving quality of health for all.

Support for H.R. 1384, the Mainstreaming Addiction Treatment (MAT) Act

The MAT Act, introduced by Representative Paul Tonko, would eliminate the current buprenorphine waiver program, allowing providers who are already able to prescribe buprenorphine for pain related conditions to meet a growing and unmet need for medication-assisted treatment. ANA supports removing non-evidence-based restrictions on medication-assisted treatment so that more providers can prescribe it for patients who desperately need it.

About Buprenorphine and Medication-Assisted Treatment

Buprenorphine is an opioid-based medication that helps curb cravings, prevent overdoses, and has allowed people suffering from opioid use disorder to recover while avoiding devastating and painful withdrawal symptoms that prevent people from being able to quit. It is considered the “gold standard” for opioid use disorder and has been in use for medication-assisted treatment for more than two decades.

To this day, prescribers are not required to have specific education or clinical training to prescribe opioid pills for pain management purposes. However, prescribing Buprenorphine for treatment of opioid use disorder requires providers to undergo extensive education courses before they can obtain the waiver necessary to prescribe. This has caused unknown numbers of prescribers to not pursue the waiver, leaving many people suffering from opioid use disorders without treatment options. An additional consequence of requiring the waiver for treatment and not pain reduction, is that many providers do not want to become the only waived provider in a geographic area. Being the only provider for treatment in an area could cause their practices to have a large influx of new patients and reduce access for patients that were already established with their practice. If all providers can prescribe medication-assisted treatment for opioid use disorder, this issue will be avoided in many cases and create more access points to care.

Giving patients access to more providers who have the ability to prescribe Buprenorphine to treat opioid use disorder is the most effective way to slow and overcome this epidemic. After France

took similar action to make buprenorphine available without a specialized waiver, opioid overdose deaths declined by 79 percent over a four-year period¹.

Conclusion

Thank you for giving nurses the opportunity to provide input on this important issue. ANA stands ready to work with the Committee to find and implement sustainable solutions regarding this important issue. If you have any questions, please contact Ingrida Lusi, Vice President of Policy and Government Affairs, at (301) 628-5081 or Ingrid.Lusi@ana.org.

¹ <https://pubmed.ncbi.nlm.nih.gov/15204673/>



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Fentanyl Scheduling Charge and Response

Topline: Maintaining the emergency scheduling order issued by the Drug Enforcement Administration to place fentanyl-related substances in Schedule I of the Controlled Substances Act is critical for the prosecution of fentanyl analogue dealers. Fentanyl and fentanyl analogues remain among the most dangerous drugs in the world and are often misrepresented as they move through criminal networks, posing a unique risk to both the public and law enforcement. This is not a fear-based response, but rather an evidence-based response. To clarify disinformation regarding the federal prosecution of fentanyl and fentanyl analogues, we respond to several common charges.

Charge: The emergency scheduling of fentanyl and fentanyl analogues fails to decrease the supply of these drugs.

Response: The increase in prosecutions since the emergency scheduling order does not reflect increase supply of fentanyl and fentanyl analogues, but rather, an increased capacity to prosecute cases previously unavailable through prosecutions under the controlled substance analogue provisions of the Controlled Substances Act. Additionally, the Drug Enforcement Administration (DEA) reports a drastic reduction in encounters with new fentanyl analogue substances since the emergency scheduling order. DEA reports an almost 90 percent decline in total encounters of fentanyl-related substances. Under the class-wide scheduling order, traffickers lack an incentive to invent new analogues as they are unable to use slight chemical changes to avoid penalties.

Charge: Extending the emergency scheduling of fentanyl and fentanyl analogues further perpetuates known problems with mandatory minimums imposed on non-violent drug users.

Response: Congress has already provided various safety valves for allowing non-violent drug offenders to avoid mandatory minimums in an effort to maintain focus on the most dangerous drug criminals. [18 U.S.C. § 3553\(f\)](#) permits a sentencing court to disregard statutory minimum sentences for low-level, nonviolent, and cooperative defendants. This safety valve was expanded under the First Step Act of 2018 to provide additional relief from mandatory minimums for defendants with minimal prior criminal records.

Maintaining the existing mandatory minimums on fentanyl and fentanyl analogues, as well as the emergency scheduling order, allows prosecutors to work with defendants to avoid harsher sentences and provide insight on criminal networks. Due to the various safety valves in place, mandatory minimums have been applied much less frequently for fentanyl and fentanyl analogue cases. In FY 2019, the DEA reports mandatory minimum statutory penalties were applied for 52% of

fentanyl and fentanyl analogue cases. However, for all other drug cases mandatory minimum statutory penalties were applied in 66% of cases.

Charge: Most fentanyl and fentanyl analogue prosecutions are prosecutions of street-level or other minor role offenders.

Response: With the exception of crimes occurring in the special jurisdiction of the United States (such as the National Park Service), federal prosecutors do not pursue simple possession charges. Drug trafficking charges involving the distribution or manufacture of controlled substances are brought. Lower-level drug dealers are often encouraged to cooperate or provide substantial assistance to law enforcement authorities in order to combat large-scale criminal drug trafficking enterprises. In exchange for such assistance, lower-level dealers are typically rewarded with a substantial sentencing reduction without regard to the statutory mandatory minimum penalty.

Charge: Class-wide scheduling harms public health considerations and scientific research on fentanyl and its analogues.

Response: According to the [U.S. Sentencing Commission's January 2021 report](#) on fentanyl and fentanyl analogues, in fiscal year 2019, fentanyl or fentanyl analogue offenders accounted for almost three-quarters (74.7%) of all drug trafficking offenders sentenced where the offense of conviction established that death or serious bodily injury resulted from the substance's use. As little as 2 milligrams of fentanyl is considered a lethal dose; therefore, a trafficker with just one kilogram of fentanyl could distribute nearly 500,000 lethal doses. Impeding the proper prosecution of fentanyl and fentanyl analogue distributors is a public health hazard.

Further, class-wide scheduling of fentanyl analogues does not harm scientific research involving Schedule I drugs. To date, DEA has approved nearly 800 researchers nationwide to perform research with Schedule I controlled substances – twice as many approved researchers than five years ago.

Charge: The Drug Enforcement Administration should consult with the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) prior to scheduling additional fentanyl analogues.

Response: Drug traffickers consistently make small alterations to fentanyl analogues to evade criminal penalties. In the absence of a class-wide emergency scheduling order, the DEA must engage in a burdensome and time-consuming eight factor analysis for each new analogue uncovered before scheduling may be considered– in spite of the fact that the Sentencing Commission has found fentanyl analogue offenses, as a whole, result in user death twice as often as regular fentanyl cases. A drug trafficker need only make slight alterations to an analogue to delay the scheduling process and avoid a more severe sentence. This severely hampers a prosecutor's ability to combat the distribution of fentanyl analogues in real time and encourages experimentation by drug traffickers at the expense of consumers who end up ingesting unknown, novel substances.

Charge: Fentanyl and fentanyl analogues can be effectively prosecuted under the controlled substance analogue provisions of the Controlled Substance Act, making the emergency scheduling order unnecessary and duplicative.

Response: Prosecuting a fentanyl analogue under the Controlled Substances Act requires prosecutors to prove not only that the substance is substantially chemically and pharmacologically similar to fentanyl but that the drug trafficker knew of such similarity. Given the speed at which fentanyl analogues are created, this two-factor *mens rea* requirement is extremely difficult to meet. The Sentencing Commission found just under a third of fentanyl offenders and over forty percent of fentanyl analogue offenders sold or advertised these substances as other drugs. As substances are distributed across their drug trafficking networks, it becomes increasingly unlikely the distributors are aware of the chemical structure and pharmacological effects of the substance being sold.

Further, prosecutions for these offenses under the Controlled Substances Act are unlikely to succeed in front of a jury. These cases require complex scientific testimony from chemists and pharmacologists that often gets lost on lay jurors, allowing drug traffickers to evade conviction and accountability for their criminal conduct. In addition to being extremely resource intensive, analogue prosecutions often devolve into a battle between experts about the positioning of molecules in chemical structures and the results of *in vitro* and *in vivo* studies involving the substance's effects on various receptors in the brain. Such debates seem remarkably misplaced when the core of the crime is a defendant trafficking in a fentanyl substance that either killed someone or easily could have. Abandoning class scheduling will result in fewer prosecutions for trafficking new and increasingly more deadly forms of fentanyl, not because fewer such crimes will have been committed, but because the prosecutions of such crimes will become much more complicated and, in some instances, impossible.

Charge: The emergency scheduling order criminalizes addiction and prevents rehabilitation.

Response: As discussed above, federal prosecutors rarely prosecute the simple possession of fentanyl and fentanyl analogues. Federal criminal prosecutions remain focused on criminal networks involving the trafficking of fentanyl and fentanyl analogues. To the extent drug traffickers also battle addiction, these individuals may be eligible for Better Choices Court or the Bureau of Prisons' Residential Drug Abuse Program. These programs maintain criminal penalties while providing an incentive for inmates to receive addiction treatment – often offering reduced sentences for such participation.

Opposition to extending the emergency scheduling order on fentanyl and fentanyl analogues rooted in criticisms of the War on Drugs and the efficiency of mandatory minimums is misplaced in the current conversation. Fentanyl remains one of the most dangerous substances in the world. Fentanyl analogues are being rapidly created to fund criminal drug networks preying on victims of the opioid epidemic. Class scheduling of fentanyl-related substances makes it more likely that fentanyl dealers will be held accountable for exploiting the addictions of their customers, for causing their deaths, and for ripping families and communities apart. A decision to abandon class scheduling would leave an analogue prosecution as the only possible alternative to hold dealers of new and increasingly more deadly forms of fentanyl accountable. Many of those who are opposed to preserving class scheduling fail to understand, or perhaps refuse to acknowledge, that analogue

prosecutions are not a viable alternative to proving a controlled substance violation. The extreme difficulty in proving that a defendant knew of the similarities in the chemical structures and pharmacological effects of a fentanyl-related substance presents an enormous hurdle to a successful federal prosecution.



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April 14, 2021

Chairwoman Anna Eshoo
Subcommittee on Health
Committee on Energy & Commerce
U.S. Senate
Washington, D.C. 20510

Ranking Member Brett Guthrie
Subcommittee on Health
Committee on Energy & Commerce
U.S. Senate
Washington, D.C. 20510

**RE: NAAUSA Statement for the Record for the April 14, 2021 Subcommittee Hearing,
"An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America"**

Dear Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee:

On behalf of the National Association of Assistant United States Attorneys (NAAUSA), representing the interests of the 6,300 Assistant U.S. Attorneys (AUSAs) working in the 93 U.S. Attorney Offices, we write to provide feedback on the importance of maintaining the emergency scheduling order issued by the Drug Enforcement Administration to place fentanyl-related substances in Schedule I of the Controlled Substances Act. Doing so is critical for the prosecution of fentanyl analogue dealers. Fentanyl and fentanyl analogues remain among the most dangerous drugs in the world and are often misrepresented as they move through criminal networks, posing a unique risk to both the public and law enforcement. In the absence of a class-wide scheduling order, prosecuting fentanyl and fentanyl analogue cases becomes extremely difficult. This poses a public health threat as it stifles the prosecution of drug traffickers and encourages chemical experimentation.

According to the [U.S. Sentencing Commission's January 2021 report](#) on fentanyl and fentanyl analogues, in fiscal year 2019, fentanyl or fentanyl analogue offenders accounted for almost three-quarters (74.7%) of all drug trafficking offenders sentenced where the offense of conviction established that death or serious bodily injury resulted from the substance's use. As little as 2 milligrams of fentanyl is considered a lethal dose; therefore, a trafficker with just one kilogram of fentanyl could distribute nearly 500,000 lethal doses. Impeding the proper prosecution of fentanyl and fentanyl analogue distributors is a public health hazard.

In the absence of class-wide scheduling, prosecutors lack the adequate capacity to prosecute cases relating to fentanyl and fentanyl analogues. Prosecuting a fentanyl analogue under the Controlled Substances Act requires prosecutors to prove not only that the substance is substantially chemically and pharmacologically similar to fentanyl, but also that the drug trafficker knew of such similarity. Given the speed at which fentanyl analogues are created, this two-factor *mens rea* requirement is extremely difficult to meet. The Sentencing Commission found just under a third of fentanyl offenders and over forty percent of fentanyl analogue offenders sold or advertised these substances as other drugs. As substances are distributed across their drug trafficking networks, it becomes increasingly unlikely the distributors are aware of the chemical structure and pharmacological effects of the substance being sold.

Further, prosecutions for these offenses under the Controlled Substances Act are unlikely to succeed in front of a jury. These cases require complex scientific testimony from chemists and pharmacologists that often gets lost on lay jurors, allowing drug traffickers to evade conviction and accountability for their criminal conduct. In addition to being extremely resource intensive, analogue prosecutions often devolve into a battle between experts about the positioning of molecules in chemical structures and the results of *in vitro* and *in vivo* studies involving the substance's effects on various receptors in the brain. Such debates seem remarkably misplaced when the core of the crime is a defendant trafficking in a fentanyl substance that either killed

someone or easily could have. Abandoning class scheduling will result in fewer prosecutions for trafficking new and increasingly more deadly forms of fentanyl, not because fewer such crimes will have been committed, but because the prosecution of such crimes will become much more complicated and, in some instances, impossible.

Drug traffickers consistently make small alterations to fentanyl analogues to evade criminal penalties. In the absence of a class-wide emergency scheduling order, the DEA must engage in a burdensome and time-consuming eight factor analysis for each new analogue uncovered before scheduling may be considered- in spite of the fact that the Sentencing Commission has found fentanyl analogue offenses, as a whole, result in user death twice as often as regular fentanyl cases. A drug trafficker need only make slight alterations to an analogue to delay the scheduling process and avoid a more severe sentence. This severely hampers a prosecutor's ability to combat the distribution of fentanyl analogues in real time and encourages experimentation by drug traffickers at the expense of consumers who end up ingesting unknown, novel substances.

Opposition to extending the emergency scheduling order on fentanyl and fentanyl analogues rooted in criticisms of the War on Drugs and the efficiency of mandatory minimums is misplaced in the current conversation. Fentanyl remains one of the most dangerous substances in the world. Fentanyl analogues are being rapidly created to fund criminal drug networks preying on victims of the opioid epidemic. Class scheduling of fentanyl-related substances makes it more likely that fentanyl dealers will be held accountable for exploiting the addictions of their customers, for causing their deaths, and for ripping families and communities apart. A decision to abandon class scheduling would leave an analogue prosecution under the Controlled Substances Act as the only possible alternative to hold dealers of new and increasingly more deadly forms of fentanyl accountable. Many of those who are opposed to preserving class scheduling fail to understand, or perhaps refuse to acknowledge, that analogue prosecutions are not a viable alternative to proving a controlled substance violation. The extreme difficulty in proving that a defendant knew of the similarities in the chemical structures and pharmacological effects of a fentanyl-related substance presents an enormous hurdle to a successful federal prosecution.

NAAUSA appreciates the Subcommittee for considering NAAUSA's perspective. If we can be of further assistance, please do not hesitate to contact our Washington Representative Natalia Castro at necastro@shawbransford.com.

Respectfully,



Lawrence J. Leiser
President

CC: Chairman Frank Pallone
Ranking Member Cathy McMorris Rogers



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The Honorable Anna Eshoo
Chairwoman, Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

April 14, 2021

Dear Chairwoman Eshoo and Ranking Member Guthrie:

Thank you for holding the hearing “An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America” today. My name is Beth Connolly, and I am the project director of the Substance Use Prevention and Treatment Initiative at the Pew Charitable Trusts (Pew), an independent, nonpartisan research and policy organization. We work collaboratively with states and at the federal level to address the nation’s opioid overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

Over the past year, the United States has battled the COVID-19 pandemic. However, we must not forget that before COVID-19, our nation was already in the midst of an opioid overdose crisis that continues to kill hundreds of Americans each day.

While we do not yet know the full impact of the pandemic on the opioid overdose crisis, provisional data from the Centers for Disease Control and Prevention predicts that more than 88,000 people will die of an overdose in the 12-month period ending in August 2020, the vast majority involving opioids.¹ This represents a nearly 27% increase in one year. The growing death toll is not isolated to a specific region of our country but is impacting American communities from coast to coast. Every state and the District of Columbia has seen overdose deaths rise, and these alarming trends have accelerated during COVID-19.

This devastating loss of life from opioid overdose is even more tragic because it is preventable. OUD is a chronic brain disease that, like other chronic diseases, can be successfully treated with medications approved by the Food and Drug Administration (FDA). A conclusive body of research demonstrates that medication for opioid use disorder (MOUD) is the most effective way to treat the disease and its use substantially reduces mortality from overdoses.

Yet individuals with OUD struggle to get effective care: In 2019, only 18.1 percent of the 1.6 million people aged 12 or older with opioid use disorder received MOUD.¹¹ As the pandemic continues to strain the U.S. health care system, these simultaneous healthcare crises are creating even greater hardships for individuals seeking OUD treatment.

To substantially slow the climbing overdose death rate, Congress must act now to make MOUD more accessible. Two bills being considered today, the **Mainstreaming Addiction Treatment Act of 2021 (H.R. 1384)** and **Medicaid Reentry Act of 2021 (H.R. 955)**, address this critical need.

Access to Evidence-Based Treatment: The Mainstreaming Addiction Treatment Act

One of the three medications approved by FDA to treat OUD, buprenorphine has proven to be critical during COVID-19. Buprenorphine can be prescribed in a primary care setting as soon as a person is ready to begin treatment. Research shows that opioid agonist medications, including buprenorphine, reduce mortality from OUD by up to 50 percent.ⁱⁱⁱ Like other chronic conditions treated in primary care, clinicians have tools to manage OUD in outpatient settings. They can issue patients a prescription for buprenorphine that can be dispensed at a pharmacy and taken at home.

Yet, despite the medication's safety and clear benefits, federal rules established by the DATA 2000 Act require practitioners to receive additional training and to obtain a special waiver (known as the X-waiver) from the Drug Enforcement Administration (DEA) before they are allowed to prescribe buprenorphine for OUD. In addition, these providers are subject to additional oversight and scrutiny after obtaining a waiver. DEA data show that only about 6% of active physicians in the U.S. had obtained an X-waiver,^{iv} and a 2020 Health and Human Services Office of Inspector General report found that 40% of U.S. counties did not have a single waived provider who can prescribe buprenorphine.^v This lack of accessible providers leaves millions of people living in the U.S., disproportionately in rural areas, without access to local health care providers who can prescribe this life-saving medication.

Pew strongly encourages Congress to pass the Mainstreaming Addiction Treatment Act (H.R. 1384). This bipartisan legislation would remove the outdated and burdensome federal rules established by the DATA 2000 Act that require health care practitioners to obtain a waiver from the DEA before prescribing buprenorphine to treat OUD. While the pandemic continues to burden a health care system already struggling to meet the needs of patients with OUD, regulations that limit buprenorphine prescribing to a small minority of clinicians are no longer justified.

Expanding access to buprenorphine can help states address the overdose crisis exacerbated by the pandemic and empower physicians working in rural and underserved communities to take immediate steps to save lives at risk of overdose. By passing the MAT Act into law, Congress can relieve prescribers of unnecessary regulatory burden and increase the number of providers who can prescribe this essential medication.

Protecting Populations Most At-Risk of Overdose: The Medicaid Re-Entry Act

The pandemic has emphasized the importance of access to treatment for our country's marginalized populations. People with OUD are more likely to contract COVID-19 and they experience worse outcomes.^{vi} This phenomenon is linked to barriers to accessing health care in

underserved communities and their higher risk for homelessness and incarceration—environments that may increase the probability of exposure to the virus.^{vii}

For individuals with OUD who are incarcerated, the ability to access care is critical, as the time immediately following release can be particularly dangerous for overdose and death.^{viii} Individuals who are presumed opioid-free behind bars have a reduced tolerance to the drug, and therefore are at high risk of overdose if they resume opioid use at their previous levels. In the first week post-release from prison, individuals are more than twice as likely to die from an overdose as any other cause.^{ix}

As part of the response to coronavirus, many jurisdictions are expediting the release of some individuals to reduce prison and jail populations. Re-entry counselors now have the difficult task of preparing already medically vulnerable individuals for quick release during a pandemic.

The **Medicaid Reentry Act** provides for Medicaid coverage in the 30-day period prior to release from a public facility. This bill has the potential to protect incarcerated populations with OUD against the heightened risk of overdose by reimbursing facilities to initiate and maintain individuals on medications for opioid use disorder prior to release, while also facilitating care continuity with community providers. Delays in starting health care coverage upon release can jeopardize this life-saving connection to community care.

Thank you for your continuing efforts to support expanding access to OUD treatment and for taking swift action to address the pandemic. As this legislative package moves forward, Pew encourages the Committee to prioritize proposals that increase the availability of evidence-based treatment for OUD and to improve access to care for marginalized populations. Pew welcomes the opportunity to work with you to reduce the human toll related to the opioid overdose crisis.

Sincerely,



Elizabeth Connolly
Director, Substance Use Prevention and Treatment Initiative

ⁱ Centers for Disease Control and Prevention. National Vital Statistics System, Vital Statistics Rapid Release. "Provisional Drug Overdose Death Counts." Accessed April 9, 2021. <https://www.cdc.gov/nchs/nvss/vsr/drug-overdose-data.htm>

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ⁱⁱⁱ National Academies of Sciences, Engineering, and Medicine. 2019. *Medications for opioid use disorder save lives*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/25310>.

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- ^v Department of Health and Human Services Office of Inspector General, "Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder" (2020).
- ^{vi} Wang, Q. Q., Kaelber, D. C., Xu, R., & Volkow, N. D. (2021). COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States. *Molecular psychiatry*, 26(1), 30-39.
- ^{vii} *ibid*; National Institute on Drug Abuse. COVID-19: Potential Implications for Individuals with Substance Use Disorders. <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders>. April 6, 2020 Accessed April 9, 2021.
- ^{viii} Binswanger, I. A., Stern, M. F., Deyo, R. A., Heagerty, P. J., Cheadle, A., Elmore, J. G., & Koepsell, T. D. (2007). Release from prison—a high risk of death for former inmates. *New England Journal of Medicine*, 356(2), 157-165.
- ^{ix} Binswanger IA et al., "Mortality after prison release: opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009." *Annals of Internal Med.* 2013; 159 (9): 592-600.



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December 11, 2019

Sen. Lindsey Graham
Chairman
Committee on the Judiciary
290 Russell Senate Office Building
Washington, DC 20510

Sen. Diane Feinstein
Ranking Member
Committee on the Judiciary
331 Hart Senate Office Building
Washington, DC 20510

Re: S. 2701 – Federal Initiative to Guarantee Health by Targeting (FIGHT) Fentanyl Act

Dear Senators Graham and Feinstein,

We write today to offer our collective support for S. 2701, the Federal Initiative to Guarantee Health by Targeting (FIGHT) Fentanyl Act.

As you are likely aware, the Drug Enforcement Agency's (DEA) temporary order classifying fentanyl-related compounds as Schedule I drugs is set to expire on February 6, 2020. The FIGHT Fentanyl Act would codify this temporary order, keeping fentanyl-related substances classified as Schedule I drugs.

In the most recent data available from the Centers for Disease Control and Prevention, there were 72,000 drug-related deaths in the United States in 2017. Of those deaths, roughly 40% involved fentanyl or a fentanyl-related compound.

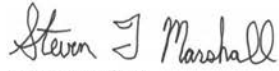
Just last month, a coalition of local, state, and federal agencies in Ohio intercepted over 20 kilograms of fentanyl, 1.5 kilograms of methamphetamine, and half a kilogram of heroin. Further testing revealed that the 20 kilograms of fentanyl were laced with carfentanil, which can be over 100 times more potent than fentanyl. The potency of the fentanyl-related substances in this single bust was enough to kill every man, woman, and child in the state of Ohio several times over.

This legislation is crucial to federal and state efforts to curb the opioid epidemic nationally and within each individual state. It is for these reasons that we commend Senators Portman and Manchin for their leadership in bringing forward this important legislation, and we urge you to take up and pass S. 2701 before the DEA's temporary order expires.

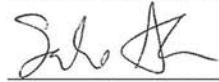
Yours,



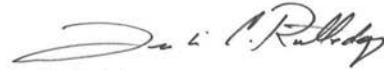
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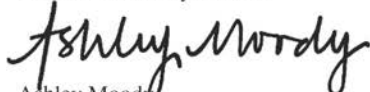
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Phil Weiser
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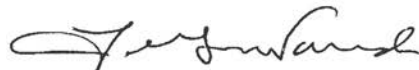
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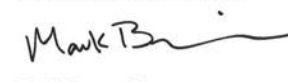
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New Jersey Attorney General

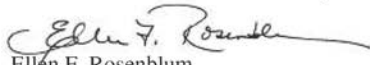
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New York Attorney General



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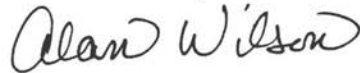
Edward Manibusan
Northern Mariana Islands Attorney General



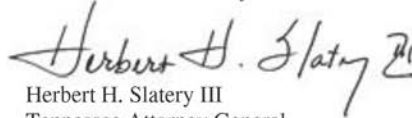
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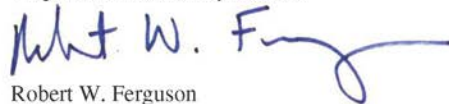
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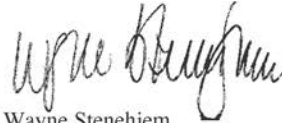
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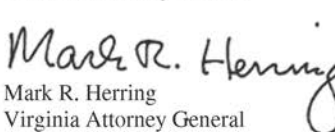
Jason R. Ravensborg
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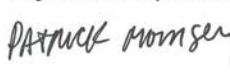
Ken Paxton
Texas Attorney General



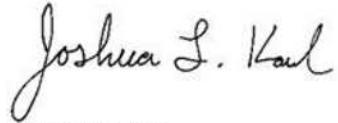
T.J. Donovan
Vermont Attorney General



Mark R. Herring
Virginia Attorney General



Patrick Morrissey
West Virginia Attorney General

A handwritten signature in black ink that reads "Joshua L. Kaul". The signature is written in a cursive, flowing style.

Joshua L. Kaul
Wisconsin Attorney General

Cc: Senator Rob Portman
Senator Joe Manchin

A handwritten signature in blue ink that reads "Bridget Hill". The signature is written in a cursive, flowing style.

Bridget Hill
Wyoming Attorney General



PRESIDENT
Jeff Landry
Louisiana Attorney General

PRESIDENT-ELECT
Tim Fox
Montana Attorney General

VICE PRESIDENT
Karl A. Racine
*District of Columbia
Attorney General*

IMMEDIATE PAST PRESIDENT
Derek Schmidt
Kansas Attorney General

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August 5, 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-232, The Capitol
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
S-230, The Capitol
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
H-204, The Capitol
Washington, DC 20515

The Honorable Charles Schumer
Minority Leader
U.S. Senate
S-221, The Capitol
Washington, DC 20510

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader McConnell,
and Minority Leader Schumer,

The undersigned attorneys general share your concern about the impact of the opioid epidemic on our country. As President Trump has recognized in the National Drug Control Strategy he released earlier this year, the opioid crisis has resulted in more American deaths in just two years than in the course of the entire Vietnam War. In 2017, there were more than 70,200 drug overdose deaths in the United States. More than 47,500 of these deaths involved an opioid, and more than half of these deaths involved a synthetic opioid such as illicit fentanyl or one of its analogues.

The impact of the epidemic has been so pervasive and so severe that life expectancy in the United States has declined for three years in a row for the first time since the influenza pandemic of 1918. The epidemic has contributed to a rise in Hepatitis C and heart valve infections (endocarditis), a rise in the number and rate of hospitalizations associated with drug withdrawal in newborns, and other significant and costly health impacts.

This loss of life and these major health consequences are matched by significant and continuing costs imposed on our criminal justice and social service systems. And the economic cost of the opioid crisis exceeded \$500 billion in 2015 – equal to 2.8 percent of the U.S. Gross Domestic Product (GDP) that year – according to the White House Council of Economic Advisers.

We all understand that effective treatment is key to saving lives and helping to stop this epidemic. In particular, research shows that Medication-Assisted Treatment (MAT) – the use of medications, in combination with counseling and behavioral therapies – is a highly effective approach to the treatment of opioid use disorders.

Unfortunately, there are three significant barriers to treating opioid use disorder that we cannot change at the state level and that must be tackled at the federal level. We share these barriers below in the hope that we can work together to remove them and allow more providers to offer treatment for opioid use disorder and other substance use disorders.

1. Replace the cumbersome, out-of-date, privacy rules contained in 42 CFR Part 2 with the effective and more familiar privacy rules contained in the Health Insurance Portability and Accountability Act (HIPAA).

42 CFR Part 2 sets forth strict requirements for the use and disclosure of patients' substance use disorder treatment records. The complexities of complying with 42 CFR Part 2 often prevent general practice providers from even attempting to treat patients with substance use disorders through the use of medication-assisted treatment (MAT), because – while providers are familiar with how to comply with the privacy requirements of HIPAA – they may be intimidated by the requirements of 42 CFR Part 2.

This regulatory scheme also sets up a strange situation in which office-based MAT providers do not have to follow the specialized requirements of 42 CFR Part 2 unless they advertise to the public that they provide MAT. So, in an era when we are trying to promote access to MAT, we are encouraging office-based MAT providers to keep secret the fact that they provide this life-saving service so they can avoid the cumbersome 42 CFR Part 2 rules.

These privacy rules were created more than 40 years ago in a time of intense stigma surrounding substance use disorder treatment. They were created to assure patients that they would not face adverse legal or civil consequences when seeking treatment by protecting confidentiality of substance use disorder patient records. Unfortunately, they now serve to perpetuate that stigma, as the principle underlying these rules is that substance use disorder treatment is shameful and records of it should be withheld from other treatment providers in ways that we do not withhold records of treatment of other chronic diseases. While maintaining confidentiality is imperative to encouraging individuals to seek and obtain treatment, the inability to share records among providers can burden coordination of care, potentially resulting in harm to the patient.

To be effective in fighting the opioid epidemic, we must treat substance use disorder as the chronic disease that it is—and that means aligning the rules regarding disclosure of substance use disorder treatment records with the protections against unwanted disclosure of patient records already contained in HIPAA, particularly as it relates to disclosure of substance abuse treatment information to authorized providers.

In seeking needed changes in 42 CFR Part 2, we are joined by Democratic and Republican lawmakers in both houses of Congress. In the House, the Overdose Prevention and Patient Safety Act (OPPS Act) (H.R. 2062) was introduced by Reps. Markwayne Mullin (R-OK) and Earl Blumenauer (D-OR); and in the Senate, the Protecting Jessica Grubb's Legacy Act (Legacy Act) (S. 1012) was introduced by Sens. Joe Manchin (D-WV) and Shelley Moore Capito (R-WV). Both bills will align Part 2 with HIPAA for the purposes of health care treatment, and both are supported by the Partnership to Amend 42 CFR Part 2, a growing coalition of more than

40 national health care organizations that includes the American Hospital Association, the American Psychiatric Association, and the American Society of Addiction Medicine.

2. Pass H.R. 2482, the Mainstreaming Addiction Treatment (MAT) Act, and eliminate unnecessary burdens on buprenorphine prescribing imposed by the Drug Addiction Treatment Act of 2000 (DATA 2000).

DATA 2000 was a step forward in substance use disorder treatment because it allowed the treatment of opioid use disorder in an office-based setting. However, it created a cumbersome bureaucratic system whereby providers who wish to prescribe buprenorphine in an office-based setting must prove to the Substance Abuse and Mental Health Services Administration (SAMHSA) that they have taken special trainings and then apply to the Drug Enforcement Administration (DEA) for a special DEA “X” number to indicate when buprenorphine is being prescribed to treat substance use disorder.

This is the only drug on the market for which prescribers have to prove they have received specialized training in order to prescribe the drug. This requirement was put in place well before the rapid rise in opioid use disorder and opioid overdose deaths that have become a national crisis. Just as opioid use disorder and opioid overdose deaths have risen dramatically in recent years, so the need for MAT with buprenorphine has risen just as dramatically. Because the need for MAT is far out-pacing the availability of such treatment, it is time to reconsider the DATA 2000 regulatory framework and other barriers that stand in the way of expanded use of buprenorphine to treat opioid use disorder and help prevent opioid overdose deaths.

The fact is that, as a partial agonist, buprenorphine is a safer drug than opioid agonists such as oxycodone and fentanyl that are readily prescribed without any requirements for training or specialized DEA numbers. So, doctors need not prove any special training to prescribe more addictive opioid pain killers but must follow complicated bureaucratic steps to prescribe a less addictive opioid (buprenorphine) for substance use disorder treatment.

Buprenorphine should not be singled out from all other drugs because it is a treatment for substance use disorder. Providers should be trained to prescribe buprenorphine the same way they are trained to prescribe other drugs – in medical schools, nurse practitioner schools, medical residencies, and continuing medical education. The stigma-based policy is endangering lives by suppressing access to treatment and should be changed.

In our effort to eliminate this antiquated policy that restricts a healthcare provider’s ability to prescribe buprenorphine, we are joined by a coalition of 22 states, led by the New York State Department of Health, seeking exactly this change.

H.R. 2482, the Mainstreaming Addiction Treatment (MAT) Act, would address this issue by eliminating the redundant and outdated requirement that practitioners apply for a separate waiver through the DEA to prescribe buprenorphine for the treatment of substance use disorder. We urge Congress to pass – and President Trump to sign – the MAT Act or similar legislation as expeditiously as possible.

3. Fully repeal the Medicaid Institutions for Mental Diseases (IMD) exclusion.

The Institutions for Mental Diseases (IMD) exclusion generally prohibits state Medicaid programs from receiving federal reimbursement for adults between 21 and 65 receiving mental health or substance use disorder treatment in a residential treatment facility with more than 16 beds.

This arcane federal policy, while well intentioned at its inception to encourage treatment in community-based settings, has proven to detrimentally limit states' ability to provide the full continuum of clinically appropriate care for Medicaid enrollees with a substance use disorder. We join the National Governor's Association and a wide range of health care and public health groups in calling on the Administration to continue working with states to expedite approval of IMD waivers, while also recognizing the need for a permanent, statutory solution to resolve this issue for all states.

The recently-enacted Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act took a step in the right direction, but it did not go far enough. The SUPPORT Act partly eliminates the IMD exclusion for a five-year period by allowing states to cover IMD services to people with at least one substance use disorder for up to 30 days over a 12-month period under certain circumstances. Congress needs to go further, by fully repealing the IMD exclusion.

We applaud the federal government for its recent constructive steps to address the opioid epidemic through both legislative and executive action, but we all know that there is more work to be done. By making the changes recommended, Congress would make effective treatment for opioid use disorders more widely and readily available so that we can save more lives and help turn the tide on this crisis.

Thank you for your consideration.

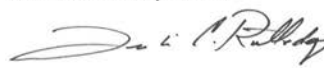
Sincerely,


Josh Stein
North Carolina Attorney General


Kevin G. Clarkson
Alaska Attorney General


Xavier Becerra
California Attorney General


Mike Hunter
Oklahoma Attorney General


Leslie Rutledge
Arkansas Attorney General


Phil Weiser
Colorado Attorney General



William Tong
Connecticut Attorney General



Karl A. Racine
District of Columbia Attorney General



Clare E. Connors
Hawaii Attorney General



Kwame Raoul
Illinois Attorney General



Jeff Landry
Louisiana Attorney General



Maura Healey
Massachusetts Attorney General



Keith Ellison
Minnesota Attorney General



Tim Fox
Montana Attorney General



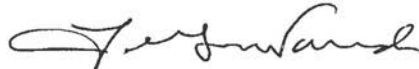
Aaron D. Ford
Nevada Attorney General



Kathleen Jennings
Delaware Attorney General



Ashley Moody
Florida Attorney General



Lawrence Wasden
Idaho Attorney General



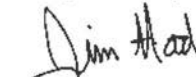
Tom Miller
Iowa Attorney General



Aaron M. Frey
Maine Attorney General



Dana Nessel
Michigan Attorney General



Jim Hood
Mississippi Attorney General



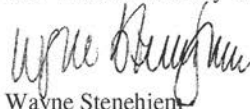
Douglas Peterson
Nebraska Attorney General



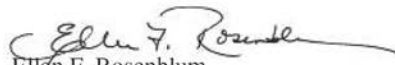
Gordon MacDonald
New Hampshire Attorney General



Hector Balderas
New Mexico Attorney General



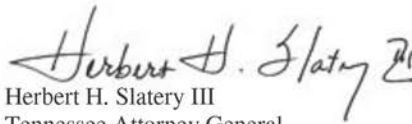
Wayne Stenehjem
North Dakota Attorney General



Ellen F. Rosenblum
Oregon Attorney General



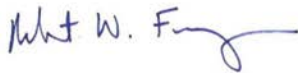
Peter F. Neronha
Rhode Island Attorney General



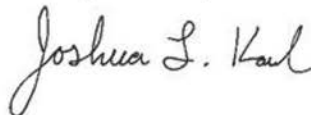
Herbert H. Slatery III
Tennessee Attorney General



T.J. Donovan
Vermont Attorney General



Robert W. Ferguson
Washington Attorney General



Joshua L. Kaul
Wisconsin Attorney General



Letitia James
New York Attorney General



Dave Yost
Ohio Attorney General



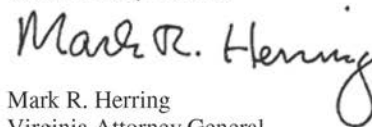
Josh Shapiro
Pennsylvania Attorney General



Jason R. Ravensborg
South Dakota Attorney General



Sean Reyes
Utah Attorney General



Mark R. Herring
Virginia Attorney General



Patrick Morrissey
West Virginia Attorney General



April 13, 2021

The Honorable Anna Eshoo
Chairwoman
House Committee on Energy & Commerce
Subcommittee on Health
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
House Committee on Energy & Commerce
Subcommittee on Health
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie:

On behalf of the Healthcare Leadership Council (HLC), we thank you for holding a hearing on, "An Epidemic Within a Pandemic: Understanding Substance Use and Misuse in America."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC –hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, and information technology companies –advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

The COVID-19 health pandemic has further exacerbated the substance use disorder (SUD) crisis in the United States. From May 2019 – June 2020, the number of deaths related to drug overdoses rose 20% and a record number of Americans died from overdoses.¹ Preliminary data expects 2020 to be the worst year on record for drug overdoses.² In order to respond to this crisis, Congress and federal agencies took swift action to ensure patients struggling with SUDs received proper care. We applaud the Drug Enforcement Agency's (DEA) decision to temporarily waive in-person requirements to prescribe controlled substances. This has allowed patients to continue to receive important medications, particularly buprenorphine. HLC also thanks the Centers for Medicare and Medicaid Services (CMS) for finalizing regulations mandated under the *SUPPORT Act* that require providers to use electronic prescribing for controlled substances (EPCS). Requiring EPCS puts a more advanced monitoring system in place to ensure that controlled substances are only prescribed when necessary and allows for relevant authorities to monitor potential trends. We encourage Congress to work with federal agencies to further implement flexibilities that would allow for patients to receive important

¹ Usha Lee McFarling, *As the pandemic ushered in isolation and financial hardships, overdose deaths reached new heights*, STAT News (February 16, 2021), <https://www.statnews.com/2021/02/16/as-pandemic-ushered-in-isolation-financial-hardship-overdose-deaths-reached-new-heights/>.

² Chris Sweeney, *A crisis on top of a crisis: COVID-19 and the opioid epidemic*, Harvard T.H. Chan School of Public Health (February 16, 2021), <https://www.hsph.harvard.edu/news/features/a-crisis-on-top-of-a-crisis-covid-19-and-the-opioid-epidemic/>.

medications through the duration of the public health emergency (PHE) while maintaining robust safety and monitoring programs.

While HLC supports the regulatory flexibilities implemented during the PHE, Congress should further examine ways to combat the SUD crisis. We support efforts to permanently remove the "X-Waiver" required under the Drug Treatment Act of 2000 that requires providers to receive a special waiver from the DEA to prescribe buprenorphine. We also encourage Congress to allow patients to receive prescriptions for controlled substances via telemedicine permanently once the waivers under the PHE expire.

As stakeholders continue to respond to the growing SUD challenges, we encourage Congress to work with federal agencies and additional partners to continue to develop educational resources on appropriate use of controlled substances as well as resources to patients struggling with SUDs. These tools will allow stakeholders to take sustainable steps in responding to the substance use disorder crisis by identifying best practices in treatment decisions and ensure that patients have essential treatment options.

HLC, through its [National Dialogue for Healthcare Innovation](#), continues to be focused on ways to address the substance use disorder crisis and looks forward to collaborating on future steps to assist patients struggling with SUDs. Please feel free to contact Tina Grande at 202-449-3433 or tgrande@hlc.org with any questions.

Sincerely,

A handwritten signature in cursive script, reading "Mary R. Grealy".

Mary R. Grealy
President

Statement to the House Energy and Commerce Health Subcommittee Hearing

"AN EPIDEMIC WITHIN A PANDEMIC: UNDERSTANDING SUBSTANCE USE AND MISUSE IN AMERICA"

April 12, 2021

Margaret Rizzo

JSAS HealthCare, Executive Director/CEO
American Association for the Treatment of Opioid Dependence
(NJ Board Member)
New Jersey Association for the Treatment of Opioid Dependence
(Officer)

The American Association for the Treatment of Opioid Dependence (AATOD), which represents 1,200 Opioid Treatment Programs throughout the United States, opposes the passage of bill number H.R. 1384 and S. 445 (The Mainstreaming Addiction Treatment (MAT) Act). We certainly support the need to expand access to the treatment of opioid use disorder, wherever it is needed, especially in rural and underserved areas. There is no need to sacrifice quality of care as access to treatment is expanded.

It is true that buprenorphine, in combination with psychosocial services, has been effectively used for two decades. However, the vast majority of individuals currently receive no counseling. This has led to lower treatment retention and poor clinical outcomes.^{1,2} Simply prescribing medication alone is not medication-assisted treatment.

In response to the opioid crisis, federal and state authorities worked urgently to implement opioid prescribing limits and increase prescriber education to mitigate the misguided prescribing practices that contributed to the opioid epidemic. This legislation moves in the opposite direction by removing the education requirements and limits that currently protect consumers and making it easier to prescribe a medication known to be highly diverted and misused.

Additionally, there is no need to eliminate the 8-hour training for practitioners as required by the original DATA 2000 legislation. There is a need to remove barriers to such treatment expansion such as Prior Authorizations by insurance companies. There is also a need to better ensure that DATA 2000 practitioners have access to other resources that can provide comprehensive services to the patients being treated.

Eliminating the waiver will massively expand access to medication, not treatment. This legislation does not provide medical professionals with the resources needed to integrate quality substance use disorder treatment into their settings. Many individuals with an opioid use disorder engage in polysubstance misuse, much of which requires psychosocial interventions,

not medication. Of adults with a substance use disorder, 37.9% also have a co-occurring mental health disorder.³

There is no data on the efficacy or quality of MAT provided in primary care settings. There is, however, data available on the rates of buprenorphine misuse. The RADARS® (Researched Abuse Diversion Addiction Related) surveillance system found that during 2018, individuals presenting for opioid treatment in the U.S. reported misuse of buprenorphine in 27.4% of cases and within these, 15.3% indicated misuse of buprenorphine by injection.⁵

The stigma surrounding MAT for opioid use disorder is generated in large part when diversion and misuse of these medications occur. Diversion control plans are not required of MAT provided in a primary care setting. The rate of buprenorphine diversion has been steadily increasing as more buprenorphine is prescribed.⁵ The number of opioid treatment admissions reporting buprenorphine as a primary drug of misuse has also steadily increased.³

We do support increasing access to patients seeking Opioid Use Disorder (OUD) treatment as follows:

- Removing infrastructure and technology barriers to telehealth in rural areas; physicians can currently initiate treatment with buprenorphine via telehealth, if infrastructure were in place;
- Considering increase in take home allowances from highly structured, highly regulated Opioid Treatment Programs (OTP's) for eligible, stable patients to reduce transportation time and costs;
- Support initiatives to use medication units and mobile vans operated by highly regulated OTP's and for which DEA has current guidelines;
- Supporting removal of Prior Authorization requirements for treatment entry, for all insurance types, expanding on CARA 3.0's proposal on this matter.
- Incentivize state and local jurisdictions to make opening OTPs easier.

The requirement to obtain a medical license has already proven insufficient to ensure safe prescribing practices of opioids. A lack of adequate prescriber training on best practice guidelines for pain management and opioid prescribing has been identified as a significant factor in the development of the opioid epidemic due to over-prescribing of opioids without any oversight. The waiver requirement addresses these past wrongs and helps protect consumers from untrained practitioners inappropriately prescribing powerful opioid medications.

¹ T McLellan, A & O. Arndt, Isabelle & Metzger, David & Woody, George & O'Brien, Charles. (1993). The Effects of Psychosocial Services in Substance-Abuse Treatment. *JAMA: the journal of the American Medical Association*. 269. 1953-9. 10.3109/10884609309149701

² Principles of Effective Treatment, A Research Based Guide (3rd Edition), National Institute on Drug Abuse, last update January 2018

³ Co-morbidity: Substance Use and Other Mental Disorders <https://www.drugabuse.gov/sites/default/files/infographic-comorbidity.pdf>

⁴ Lofwall, M.R, Walsh, S. L. 2014. A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. *Journal of Addiction Medicine*. Sep-Oct;8(5):315-26.

⁵ Treatment Center Programs Combined, 2008-2018, RADARS® (Researched Abuse Diversion Addiction Related)

END SUD

Together, we're ending substance use disorder.

April 13, 2021

The Honorable Frank Pallone, Jr.
Chair
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chair Pallone and Ranking Member McMorris Rodgers:

Thank you for holding a hearing on "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America." Urgent action is needed to stem the accelerating overdose crisis in the United States and we appreciate your prioritizing substance use disorder prevention, treatment, and recovery early in this session.

End Substance Use Disorder (End SUD) is a national, nonpartisan campaign that advances policies to prevent and treat substance use disorder. We are a nonprofit advocacy organization committed to doing what works to end the pain and suffering caused by substance use disorder so our loved ones can heal, earn a living, spend time with their families, and contribute to their communities. End SUD believes in science and in ethics: we support only policies backed by research and evidence and we do not take contributions from pharmaceutical companies, treatment facilities, or other organizations that make money on substance use disorder. End SUD leads coalitions of healthcare and behavioral health providers, people and families with substance use disorder, harm reduction advocates, law enforcement officers, social justice leaders, and local officials that serve millions of Americans.

The need for Congress to act is urgent: The United States just suffered the deadliest year on record for overdose deaths.ⁱ More than 88,000 Americans are estimated to have died of an overdose in the twelve months ending in August 2020, the vast majority from opioids.ⁱⁱ Drug overdose is a primary cause of death for new mothersⁱⁱⁱ and the leading cause of death for Americans under the age of 50.^{iv} Veterans,^v rural Americans,^{vi} and persons of color^{vii} all disproportionately suffer from the overdose crisis. Without action, hundreds of thousands more Americans will die from an overdose over the next decade.^{viii}

To help end the overdose crisis, we strongly urge Congress to pass the Mainstreaming Addiction Treatment Act (H.R. 1384). We applaud you for including this legislation in the hearing and will look forward to working together to pass this bill in the House of Representatives. The Mainstreaming Addiction Treatment Act is a common-

Statement of Support, End Substance Use Disorder (End SUD)
Mainstreaming Addiction Treatment Act (H.R. 1384)
Page 2

sense solution that will cut through federal red tape to increase participation in treatment, help eliminate stigma, and reduce healthcare and criminal justice costs.^{ix} The bill could save tens of thousands of Americans every year from overdose death and help them secure long-term recovery.^x

The Mainstreaming Addiction Treatment Act will help build universal access to buprenorphine, a lifesaving treatment for opioid use disorder, by allowing all healthcare providers with a standard controlled medication license to prescribe buprenorphine just as they prescribe medications for other chronic medical conditions. The bill also launches a national education campaign to connect healthcare providers to publicly available training and mentorship resources on best practices for treating substance use disorder.

These actions are needed because as few as 1 in 5 Americans with opioid use disorder receive buprenorphine.^{xi} Buprenorphine is a safe, effective treatment that cuts the risk of overdose death in half and helps people secure long-term recovery.^{xii} The medication has been FDA-approved for nearly twenty years, is available in generic, and is one of the most cost-effective treatments for opioid use disorder.^{xiii} Buprenorphine is safer and easier to manage than commonly prescribed medications like insulin and blood thinners.^{xiv} And during the COVID-19 pandemic, buprenorphine is the only medication for opioid use disorder that can be initiated via telehealth. Public health officials recognize buprenorphine as one of the gold standards of care for opioid use disorder and as a necessary tool to help end the overdose crisis.^{xv}

But despite the broad recognition of buprenorphine's safety and effectiveness, Americans with opioid use disorder still suffer from a severe lack of access to this lifesaving medication. The reason so few in need can access buprenorphine is that almost no healthcare providers can or actually do prescribe the medication for opioid use disorder. Fewer than 7 in 100 eligible healthcare providers have the federal registration required to prescribe buprenorphine for opioid use disorder.^{xvi} Of those providers who have the federal registration, fewer than 1 in 3 actually prescribe buprenorphine.^{xvii} And half of those providers who do prescribe buprenorphine treat five or fewer patients (while rejecting up to half of patients who request the medication).^{xviii} In one of the worst public health crises in modern history, our healthcare providers are simply not equipped with or utilizing the tools we have to successfully treat opioid use disorder.

Current federal law stands in the way of healthcare providers prescribing buprenorphine for opioid use disorder. While all healthcare providers with a standard controlled medication license can prescribe buprenorphine to a person in pain, the Drug Addiction Treatment Act of 2000 ("DATA 2000") places onerous burdens on healthcare providers in prescribing the exact same medication to a person with substance use disorder.^{xix} To prescribe buprenorphine for opioid use disorder, DATA 2000 requires that physicians, advanced practice registered nurses, and physician assistants undergo 8-24

Statement of Support, End Substance Use Disorder (End SUD)
Mainstreaming Addiction Treatment Act (H.R. 1384)
Page 3

hours of training, undertake a 2-3 month registration process with SAMHSA and the DEA, adhere to strict limits on the number of patients they can treat, have the ability to refer patients to counseling, mark prescriptions with an “X” using a special DEA number, and submit their patient records and offices to DEA inspection. These requirements are generally referred to as the “DATA 2000 Waiver” or the “X-Waiver.”

The intent of DATA 2000 was to ensure that primary care physicians could prescribe buprenorphine for opioid use disorder in the normal course of their medical practice, but the law has instead imposed significant barriers to care. Congress passed DATA 2000 in part because, without DATA 2000, the Narcotic Addict Treatment Act of 1974 would have restricted buprenorphine’s use to highly regulated opioid treatment programs. The Secretary of Health and Human Services requested at the time that Congress ensure physicians could prescribe buprenorphine in private practice.^{xx} By imposing bureaucratic requirements on physicians, however, DATA 2000 did not expand access to buprenorphine to the extent needed to stop the opioid overdose crisis.

Soon after it became law, Congress recognized that DATA 2000 would not increase access to buprenorphine enough to prevent significant numbers of opioid overdose deaths. Since 2005, Congress has repeatedly tried to expand access to buprenorphine by expanding the type of providers who can obtain a DATA 2000 waiver, increasing the numbers of patients that waived healthcare providers can treat, and exempting certain healthcare providers from the waiver requirements.^{xxi} In addition, the federal government has spent millions of dollars to recruit more medical professionals to obtain the DATA 2000 waiver. All of these efforts reflect broad support for expanding access to buprenorphine.

We applaud the commitment to expanding access to buprenorphine, but these efforts have not resulted in widespread use of this life-saving treatment. Each of the federal requirements to prescribe buprenorphine to a person with opioid use disorder reinforces each other and dissuades providers from prescribing the medication. The requirements foster stigma towards people with opioid use disorder^{xxii} and impose cumbersome regulations on healthcare providers that are outside the bounds of evidence and do not align with how healthcare providers learn and practice.^{xxiii} Nearly 7 in 10 physicians surveyed state that the federally-mandated training course discourages providers from prescribing buprenorphine.^{xxiv} And nearly 8 in 10 physicians surveyed report a lack of time as a reason not to prescribe buprenorphine.^{xxv} Finding, paying for, and taking the training discourages providers from seeking to prescribe buprenorphine.^{xxvi} Once registered, the patient limits, recordkeeping requirements, and DEA audits overly tax providers’ time and disincentivize them from treating patients with opioid use disorder.^{xxvii} All together, the federal requirements limit the number of healthcare providers who can prescribe buprenorphine for opioid use disorder, which creates a vicious cycle: The fewer healthcare providers who obtain the federal registration to prescribe buprenorphine, the

Statement of Support, End Substance Use Disorder (End SUD)
Mainstreaming Addiction Treatment Act (H.R. 1384)
Page 4

fewer healthcare providers who will seek to obtain that registration and actually prescribe the medication.^{xxxviii} At every step of the federal process, healthcare providers choose not to prescribe buprenorphine.

Moreover, healthcare providers who can prescribe buprenorphine are not equitably distributed across communities in need. According to the National Academy of Sciences, Engineering and Medicine, even if all healthcare providers who have the federal registration actually prescribed buprenorphine up to the full number of patients allowed under federal law, just half of people with opioid use disorder would receive treatment.^{xxxix} More than twenty million Americans live in a county without a provider who has the federal registration.^{xxx} Rural Americans,^{xxxi} veterans,^{xxxii} pregnant people,^{xxxiii} and persons of color^{xxxiv} all suffer disproportionately from a lack of access to buprenorphine. This severe lack of access to buprenorphine is fueling the overdose crisis, causing multitudes of preventable deaths.

In addition to restricting access to lifesaving care, the DATA 2000 requirements are outside the bounds of evidence. The National Academy of Sciences, Engineering and Medicine has noted that “no evidence base supports the waiver process itself,” regardless of questions as to why healthcare providers may or may not obtain a waiver or prescribe buprenorphine once they have the waiver.^{xxxv} Indeed, there is no other disease in the country for which medical treatment is subject to these registration requirements and patient limits.^{xxxvi}

To build universal access to buprenorphine, we urge Congress to pass the Mainstreaming Addiction Treatment Act (H.R. 1384). The bill will remove the DATA 2000 waiver and expand access to mentorship and education resources on treating patients with substance use disorder. To further expand access to care, Congress can also improve insurance coverage for the medication by removing prior authorization requirements and improving reimbursement rates.

We look forward to working together to enact the solutions proven to end death and disability caused by substance use disorder so our families can stay together and our communities can thrive.

Sincerely,



Erin Schanning
President
End Substance Use Disorder (End SUD)

Statement of Support, End Substance Use Disorder (End SUD)
Mainstreaming Addiction Treatment Act (H.R. 1384)
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ⁱ Lev Facher, *The 'other' epidemic: Amid Covid-19, addiction experts fear Biden could back-burner the overdose crisis*, STAT News (Mar. 2, 2021) ("2020 has by far the highest number of deaths ever recorded," Nora Volkow, the director of the National Institute on Drug Abuse, said in an email. "It's quite dramatic.").

ⁱⁱ Centers for Disease Control and Prevention ("CDC"), *12 Month-Ending Provision Number of Drug Overdose Deaths* (Apr. 12, 2021); CDC, *Overdose Deaths Accelerating During COVID-19: Expanded Prevention Efforts Needed* (Dec. 17, 2020).

ⁱⁱⁱ Max Jordan Nguemini Tiako, M.S. et al., *Prevalence and Geographic Distribution of Obstetrician-Gynecologists Who Treat Medicaid Enrollees and Are Trained to Prescribe Buprenorphine*, 3(12) JAMA Network Open (Dec. 11, 2020).

^{iv} CDC, *Underlying Cause of Death 1999-2018 on CDC WONDER Online Database*.

^v U.S. Government Accountability Office ("GAO"), *Report to Congressional Committees: Veterans Healthcare, Services for Substance Use Disorders, and Efforts to Address Access Issues in Rural Areas*, at 1 (Dec. 2019) ("Veterans are 1.5 times more likely to die from opioid overdose than the general population, according to VA and Centers for Disease Control and Prevention data.").

^{vi} U.S. Dep't Health and Human Svcs. ("HHS"), *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (2020) ("In total, 1,119 counties had high indicators for at least two of the three opioid misuse and abuse measures (i.e., drug overdose mortality, nonmedical use of pain relievers, and opioid prescribing) included in our analysis, thereby meeting OIG's definition of 'high need'...More than half (61 percent) of these high-need counties are in rural areas.").

^{vii} Substance Abuse and Mental Health Svcs. Admin. ("SAMHSA"), *The Opioid Crisis and the Black/African American Population: An Urgent Issue*, at 3-5 (2020) ("From 2011-2016, compared to all other populations, Black/African Americans had the highest increase in overdose death rate for opioid deaths involving synthetic opioids like fentanyl and fentanyl analogs."); SAMHSA, *The Opioid Crisis and the Hispanic/Latino Population: An Urgent Issue*, at 4 (2020) ("From 2014-2017, among the Hispanic population drug overdose death rates involving all types of opioids increased, with the sharpest rise from synthetic opioids. Death rates involving synthetic opioids increased by 617 percent, and was the second highest for Hispanics compared to all other race/ethnicities."); RADM Michael E. Toedt, MD, FAAP, Chief Medical Officer, Indian Health Service, *Testimony Before the Senate Committee on Indian Affairs, Oversight Hearing: "Opioids in Indian Country: Beyond the Crisis to Healing the Community"* (Mar. 14, 2018) ("The Centers for Disease Control and Prevention (CDC) reported that American Indians and Alaska Natives had the highest drug overdose death rates in 2015 and the largest percentage increase in the number of deaths over time from 1999-2015 compared to other racial and ethnic groups. During that time, deaths rose more than 500 percent among American Indians and Alaska Natives. In addition, because of misclassification of race and ethnicity on death certificates, the actual number of deaths for American Indians and Alaska Natives may be underestimated by up to 35 percent.").

^{viii} Max Blau, *Opioids could kill nearly 500,000 Americans in the next decade*, STAT News (Jun. 27, 2017).

^{ix} National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Medications for Opioid Use Disorder Save Lives*, Nat'l Acad. Press (2019).

^x Kevin Fiscella, M.D., M.P.H., Sarah E. Wakeman, M.D., Leo Beletsky, J.D., M.P.H., *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver*, 76(3) JAMA Psychiatry 229-30 (2018).

^{xi} Rebecca Haffajee, Ph.D., J.D., M.P.H. et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 Am. J. Prev. Med. S230-42 (2019).

^{xii} National Academy of Sciences, Engineering, and Medicine (2019).

^{xiii} Congressional Research Service, *Buprenorphine and the Opioid Crisis: A Primer for Congress* (2018); National Academy of Sciences, Engineering, and Medicine (2019); SAMHSA, *Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder* (2020).

^{xiv} Sarah E. Wakeman, M.D. and Michael L. Bennett, M.D., *Primary Care and the Opioid-Overdose Crisis – Buprenorphine Myths and Realities*, 379 New England J. of Med. 1-4 (2018).

^{xv} See National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Opportunities to Improve Opioid Use Disorder and Infectious Disease Services*, Nat'l Acad. Press (2020); U.S. Dept. Health & Human Svcs., Office of the Surgeon General ("U.S. Surgeon General"), *Facing Addiction in America: The U.S. Surgeon General's Spotlight on Opioids* (2018).

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- ^{xvi} In January 2021, there were approximately 91,000 physicians, advanced practice registered nurses, and physicians assistants with a DATA 2000 Waiver. Lev Facher, *Trump administration will let nearly all doctors prescribe addiction medicine buprenorphine*, STAT News (Jan. 14, 2021). There are approximately 1.4 million of those providers in the United States. Kaiser Family Foundation, *Professionally Active Physicians* (Mar. 2020); Letter from American Assoc. of Nurse Practitioners ("AANP") and American Academy of Physician Assistants ("AAPA") to the Hon. Alex Azar (Jan. 15, 2021).
- ^{xvii} National Academy of Sciences, Engineering, and Medicine (2019).
- ^{xviii} *Id.*; Andrew S. Huhn, Ph.D. and Kelly E. Dunn, Ph.D., *Why Aren't Physicians Prescribing More Buprenorphine?*, 78 J. Substance Abuse Treatment, 1-7 (2017).
- ^{xix} DATA 2000, Publ. Law No. 106-310 (2000).
- ^{xx} Drug Addiction Treatment Act of 1999, *Hearing Before the Subcommittee on Health and Environment of the Committee on Commerce*, 106th Congress 10-20 (Jul. 30, 1999).
- ^{xxi} Pub. Law 109-56, 119 Stat. 591 (2005); Pub. Law 109-469 § 1102, 120 Stat. 3540 (2006); Comprehensive Addiction and Recovery Act of 2016 ("CARA"), Pub. Law 114-198, 130 Stat. 720-23 (2016); Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities ("SUPPORT") Act, Pub. Law 115-271 § 3201, 132 Stat. 3843-44 (2018); Further Continuing Appropriations Act, 2021, and Other Extensions Act, Pub. Law No. 116-125 § 1302, 134 Stat. 1046 (2020) (provisions known as the "Easy MAT Act").
- ^{xxii} See National Academy of Sciences, Engineering, and Medicine (2020); Kevin Fiscella, et al. (2018); Haffajee, et al. (2019); Sonia Mendoza, et al., *Shifting blame: Buprenorphine prescribers, addiction treatment, and prescription monitoring in middle-class America*, 53(4) Transcult Psychiatry 465-87 (2016).
- ^{xxiii} National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine (2020); Haffajee, et al. (2019).
- ^{xxiv} Mendoza, et al. (2016).
- ^{xxv} JR DeFlavio, et al., *Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians*, 15 Int'l J. Rural and Remote Health, Research, Education, Practice and Policy 3019 (2015).
- ^{xxvi} Haffajee, et al. (2019).
- ^{xxvii} National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine (2020); De Flavio, et al. (2015); Haffajee, et al. (2019); Huhn and Dunn (2017).
- ^{xxviii} See De Flavio, et al. (2015); Haffajee, et al. (2019); Eliza Hutchinson, M.D. et al., *Barriers to Primary Care Physicians Prescribing Buprenorphine*, 12(2) Annals of Family Medicine (2014); Mendoza, et al. (2016).
- ^{xxix} National Academy of Sciences, Engineering, and Medicine (2019).
- ^{xxx} Nat'l Inst. of Health, *Physician-pharmacist collaboration may increase adherence to opioid addiction treatment* (2021).
- ^{xxxi} HHS, *Geographic Disparities* (2020), at 9 ("In total, 72 percent of counties with low-to-no patient capacity are in rural areas (for comparison purposes, 63 percent of counties nation-wide are rural). The lack of waived providers in rural areas may reflect a wider problem with shortages and maldistribution of primary care and other providers.").
- ^{xxxii} GAO (2019), at 26-27 ("Across all 140 VHA health care systems, veterans with an opioid use disorder received medication-widoassisted treatment (in specialty and nonspecialty settings) at a higher rate in urban locations (34 percent) than in rural locations (27 percent) in fiscal year 2018. Despite the similar rates of waived providers in rural and urban areas, as previously mentioned, rural veterans with opioid use disorder use medication-assisted treatment at a lower rate.").
- ^{xxxiii} Tiako, et al. (2020) ("Despite its effectiveness, buprenorphine remains inaccessible for many women with OUD who are pregnant. A study of treatment episodes for prescription OUD during pregnancy showed that medication for OUD was administered only during a third of treatment episodes, and a more recent study of women enrolled in Medicaid who were pregnant noted that nearly half of pregnant patients with OUD receive no medication for OUD.").
- ^{xxxiv} Tiako, et al. (2020) ("Studies have shown that, as a result of racial segregation, buprenorphine availability is associated with a greater proportion of White residents at the neighborhood and county levels, and methadone availability is associated with greater proportions of Hispanic and Black residents. Within the context of pregnancy, a study reported that Black and Hispanic women (both overrepresented among Medicaid recipients) are less likely to receive any pharmacotherapy for OUD."); Pooja A. Lagisetty, M.D., M.Sc. et al., *Buprenorphine Treatment Divide by Race/Ethnicity and Payment*, 76(9) JAMA Psychiatry 979-81 (2019) ("This study demonstrates that buprenorphine treatment is concentrated among white persons and those with

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private insurance or use self-pay.”); Martha Bebinger, *Opioid Addiction Drug Going Mostly To Whites, Even As Black Death Rate Rises*, NPR (May 8, 2019) (“White drug users addicted to heroin, fentanyl and other opioids have had near exclusive access to buprenorphine...‘White populations are almost 35 times as likely to have a buprenorphine-related visit than black Americans,’ says Dr. Pooja Lagisetty, an assistant professor of medicine at the University of Michigan Medical School and the study’s corresponding author.”).

^{xxxv} National Academy of Sciences, Engineering, and Medicine (2019).

^{xxxvi} Christine Vestal, *Waiting Lists Grow for Medicine to Fight Opioid Addiction*, The Pew Charitable Trusts (Feb. 11, 2016).



THE OFFICE OF SENATOR TELENA CRUZ NELSON

I MINA'TRENTAI SAIS NA LIHESLATURAN GUAHAN | 36th GUAM LEGISLATURE

COMMITTEE ON

EDUCATION AND
INFRASTRUCTURAL
ADVANCEMENT

BORDER
PROTECTION AND
MARITIME
TRANSPORTATION

GUAHAN
PRESERVATION AND
SELF-DETERMINATION

FEDERAL AND
FOREIGN RELATIONS

Transmitted Via Email:

frank.pallone@mail.house.gov

April 14, 2021

The Honorable Representative Frank Pallone, Jr.
Chairman, House Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

SUBJECT: Letter of Support- H.R. 955

Dear Chairman Pallone,

Buenas yan Háfa Adai! On behalf of the 36th Guam Legislature, I wish to express my support of H.R. 955, the "Medicaid Reentry Act of 2021," relative to making Medicaid available to inmates during the 30-day period preceding their release.

Our primary adult correctional facility, the Guam Department of Corrections (DOC) faces unique challenges due to our geographic location. Approximately 80%-90% of inmates suffer from chronic care issues and mental health issues that require continuity of care after their release. Early enrollment to public health insurances like Medicaid is a highly efficient measure would ensure that inmates are informed and provided the support all members of our community should have. The facility lacks a full-time psychiatrist and adequate dental care. As is often the case, many rehabilitated prisoners are lost in navigating the health care system and have difficulty accessing the resources available to them. The inability to pay for or access necessary medical care and health needs to treat illnesses such as End-Stage Renal Disease, Dialysis, and addiction, can lead to adverse consequences including relapse. DOC's recidivism rate is alarmingly high, with data from 2019 reporting that nearly 64% of inmates were previously convicted of misdemeanors or felonies. H.R. 955 is a bold and imperative step we must take to make meaningful change. To work in service of an individual, including those who have previously erred or committed a crime, is to also work in service of our community at-large, and our nation as a whole.

We thank you for your time and consideration. Should you wish to contact our office, please reach us via email at senatortcnelson@guamlegislature.org or through phone at +1(671) 989-7696.

Sincerely,

Senator Telena Cruz Nelson

Chairwoman, Committee on Federal and Foreign Relations

36th Guam Legislature

ADA'S PLAZA CENTER, STE 202 A, 173 ASPINALL AVENUE HAGATÑA, GUAM 96910
TEL: (671) 989-7696 / 4678 | EMAIL: senatortcnelson@guamlegislature.org



THE OFFICE OF SENATOR TELENA CRUZ NELSON

I MINA'TRENTAI SAIS NA LIHESLATURAN GUAHAN | 36th GUAM LEGISLATURE

COMMITTEE ON

EDUCATION AND
INFRASTRUCTURAL
ADVANCEMENT

BORDER
PROTECTION AND
MARITIME
TRANSPORTATION

GUAHAN
PRESERVATION AND
SELF-DETERMINATION

FEDERAL AND
FOREIGN RELATIONS

Transmitted Via Email:

frank.pallone@mail.house.gov

April 14, 2021

The Honorable Representative Frank Pallone, Jr.
Chairman, House Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

SUBJECT: Letter of Support– H.R. 2355, H.R. 2364, H.R. 2366, H.R. 2379, and H.R. 2405

Dear Chairman Pallone,

Buenas yan Hafa Adai! On behalf of the 36th Guam Legislature, I wish to express my support of H.R. 2355, H.R. 2364, H.R. 2366, and H.R. 2405, all relative to facilitating responsible and informed dispensation, use, and research of controlled substances, with specific focus on opioids. I'd like to further request that Guam be considered for eligibility for H.R. 2379, the "State Opioid Response Grant Authorization Act of 2021."

I have sponsored and introduced legislation that would require prescribers in Guam to register into our Prescription Drug Monitoring Program, establish a prescriber and patient contract, and ensure that patients are adequately informed of their options and alternatives to opioids. Approximately 42% of prescriptions are for opioids and while these medications are a powerful pain-reducing medication and have aided thousands of lives suffering from chronic pain, they are also highly addictive and pose several potentially harmful effects to our individuals and our community. Only 10% of prescribers on Guam actively use our PDMP database, making it difficult to adequately assess and address our opioid addiction. Supporting the health and safety of the community is a critical step towards curbing the island and the nation's rising opioid crisis and legislation and education should be at the first line of defense.

We thank you for your time and allowing me to express my dedication to the continued and necessary fight against the opioid abuse. Should you wish to contact our office, please reach us via email at senatortcnelson@guamlegislature.org or through phone at +1(671) 989-7696.

Sincerely,

Senator Telena Cruz Nelson
Chairwoman, Committee on Federal and Foreign Relations
36th Guam Legislature

ADA'S PLAZA CENTER, STE 202 A, 173 ASPINALL AVENUE HAGATNA, GUAM 96910
TEL: (671) 989-7696 / 4678 | EMAIL: senatortcnelson@guamlegislature.org

April 13, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Immediate Action Requested to Combat the Dire Addiction Crisis

Dear Secretary Becerra,

The undersigned organizations write to emphasize the urgency of addressing the ongoing addiction crisis, which has been severely exacerbated by the COVID-19 pandemic. Forty-two states have reported significant increases in overdose deaths since the onset of the pandemic. To immediately save lives, we urge you to take decisive action to eliminate the X-Waiver, which is required by the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe buprenorphine, one of three FDA-approved medication-assisted treatments (MAT) indicated for the treatment of opioid use disorder (OUD).

Significant Access Challenges and Barriers

Despite the overwhelming evidence of buprenorphine's effectiveness for treating OUD, it remains highly underutilized with only about 20 percent of individuals with an OUD receiving any treatment¹, and even less receiving MAT. The waiver requirement has prevented those with OUD from receiving life-saving care, because more than 95 percent of practitioners lack the X-waiver and thus are unable prescribe buprenorphine. Forty percent of U.S. counties do not have a single provider that can prescribe buprenorphine for OUD in an office setting, according to an important January 2020 report by the Department of Health and Human Services (HHS) Inspector General.² The treatment gap is even greater in rural communities, with two-third of those counties representing individuals that live in rural areas³.

Perpetuating Stigma

The horrendous irony of the opioid epidemic has been that any DEA-licensed prescriber can prescribe powerful opioids that can, in a short period of time, lead to OUD. The existence of the X-Waiver sends a terrible message to practitioners and the public alike: that treating OUD with

¹ Saloner B and Karthikeyan S. Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013. *JAMA*. 2015 October; 314(14): 1515-1517.

² Office of Inspector General, U.S. Department of Health and Human Services, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, January 2020, <https://oig.hhs.gov/oci/reports/oci-12-17-00240.pdf>.

³ Shatterproof, *County buprenorphine access in the United States*, April 2020, https://www.shatterproof.org/sites/default/files/2020-04/Shatterproof%20OUD%20Brief_R03_42220.pdf

buprenorphine requires separate, stigmatizing rules and that buprenorphine is inherently more dangerous than the powerful opioids that have fueled this crisis.

The Urgent Need

The current need could not be greater. During the ongoing COVID-19 pandemic, fatal drug overdoses have skyrocketed, with the Centers for Disease Control and Prevention estimating that more than 81,000 Americans died from drug overdoses during a 12-month period ending in May 2020.⁴ This dramatic increase, which reflects only a few months of the pandemic's negative effects, has undone all the gains in reducing fatal overdoses.

In an attempt to address this escalating crisis, the prior administration released new practice guidelines ("Notice") on January 14, 2021, that would have made a number of changes to the X-Waiver. Specifically, the Notice gave physicians the option to prescribe buprenorphine, for up to 30 patients, without needing to satisfy some of the requirements to obtain an X-Waiver.⁵ While we do not believe the Notice would have completely resolved the issues for patients to access buprenorphine for OUD, our organizations lauded this as a strong first step in that direction.

While the subsequent pulling of the Notice on January 21, 2021, was a disappointment due to its potential to save lives, we understand that HHS must be confident that its actions comply with federal law. **Nonetheless, because the severity of the crisis persists, we urge HHS to immediately take any actions within its power to reduce the disproportionately high barrier to life-saving OUD treatment with buprenorphine created by the X-Waiver. Further, we urge the Administration to publicly call upon Congress to eliminate the X-Waiver completely. It should also call upon Congress to include provisions to increase substance use disorder education for all DEA-licensed prescribers in order to increase early identification and treatment of these disorders.**

These actions would be fully consistent with what the President called for during the 2020 presidential campaign, when he pledged to "ensure that any undue restrictions on [buprenorphine] prescribing are lifted..."⁶ and cited a *JAMA Psychiatry* article estimating that eliminating the X-Waiver could save more than 30,000 American lives each year.⁷ This estimate was made prior to the rising overdose deaths associated with the pandemic. By taking immediate action within its powers, clearly communicating with stakeholders, and unambiguously calling upon Congress to eliminate the X-Waiver, the Administration can proactively steer our country

⁴ "Overdose Deaths Accelerating During COVID-19," *Centers for Disease Control and Prevention*, December 17, 2020, <https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html>.

⁵ Announcement of Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, Department of Health and Human Services, <https://www.hhs.gov/sites/default/files/mat-physician-practice-guidelines.pdf>, last visited March 10, 2021.

⁶ "THE BIDEN PLAN TO END THE OPIOID CRISIS," *Biden-Harris Campaign Website*, <https://joebiden.com/opioidcrisis/>.

⁷ Fiscella K, Wakeman SE, Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. *JAMA Psychiatry*. 2019;76(3):229–230. doi:10.1001/jamapsychiatry.2018.3685

in the direction necessary to fulfill its promise that all individuals living with OUD have access to potentially life-saving treatment.

There is no time to lose. With the Administration's leadership, we can finally end this discriminatory and stigmatizing provision that costs far too many lives. We look forward to working with you to realize the vision of all Americans with a substance use disorder receiving the treatment they need.

Sincerely,

Association for Behavioral Health and Wellness
 The Kennedy Forum
 Shatterproof
 America's Health Insurance Plans
 American Academy of Physical Medicine and Rehabilitation
 American Association for Psychoanalysis in Clinical Social Work
 American College of Medical Toxicology
 American Foundation for Suicide Prevention
 Array Behavioral Care
 Ascension
 Assisted Recovery Centers of America
 Association for Ambulatory Behavioral Healthcare
 Big Cities Health Coalition
 Blue Cross Blue Shield Association
 Centerstone
 Central City Concern
 Cigna
 Cities Thrive Coalition
 City of New York
 College of Healthcare Information Management Executives (CHIME)
 College of Psychiatric and Neurologic Pharmacists (CPNP)
 Community Catalyst
 Global Alliance for Behavioral Health and Social Justice
 Harm Reduction Coalition
 Healthcare Leadership Council
 Health Innovation Alliance
 HIV Alliance
 innovaTel Telepsychiatry
 Inseparable
 The Levenson Foundation
 Live4Lali
 Magellan Health
 Mass General Brigham

Mental Health America
 NACBHDD and NARMH
 National Alliance on Mental Illness
 National Association of Addiction Treatment Providers
 National Association of Attorneys General
 National Association of Pediatric Nurse Practitioners
 National Council for Behavioral Health
 National Health Law Program
 National Safety Council
 New Directions Behavioral Health
 OCHIN
 Partnership to End Addiction
 PAs in Virtual Medicine and Telemedicine
 Pharmaceutical Care Management Association (PCMA)
 Police, Treatment, and Community Collaborative (PTACC)
 Psychotherapy Action Network Advocacy
 PursueCare
 QueerDoc
 SMART Recovery
 Stop Stigma Now
 Student Coalition on Addiction
 The International Society for Psychiatric Nurses
 The Voices Project
 Treatment Advocacy Center
 Treatment Communities of America
 UPMC
 USC Institute for Addiction Science
 Well Being Trust
 Young People in Recovery

Cc: Tom Coderre (Substance Abuse and Mental Health Services Administration)
 Merrick Garland (U.S. Department of Justice)
 D. Christopher Evans (U.S. Drug Enforcement Administration)
 Regina LaBelle (Office of National Drug Control Policy)
 Representative Paul Tonko (D-NY)
 Representative Antonio Delgado (D-NY)
 Representative Anthony Gonzalez (R-OH)
 Representative Mike Turner (R-OH)
 Senator Maggie Hassan (D-NH)
 Senator Lisa Murkowski (R-AK)

To Congressional Policymakers:

April 13, 2021

I am writing you in opposition of extending class wide scheduling for fentanyl analogues. As a trained and board-certified physician specializing in Emergency Medicine, Medical Toxicology, and Addiction Medicine, I am intimately familiar with the synthetic opioids like fentanyl analogues that have driven increases in overdose deaths in recent years, and not only do I treat these overdoses, but I follow patients with addiction to opioids long term both in and out of the hospital. I am also the person on the other end of the phone when people call Poison Help with concerns like drug exposures and overdose. I have seen more overdoses than I can count, most of them from fentanyl and fentanyl analogues, and this response is not going to solve the problem Americans are facing from these drugs.

Since class wide scheduling was first introduced we have only seen further increases in both overdoses and deaths from fentanyl and fentanyl analogues. 2019 and 2020 each set new records in terms of drug overdoses, and there is no indication that this trend is even slowing down relative to enactment of this policy. As drug-related harms rise unchecked in response to class wide scheduling we are actually seeing additional harms related to increased sentencing and harsher penalties for people who use drugs.

While fentanyl is the driving cause of our current overdose crisis, fentanyl analogues play a much smaller role but receive greater amounts of attention when they are discovered in testing of samples and victims, likely because they are often novel compounds that are poorly understood. Limiting our ability to research and study these drugs, and gain understanding, by making them Schedule I substances. Of the fentanyl analogues we do understand, it is apparent that many of them can have very different properties, actions and effects than standard fentanyl and so while they appear similar at a molecular level they do not always behave similarly. Some of the analogs are a direct result of the same early drug discoveries that produced fentanyl, an invaluable therapeutic medicine, and drugs like remifentanyl and sufentanil are analogs that are also very valuable in medicine. Some of the analogs we know about have been discovered through illicit drug discovery, like alpha-methylfentanyl, which despite being categorized as Schedule I in the 1980s is actually less likely to cause overdose and could have valuable therapeutic uses.

Myths about fentanyl and fentanyl analogues have dominated the narrative in recent years. Despite being first discovered in the street drug supply in the late 1970s, it wasn't until the past few years that people started to believe things like it could be possible to overdose from fentanyl by touching it, by breathing it in the air, or by being near fentanyl or someone who used fentanyl. None of those things are true. These substances, as diverse as they may be, can only cause overdose when intentionally ingested. What that means is that we need to focus on protecting people who use drugs and providing resources to prevent and treat overdoses, rather than adding additional stigma to this vulnerable population.

In my personal experience in recent years I now see overdose victims not receive appropriate (and lifesaving) resuscitation because of fears about fentanyl, and particularly fears about fentanyl analogues being so much more dangerous that they get nicknames like "elephant tranquilizer." I have personally resuscitated patients who have overdosed on carfentanil without any adverse effect to myself and with standard amounts of reversal agent, naloxone (Narcan).

Over the past year of our coronavirus pandemic I have additionally seen firsthand serious shortages of drugs like fentanyl lead to adverse outcomes for patients. Fentanyl is one of the most commonly-used medications to treat people with serious respiratory disease and critical illness, in addition to its use as a pain medication. Of the many fentanyl analogues that exist and those that have yet to be discovered, there is bound to be a drug that would have therapeutic benefits in treating the sick, and to limit ourselves further when we are already seeing limitations would be unwise.

There are plenty of easy and evidence-based policy actions that can be taken to save the lives of Americans, to prevent overdoses and to reduce rates of substance use and addiction. Class wide scheduling has not accomplished any of those aims and the available scientific and medical evidence does not support extending it. I would urge you to consider facts rather than fear and not to extend this policy.

Ryan Marino MD
rtmarino@gmail.com

Assistant Professor, Departments of Emergency Medicine & Psychiatry
Case Western Reserve University School of Medicine

Medical Toxicologist
Cincinnati Children's Hospital Drug & Poison Information Center

**Medication Assisted Treatment Leadership Council
Statement for the Record**

**House Energy & Commerce Health Subcommittee Hearing on
An Epidemic Within a Pandemic: Understanding with Substance Use and Misuse in America
April 14, 2021**

Chairwoman Eshoo, Ranking Member Guthrie, and members of the Subcommittee, thank you for accepting this statement on behalf of the Medication Assisted Treatment Leadership Council (MAT LC). MAT LC is comprised of nearly 300 Opioid Treatment Program (OTP) facilities and Office-Based Opioid Treatment (OBOT) practices across 40 states, including nearly 40 in California and 11 in Kentucky. Our health care teams provide lifesaving care to more than 100,000 patients suffering from opioid use disorder (OUD) every day.

OTPs are highly-regulated, highly-structured, comprehensive treatment programs that provide Medication-Assisted Treatment (MAT). We are subject to rigorous oversight at the federal, state and local levels – including SAMHSA, the DEA, state regulatory and Medicaid authorities and pharmacy boards. Each of our facilities must be continuously accredited by a SAMHSA-approved body.

OTPs have been the gold standard in treating OUD for the past 50 years. OTPs deliver patient-centered, integrated care under one roof. We employ physicians, pharmacists, nurses, counselors, administrators, social workers, and clerical staff to form interdisciplinary treatment teams that provide daily care to patients suffering from OUD. A patient suffering from OUD has access to the full range of MAT services and medications within the OTP setting, although the vast majority of these patients receive MAT with methadone.

It is critical that the Subcommittee understand that medication alone is not treatment. Medication merely helps to stabilize OUD patients, allowing them to receive the behavioral health services that are critical to recovery. OTPs are required, by law, to provide counseling to our patients. Those who are new to treatment or not succeeding in treatment receive more frequent counseling. Our patients are also subject to at least eight random toxicology screens each year. This ensures that medication is being properly used and that illicit drug use is not continuing – both of which help guide clinical decision-making. Lastly, OTPs are required to employ robust anti-diversion measures to protect patients from abusing the medication or selling it in the community.

Many of our companies also operate OBOTs, where patients receive medication as well as the full suite of MAT services (counseling, testing, training, etc.) that they would receive in the OTP setting. We believe this fact distinguishes our OBOTs from many of the OBOTs across the country that do not offer the full suite of MAT services and supports. Often times, patients only get medication, usually buprenorphine, in the OBOT setting. Unlike OTPs, OBOTs do not have to provide or refer for counseling and are not required to use toxicology testing to ensure patients are taking the buprenorphine they are being prescribed. OBOT providers are required to have just eight hours of online training on buprenorphine and little or no training in addiction medicine. The only large study of OBOTs concluded that "the quality of care received seemed generally poor."¹ This is not an indictment on these providers so much as it is evidence that many are simply not trained adequately and do not have the requisite resources to deal with complex patients who are suffering from OUD. Our OBOTs, however, are built on the OTP model which places an emphasis on ensuring patients receive more than just medication and benefit from the behavioral support system in place to ensure the greatest likelihood of recovering. Our OBOTs are not required to provide counseling, toxicology screening, or employ anti-diversion programs, but they do because we know, through decades of experience, this is the level of care patients suffering from OUD need.

In 2000, Congress sought to expand OUD treatment to the physician office setting. In exchange for forgoing significant oversight and regulation, Congress placed a limit on the number of OUD patients each OBOT physician could treat (30 in the first year, up to 100 beginning in year two). The patient limits were put in place to ensure that these physicians, many of whom have little training in addiction treatment or relationships with mental health providers, did not become unregulated addiction treatment practices.

In 2018, Congress passed the SUPPORT Act which vastly expanded these patient limits. Physicians can now prescribe up to 275 patients after just eight hours of online training – a 175% increase over the previous limit. This means that, currently, physicians can treat 14 patients per day for opioid addiction if the physician sees each patient just once per month (many of these complicated patients should be seen more frequently than once per month). Two-thirds of the highly specialized OTPs across the country treat fewer than 200 patients.

The SUPPORT Act also allows nurse midwives, nurse anesthetists, and other mid-level clinicians to prescribe buprenorphine to OUD patients. There is no requirement that OBOT patients receive counseling for their addiction or receive random toxicology screenings. Congress opted for a massive expansion of opioid (buprenorphine) prescribing authority in the OBOT setting without any understanding if these patients were receiving quality care under the previous patient limits. We believe the current patient limits are already set too high absent additional oversight, quality reporting, and training requirements. OTPs are not subject to patient limits because we are heavily regulated, as any addiction treatment center that prescribes opioids should be.

¹ Gordon, et al, "Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program," *Journal of Addiction Medicine*, 2015.

Policymakers should question whether special interests seeking to eliminate the patient limits and federal oversight are simply trying to take advantage of the pandemic to expand business opportunities. Consider that there are currently nearly 97,000 physicians and clinicians waived to prescribe buprenorphine to more than 6 million patients. That is more than triple the number of patients who are estimated to suffer from OUD. The number of prescribers and their prescribing authority already dwarfs those who are actually in need. Deregulating OBOTs will do nothing to expand access to care. Instead, Congress should seek to ensure that OBOTs, especially those prescribing to a high number of patients, are indeed offering full-service MAT, just like our OBOTs do. Some OBOTs do a great job of providing MAT and a baseline of consistent oversight and regulations would ensure that patients are likely to receive evidence-based treatment in the OBOT setting.

Congress commissioned an HHS study that will include recommendations on where OBOT patient limits should be set. In developing these recommendations, the Secretary is required to examine:

- the average frequency with which qualifying practitioners see their patients;
- the average frequency with which patients receive counseling, including the rates by which such counseling is provided by such a qualifying practitioner directly, or by referral;
- the frequency of toxicology testing, including the average frequency with which random toxicology testing is administered;
- the average monthly patient caseload for each type of qualifying practitioner;
- the treatment retention rates for patients;
- overdose and mortality rates; and
- any available information regarding the diversion of drugs by patients receiving such treatment from such a qualifying practitioner.

The MAT LC firmly believes that Congress should wait to further legislate on the OBOT patient limits before fully considering the findings of the OBOT quality of care report and Secretarial recommendations that it commissioned. That is why **the MAT LC strongly opposes H.R. 1384, the Mainstreaming Addiction Treatment Act of 2021**, which would eliminate any OBOT addiction training requirements and allow OBOT physician and practitioners to treat an unlimited number OUD patients without any oversight from the DEA or SAMHSA. If HHS' report shows that patients are indeed receiving regular counseling, that medication is not being diverted, and that practitioners can appropriately manage 275 patients, then Congress could consider increasing the patient limits above the 175% increase it passed a little over two years ago.

Proponents of H.R. 1384 argue that patient limits do not exist for other diseases. This is true. But consider that OUD patients are extremely complex patients that should be treated by professionals trained in addiction medicine. Nine of the 11 diagnostic criteria for opioid use disorder are behavioral components, just two are physiological (Diagnostic and Statistical Manual of Mental Disorders-V). Would you trust a podiatrist to treat cancer? Would you want a dentist to perform heart surgery? Physicians and surgeons specialize in areas of medicine for a reason. A baseline level of training in treatment OUD should be required.

Proponents of H.R. 1384 will also note that some foreign countries, like France, do not impose limits on the number of patients receiving buprenorphine. In France, patients can only receive up to seven days of buprenorphine before returning the physician for another prescription. Physicians in France usually request that pharmacists provide daily, supervised dosing of buprenorphine.² In the U.S., patients can go up to six months without seeing their physician and still receive refills for their buprenorphine prescription every month. Buprenorphine diversion is also a significant problem in France. “Diversion (i.e., selling or giving away medication) of buprenorphine to the illicit market is also a major concern and has contributed to an extensive black market in some European countries.”

Buprenorphine diversion is already an issue in the U.S. as well. In fact, a recent Johns Hopkins study found that “approximately 43% [of those receiving buprenorphine] filled an opioid prescription during the treatment episode and 67% filled at least one prescription opioid following their treatment episode.”³

The MAT LC supports H.R. 2379, the *State Opioid Response Grant Reauthorization Act*, with important modifications. While we support the new funding associated with this legislation, we would like to see a portion of this money earmarked specifically for MAT in the OTP and OBOT settings so that the money is actually reaching patients. Such funding could be used to offset the cost of treatment for those who are unable to pay, to hire and train new mental health professionals, etc.

Additionally, we would like the Committee to consider amending the State Opioid Response grant program to ensure that all OTPs have access to this stream of federal funding. This epidemic requires an “all qualified hands on deck” approach. Given the track record of patient outcomes and robust regulatory and oversight structures associated with OTPs, Congress can be comfortable knowing this money will be spent efficiently and focused on what most important – patients suffering from OUD.

² Buprenorphine substitution treatment in France: drug users' views of the doctor-user relationship, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1950347/>

³ <http://www.jhsph.edu/news/news-releases/2017/many-patients-receive-prescription-opioids-during-medication-assisted-treatment-for-opioid-addiction.html>

The MAT LC also supports H.R. 2067, the *Medication Access and Training Expansion Act*. We agree that providers would benefit from additional training in addiction medicine, particularly those who seek to administer MAT to patients suffering from OUD. However, this baseline training should not be considered a replacement for oversight and regulation or a green light to treat an unlimited number of patients. This bills should be seen as being complimentary of the current X-waiver.

In order to combat the opioid abuse epidemic, the MAT LC urges Congress to make permanent a provision in the SUPPORT Act which requires state Medicaid programs to cover all FDA-approved medication to treat OUD. We also suggest removing tax-status limitations through the Substance Abuse Block Grant and specifically earmarking funds derived from opioid settlements for treatment purposes, including those provided in the OTP setting. Lastly, there is much Congress could do to encourage greater collaboration between providers involved in treating OUD, including funding for programs like Vermont's "hub and spoke" model which connects physician practices (spokes) with OTPs (hubs) to help manage patient care and offer expertise.

Thank you for considering our comments today. The MAT LC looks forward to working with the Committee as it seeks to move legislation to combat this deadly disease.

Sincerely,

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BayMark Health Services

Jay Higham
CEO
Behavioral Health Group

Nick Stavros
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Francis Sauvageau
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**Statement for the
U.S. House Committee on Energy & Commerce, Health Subcommittee
Hearing on "Combating the Substance Use Disorder Epidemic Amid the COVID-19 Pandemic"
April 14, 2021**

Thank you for holding this hearing to discuss how the COVID-19 pandemic has exacerbated the existing substance use and overdose crises in America and to identify additional legislative action to provide Americans the help, treatment and care they need to recover from this difficult time and prevent further impacts. The National Safety Council (NSC) appreciates the opportunity to submit these comments for the record.

NSC is America's leading nonprofit safety advocate and has been for over 100 years. As a mission-based organization, we work to eliminate the leading causes of preventable death and injury, focusing our efforts on the workplace, roadway and impairment. We create a culture of safety to keep people safer at work and beyond the workplace so they can live their fullest lives. Our more than 15,000 member companies, including federal agencies, represent seven million employees at nearly 50,000 U.S. worksites.

The COVID-19 pandemic has taken a serious toll on the mental health of Americans, with 40% of U.S. adults reporting that they struggled with mental health or substance use in June 2020.¹ Studies show that from February to December 2020, the risk of having a general anxiety disorder increased by 80%, and the risk of having a depressive disorder has increased by 145%,² with women showing the largest increases in stress and anxiety. Most recently, we learned that the percentage of adults who had anxiety or a depressive disorder symptoms during the past seven days, and those with unmet mental health needs during the past four weeks, increased significantly from August 2020 to February 2021. One in four adults who experienced such symptoms reported that they needed but did not receive counseling or therapy for their mental health.³

Mental distress and illness are closely linked with substance use and misuse. Recently released data show the 2018 decrease in both general and opioid-related overdose fatalities was reversed in 2019. The number of drug overdose fatalities topped 70,000 in 2019, and opioid overdose fatalities neared 50,000.⁴ The U.S. reached a tragic new high in the 12-month period ending in August 2020, with over 88,000 opioid overdose fatalities reported.⁵ Lastly, over 40 states are reporting an increase in opioid overdose fatalities since the beginning of the pandemic.⁶ These increases may be linked, in part, to increased feelings of stress, loss of control, and isolation in response to the pandemic and subsequent quarantine during stay-at-home orders, as well as impacts on varying socioeconomic factors that increase risk for substance use (e.g., financial and housing insecurity).⁷

To address the increased rate of substance use and mental health challenges, NSC supports creation of cooperative programs at the National Institute for Occupational Safety and Health (NIOSH) to provide employers with access to substance use mental health support resources. Multiple studies

¹ Czeisler ME, Lane RI, Petrosky E, et al. Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1049–1057. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>

² <https://connect.nationalalliancehealth.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=1b159a27-931e-6069-03b2-30e0ce570e32&forceDialog=0>

³ https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm?s_cid=mm7013e2_e&ACSTrackingID=USCDC_921-DM53115&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20March%2026%2C%202021&deliveryName=USCDC_921-DM53115

⁴ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁵ <https://emergency.cdc.gov/han/2020/han00438.asp>

⁶ <https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf>

⁷ https://tools.niehs.nih.gov/wetp/public/hasL_get_blob.cfm?ID=12121

show that for people experiencing a mental illness during their lives, nearly half will also experience a substance use disorder and vice versa.⁸ Given that NIOSH has extensive workplace knowledge and makes “Mental Health in the Workplace” a priority area within the Total Worker Health program, NSC recommends NIOSH as the home for such a program.⁹

NSC encourages the Committee to focus on the following three areas in particular – the employer role in addressing the opioid crisis, expanding access to treatment and recovery services and supports, and addressing racial inequities.

The opioid crisis – the employer role

According to the Centers for Disease Control and Prevention (CDC), 95% of all opioid overdoses in the U.S. strike working age adults.¹⁰ Over 70% of adults with a substance use disorder (SUD) are in the workforce,¹¹ and 75% of employers have been impacted by employee opioids use in the workplace.¹² Employers have an essential role to play in preventing opioid use and misuse and supporting employees through treatment and recovery. Research has demonstrated that providing wrap-around services enhances treatment retention and improves treatment outcomes.¹³ People in workplace-mandated treatment have better or similar outcomes on a variety of metrics, including employment stability at 1 and 5 years after treatment.¹⁴

The annual cost to employers of an untreated SUD ranges from an average of \$8,255 – \$14,000 per employee, depending on their industry and role, and workers with substance use disorders miss two more weeks of work annually than their peers, averaging nearly five working weeks (24.6 days) a year.¹⁵ However, workers in recovery, who have reported receiving substance use treatment in the past and have not had a substance use disorder within the last 12 months, miss the fewest days of any group – even the general workforce – at 10.9 days. Additionally, each employee who recovers from a SUD saves their company over \$8,500 on average in turnover, replacement and healthcare costs.¹⁶ Given these numbers are dated through 2019, NSC expects to see these costs grow throughout 2020 and into 2021. NSC has a free, online tool for employers to estimate the cost of substance use in their workplace based on the size of the employee base, industry, and state at nsc.org/drugsatwork.

Workplaces are currently facing unprecedented challenges related to the COVID-19 pandemic with increased rates of substance use, and employers must be part of the solution. Employers will need resources, support and training to increase access to treatment, create recovery-ready workplaces, and take other steps necessary to combat the continued substance use and opioid crisis. Recovery-ready workplaces must not only focus on supporting recovery, but also providing a full spectrum of resources and support for employees and their families to address prevention and treatment needs, as well as reduce stigma.

Recommendations:

- NSC supports the first year priorities set by the Biden-Harris Administration Office of National Drug Control Policy (ONDCP).¹⁷ In particular, NSC encourages the Committee to focus on the actions underpinning Priority 6: *Advancing recovery-ready workplaces and expanding the addiction workforce*.

⁸ <https://www.drugabuse.gov/publications/research-reports/common-comorbidities-substance-use-disorders/part-1-connection-between-substance-use-disorders-mental-illness>

⁹ <https://www.cdc.gov/niosh/twh/priority.html>

¹⁰ <https://www.cdc.gov/niosh/topics/opioids/data.html>

¹¹ <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>

¹² NSC Employer Survey, 2019

¹³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4711315/>

¹⁴ <https://ps.psychiatryonline.org/doi/full/10.1176/ps.2009.60.5.646>

¹⁵ <https://www.nsc.org/getmedia/9dc909e1-041a-41c5-a607-c4cef2390973/Substance-Use-Disorders-by-Occupation.pdf>

¹⁶ Ibid

¹⁷ See: <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>

- Support funding for NIOSH workplace supported recovery programs (WSRP).¹⁸ WSRPs use a variety of tactics to prevent exposure to workplace factors that could cause or perpetuate a substance use disorder and lowers barriers to seeking and receiving care and maintaining recovery.
- Provide funding and support for training and re-entry programs focusing on:
 - Helping people with a substance use disorder re-enter the workforce (job / skills training). The SAMHSA Treatment, Recovery, and Workforce Support Grant¹⁹ is an excellent example of providing funding for these programs.
 - Ensuring the workplace is prepared (training supervisors and managers, creating supportive policies). For example, the Opioids & Substance Use: Workplace Prevention & Response Worker Training Program from the National Institute of Environmental Health Sciences (NIEHS) at the National Institutes of Health (NIH).²⁰
 - Providing funding and incentives to workplaces who become recovery-friendly and/or focus on hiring workers in treatment/recovery.
- Expand and enhance research and development of evidence-based and promising recovery services and programs, such as peer-to-peer support programming.
- Increase employment programs for people in recovery to ensure employees can return to work after successful completion of a treatment program.
- Expand access to transitional housing, job training, and social services for people in recovery.

Expanding and increasing access to evidence-based treatment and recovery supports

Treatment for mental health and SUD is effective, but access to treatment, which was a significant barrier before the COVID-19 pandemic, has been strained further. Only 10.3% of people with an SUD in 2019 received any treatment, and only 18% of people with an opioid use disorder (OUD) received medications for addiction treatment (MAT).²¹ Additional disruptions have occurred in recovery support systems which are critical given that social exclusion and the inability to find employment are associated with relapse and exacerbated struggles with substance use.²² Of note, both of these experiences have become more common during of the pandemic. Given the clear need for increased access to treatment, there are a variety of tactics the federal government should consider, as well as actions to support individuals in recovery.

Recommendations:

- Expand and enhance research and development of evidence-based treatment programs and other programming to treat and manage SUDs.
- Increase insurance coverage of medications for addiction treatment and other behavioral health services, including via employer-sponsored insurance plans.
- Expand and enhance research and development of specialized evidence-based treatment programs for vulnerable populations.
- Support community-based programs – such as housing services, job training and other initiatives that assist individuals in treatment.

¹⁸ See: <https://www.cdc.gov/niosh/topics/opioids/wsrp/default.html>

¹⁹ See: <https://www.samhsa.gov/grants/grant-announcements/ti-20-013>

²⁰ See: <https://tools.niehs.nih.gov/wetp/index.cfm?id=2587>

²¹ <https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFR1PDFW090120.pdf>

²² <https://www.sciencedirect.com/science/article/pii/S0955395917300877>

- Expand and enhance the public reporting of quality measures for all addiction treatment programs to guide individuals in locating evidence-based treatment.
- Increase appropriations for treatment and recovery programs.
- Increase access to MAT for OUD – methadone, buprenorphine and other opioid agonist therapies; Vivitrol and other opioid antagonist therapies.
- Evaluate the X-Waiver training requirement (the training requirement stemming from the Drug Addiction Treatment Act of 2000):
 - Update or remove requirements as /necessary,
 - Incentivize providers to get the DATA 2000 waiver to prescribe buprenorphine for OUD, and
 - Eliminate the cap on the number of patients whom providers with the DATA 2000 waiver can treat with buprenorphine.
- NSC supports the Mainstreaming Addiction Treatment (MAT) Act (H.R.1384/S.445) which would eliminate the training and X-waiver requirements for physicians who want to prescribe buprenorphine.
- NSC supports the Medication Access and Training Expansion (MATE) Act (H.R.2067) to expand the number of practitioners educated about screening patients with SUDs and enable them to use evidence-based approaches.

Supporting EEOC Actions and Clarifications to Increase Access to Treatment

The Equal Employment Opportunity Commission (EEOC) issued two new guidance documents²³ addressing the opioid epidemic and its impact on the workplace in August 2020, providing clarity on opioid use disorder and its relation to the Americans with Disabilities Act (ADA). This guidance is critically important for workplaces as they support employees with an opioid use disorder.

Recommendation:

- Clearly state support for the recent EEOC clarification to ensure employers are aware of and abide by the guidance stating that individuals on medications for addiction treatment (MAT) are protected from disability discrimination.

Enforcing and Supporting Parity

Mental health parity and addiction equity is a critical component of combatting the opioid crisis, so that coverage, payment and treatment for mental health conditions and substance use disorders are equal to that of other chronic and acute health conditions. Mental health parity, as designated by the Mental Health Parity and Addiction Equity Act (MHPAE), makes effective care available to those suffering from mental illness and/or substance use disorder. Work needs to be done to ensure that those in need of mental health and substance use treatment receive it to prevent tens of thousands of unnecessary deaths.

Recommendation:

- Support the following recommendations for employers from President Obama's Mental Health and Substance Use Disorder Parity Task Force final report from October 2016:²⁴
 - Supporting consumers and providing parity education and awareness,
 - Clarifying parity requirements and improving implementation, and

²³ <https://www.eeoc.gov/newsroom/eeoc-releases-technical-assistance-documents-opioid-addiction-and-employment>

²⁴ <https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.pdf>

- Improving and enhancing compliance and monitoring.

Medicaid

Medicaid is a critical tool to reduce overdose deaths, help individuals receive treatment, receive recovery support and mitigate impacts of mental illnesses and increase treatment. There are several points where Medicaid and substance use intersect, including:

- Currently, nearly 17% of Medicaid beneficiaries have a SUD.²⁵
- Evidence demonstrates that Medicaid expansion states have seen improvements in access to medications and SUD treatment services following expansion.
- Medicaid expansion is associated with increases in overall prescriptions for Medicaid-covered prescriptions, including medications to treat OUD and opioid overdose.²⁶
- Medicaid is one of the largest sources of federal funding of health care services for individuals with OUD, including medications for addiction treatment (MAT).²⁷

Recommendation:

- Medicaid expansion without work requirements to qualify should be prioritized for SUD and mental health treatment.
- NSC supports the Medicaid Reentry Act of 2021 (H.R.955) to restore Medicaid access to addiction treatment for incarcerated individuals up to 30 days before their release and encourages this Committee to advance this legislation. Releasing individuals who are incarcerated without connections to healthcare providers, medical coverage, safe and stable housing, or a support system can greatly increase their risk of relapse, overdose and death.^{28,29}

Addressing Racial Inequities

NSC recognizes the need to confront racial and other equity issues related to existing drug policies throughout this process, especially given the disproportionate impact that the COVID-19 pandemic has had on communities of color and other vulnerable populations, and encourages Congress to do the same. Collaboration among community leaders, associations, advocates and the general population with policymakers, government agencies, educators, prevention specialists, employers and workplaces, and treatment and recovery providers is urgently needed, given the intertwining and exacerbating nature of substance use, the COVID-19 pandemic, and the impacts on Black, Indigenous, and People of Color (BIPOC).

The COVID-19 pandemic has disproportionately impacted BIPOC, which can be seen by cumulative infection, hospitalization and death rates that are higher among minority racial/ethnic groups than whites.³⁰ Certain social determinants of health and other risk factors for increased substance use may contribute to this increased risk including social stressors (e.g., discrimination, stigma, profiling), access to and utilization of healthcare, socioeconomic disparities (e.g., employment, housing, factors relating to school and education³¹) and access to transportation.³² People of color are more likely to work in jobs that require a physical presence in the workplace and are more likely to use public transportation, which puts them at increased risk for exposure to COVID-19.³³ Furthermore, early data

²⁵ https://www.kff.org/report-section/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals-issue-brief/#endnote_link_223575-4

²⁶ <http://files.kff.org/attachment/Report-The-Effects-of-Medicaid-Expansion-under-the-ACA-Updated-Findings-from-a-Literature-Review.pdf>

²⁷ <https://www.gao.gov/assets/710/704043.pdf>

²⁸ <https://www.drugabuse.gov/publications/drugfacts/criminal-justice>

²⁹ <https://www.fiercehealthcare.com/hospitals/industry-voices-incarcerated-people-need-health-coverage-to-help-stop-drug-overdose-and>

³⁰ <https://pubmed.ncbi.nlm.nih.gov/33231496/>

³¹ <https://www.cdc.gov/healthyyouth/substance-use/index.htm>

³² <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>

³³ <https://synergist.aiha.org/202101-confronting-two-crises>

points to racial disparities in COVID-19 vaccinations, underscoring the importance of focusing on equity both regarding the vaccine rollout and its impact on the workplace.³⁴

Access to treatment is critical, and is even more limited for BIPOC with SUDs. White Americans are 17% more likely to receive mental health treatment than Black or Hispanic people, and 20% more likely than Asian Americans.³⁵ Regardless of socioeconomic status, data shows that Black individuals enter addiction treatment four to five years later than white individuals.³⁶ Individuals in Latino communities who need treatment for an SUD are also less likely to access care.³⁷ Addressing these discrepancies is made even more critical with rates of overdose increasing for some communities of color during the pandemic.^{38,39} In 2019, CDC reported although African Americans and Hispanics experience similar rates of opioid misuse when compared to the general population, they experienced the greatest increase in overdose death rates from synthetic opioids (such as fentanyl) from 2014 to 2017.

Substance use and SUDs impact all population groups in the U.S. and strategies to address them must be tailored to the diversity of targeted communities. Promoting a one-size-fits-all strategy inhibits access to appropriate, quality prevention and treatment for culturally diverse populations, as well as the efficacy of those interventions. An interdisciplinary, multi-level team approach including community leaders, associations, advocates and the general population working with policymakers, government agencies, educators, prevention specialists, employers and workplaces, and treatment and recovery providers is critical to understand the related issues and treatment barriers, as well as successful community-informed strategies.

Recommendation:

- NSC encourages the Committee to focus on the *Advancing racial equity in our approach to drug policy* (Priority 2) set by the Office of National Drug Control Policy (ONDCP).⁴⁰

Conclusion

The COVID-19 pandemic has undoubtedly increased risk factors for developing a SUD or OUD. The long-term effects of these risk factors may not be seen for some time, but warrant an increased focus on prevention and mental wellbeing. NSC looks forward to working with you to address these priorities and enhance evidence-based prevention efforts in the future. Working together, we can enable people to live their fullest lives.

³⁴ <https://www.kff.org/racial-equity-and-health-policy/issue-brief/how-are-states-addressing-racial-equity-in-covid-19-vaccine-efforts/>

³⁵ <https://synergist.aiha.org/202101-confronting-two-crises>

³⁶ <https://www.tandfonline.com/doi/full/10.1080/15332640.2017.1336959>

³⁷ <https://www.samhsa.gov/data/sites/default/files/NSDUH117/NSDUH117/NSDUHSR117HispanicTreatmentNeeds2012.pdf>

³⁸ 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. Data are from the Multiple Cause of Death Files, 1999-2019, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10.html>

³⁹ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2775360>

⁴⁰ See: <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>



April 13, 2021

To: Members of the Subcommittee on Health of the House of Representatives' Committee on Energy and Commerce

From: National Viral Hepatitis Roundtable

Subject: Support for H.R. 1384, the "Mainstreaming Addiction Treatment Act of 2021"

On behalf of National Viral Hepatitis Roundtable (NVHR), a coalition of patients, health care providers, community-based organizations, and public health partners fighting for an equitable world free of viral hepatitis, I am writing to express our strong support for H.R. 1384.

In the wake of the opioid overdose epidemic, the Centers for Disease Control and Prevention (CDC) have reported rising rates of hepatitis B and hepatitis C - alongside multistate outbreaks of hepatitis A and significant clusters of new HIV infections - linked to injection drug use. In the case of hepatitis C, several modeling studies have demonstrated that effective prevention of new infections among people who inject drugs (PWID) requires a combination approach entailing the scale-up of syringe services programs (SSPs), increased uptake of hepatitis C treatment, and improved access to medications for opioid use disorder (MOUD, such as methadone and buprenorphine, also referred to as medications for addiction treatment [MAT]).

NVHR believes that the outdated statutory waiver requirements governing the prescribing of buprenorphine have substantially hampered the integration of buprenorphine prescribing in clinical care, with a range of unintended consequences that include racial and geographic disparities in access to treatment along with rising overdose mortality and rates of acute viral hepatitis. H.R. 1384 would begin to rectify these conditions by removing the separate X-waiver requirements for practitioners already permitted to prescribe controlled substances. If enacted into law, H.R. 1384 would not only dramatically increase the number of practitioners capable of prescribing buprenorphine, but also effectively address the undue stigma embedded in current statute towards effective treatment for patients with opioid use disorders.

In closing, NVHR commends the work of the Subcommittee in focusing on meaningful Congressional actions to alleviate the struggles and suffering of people with substance use disorders and their families and communities. We encourage the Subcommittee to report out



H.R. 1384 favorably and maintain attention and commitment to tackling the syndemics of substance use and viral hepatitis in future hearings.

Daniel Raymond
Director of Policy
National Viral Hepatitis Roundtable
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April 13, 2021

The Honorable Anna Eshoo, Chairwoman
 The Honorable Brett Guthrie, Ranking Member
 Energy and Commerce Committee, Health Subcommittee
 United States House of Representatives
 Washington, D.C. 20510-6200

Dear Representatives Eshoo and Guthrie:

Partnership to End Addiction is a national nonprofit uniquely positioned to reach, engage and help families impacted by addiction. With decades of experience in research, direct service, communications and partnership-building, we provide families with personalized support and resources — while mobilizing policymakers, researchers and health care professionals to better address addiction systemically on a national scale.

We are grateful that the Subcommittee will be hosting the upcoming legislative hearing, "An Epidemic within a Pandemic: Understanding Substance Use and Misuse, in America." The COVID-19 pandemic has exacerbated the country's unrelenting addiction crisis. Grief, anxiety, social isolation, stress, and economic uncertainty are leading to increased substance use and putting people in recovery at risk for relapse. While it was already very difficult to obtain addiction treatment prior to the pandemic, COVID restrictions have added yet another set of barriers and made it even more difficult to access in-person care. These factors, combined with deadly synthetic opioids and illicit fentanyl in the drug supply, have caused drug overdose deaths to skyrocket to record levels.¹ During the pandemic, more than 240 people have died each day from a drug overdose. It is imperative that Congress continues to focus its attention on substance use, provides adequate funding for services and institutes a public health approach to address this deadly public health threat.

We are encouraged by this hearing, the recent funding for substance use services in the American Rescue Plan Act of 2021 and a number of bills currently before Congress that reflect a public health approach. We support a number of the bills that the Subcommittee will be considering in its upcoming hearing, including:

- H.R. 955, the Medicaid Reentry Act of 2021
- H.R. 1384, the Mainstreaming Addiction Treatment Act of 2021
- H.R. 2067, the Medication Access and Training Expansion Act

The Medicaid Reentry Act of 2021 would help individuals access community-based addiction treatment services upon release during the critical period when individuals are released from incarceration and face a significant risk for overdose.² Individuals who are released from incarceration are often unable to obtain care during a time when they need it most because they lack insurance coverage to pay for treatment. Medicaid is generally prohibited from paying expenses incurred while a beneficiary is incarcerated, and reinstating coverage following release can take weeks or months. The Medicaid Reentry Act would allow states to restart benefits for Medicaid-eligible individuals 30 days prior to

¹ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

² <https://www.nejm.org/doi/full/10.1056/nejmsa064115>



release, easing connections to community-based addiction treatment services and reducing the risk of overdose following release.

The Mainstreaming Addiction Treatment (MAT) Act of 2021 would remove another unnecessary barrier to care: the buprenorphine waiver requirement. Buprenorphine is an effective medication for treating opioid use disorder but health care providers who prescribe this medication are subject to unique requirements to obtain a “waiver” from the federal government and a limit on the number of patients that they are able to treat at a given time. These requirements do not exist for any other medication and are incompatible with the goal to increase access to evidence-based treatment for opioid use disorder.³ While removing the waiver is a critical step, more is needed to ensure access to quality, effective addiction treatment.

One important way to increase access to treatment is to improve health care provider training on substance use and addiction, a barrier that is addressed by the Medication Access and Training Expansion (MATE) Act. The MATE Act would require prescribers to undergo opioid and substance use disorder training before receiving or renewing their license to prescribe controlled substances. Currently, health care providers only receive minimal training to address addiction and are unequipped to identify, treat and manage one of the biggest public health crises in our country. In order to expand effective treatment, health care professionals must be trained to treat addiction as they do any other complex disease. At a minimum, prescribers must have a working understanding of addiction before they are permitted to prescribe addictive narcotics.⁴

We also encourage the Subcommittee to consider a few other important bills currently before Congress, including:

- The Family Support Services for Addiction Act (H.R. 433)
- The [Opioid Patients' Right to Know Act \(H.R. 1185\)](#)
- The Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act (S. 586)

The Family Support Services for Addiction Act would establish a grant program for family community organizations that provide support for individuals struggling with substance use disorder and their families. We know that when families are involved and empowered, the outcomes for their loved ones are better. This legislation fills a significant gap in federal addiction resources by providing family programs with support and funding for their critical services.

Given the overprescribing of prescription opioids that fueled the current addiction crisis, we also believe it is important for patients to have access to non-opioid alternatives for pain. The [Opioid Patients' Right to Know Act](#) would create a grant program to incentivize states to require prescribers to discuss the addictive qualities of opioids and inform patients of alternative treatment options prior to prescribing opioids for acute pain. While a companion bill has not yet been introduced in the House, a bill currently introduced in the Senate, the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act would change federal reimbursement policy to expand access to non-opioid approaches to acute pain management.

³ For additional information, please refer to our position statement on the Buprenorphine Prescribing Waiver: <https://drugfree.org/article/buprenorphine-prescribing-waiver/>

⁴ For more information, please read our position statement on Addiction Training for Health Care Professionals: <https://drugfree.org/article/addiction-training-for-health-care-professionals/>



Thank you very much for your willingness to accept our comments on the legislation that will be considered at the Subcommittee's upcoming hearing and other bills before Congress. We believe that these bills would remove unnecessary barriers and move us toward the comprehensive, public-health based approach necessary to overcome our nation's addiction crisis. We are deeply grateful to the Subcommittee's commitment to helping individuals struggling with substance use and addiction and their families.

Sincerely,

Marcia Lee Taylor
Chief External and Government Relations Officer

Shatterproof Statement for the Record
U.S. House Committee on Energy and Commerce Health Subcommittee
Hearing on “An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America”
April 14, 2021

Shatterproof is pleased to submit a statement in support of the Medication Access and Training Expansion (MATE) Act of 2021 (H.R. 2067) and the Mainstreaming Addiction Treatment (MAT) Act of 2021 (H.R. 1384), which are among the bills before the Health Subcommittee. Shatterproof applauds the Subcommittee’s recognition that our nation has witnessed a historically high number of overdose deaths during the COVID-19 pandemic. Congress must take swift, bipartisan action to advance policy changes that will reverse the opioid epidemic and restore the gains made in the fight against this crisis. Among these changes, ensuring that prescribers of controlled substances have training in addiction treatment and expanding access to buprenorphine to treat substance use disorder (SUD) are essential to preventing additional loss of life.

The MATE Act of 2021 would ensure that Drug Enforcement Administration (DEA)-licensed prescribers have a baseline level of knowledge of how to treat and manage patients with SUD. The legislation would help train prescribers to use evidence-based approaches, including medications for addiction treatment (MAT), to care for patients. The legislation requires prescribers to attest on their application for a DEA license that they have completed at least 8 hours of education on treating and managing patients with SUD. The MATE Act of 2021 will help normalize addiction medicine and reduce the stigma that undermines the national response to the addiction and overdose crisis.

While more than 21 million Americans needed treatment for SUD in 2019, only 4.2 million reported receiving any form of SUD care.¹ Despite the effectiveness of MAT, it is vastly underused. One obstacle is that less than 6 percent of health care providers in the U.S. have obtained the required X-waiver training to prescribe buprenorphine for opioid use disorder (OUD). The MAT Act of 2021 would end the X-waiver requirement and significantly expand access to the gold standard for addiction treatment. Removing barriers to buprenorphine saves lives; within three years of similarly deregulating buprenorphine prescribing requirements, France experienced a 79 percent decline in fatal overdoses.

As the addiction and overdose crisis continues to ravage communities across the country, Congress must expeditiously pass the MATE Act of 2021 (H.R. 2067) and the MAT Act of 2021 (H.R. 1384).

About Shatterproof: Shatterproof is a national nonprofit organization dedicated to reversing the addiction crisis in the United States. Shatterproof harnesses the models of business, the rigor of science and the power of a national movement to create change and save lives through three

¹ Substance Abuse and Mental Health Services Administration (SAMHSA), *Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health*, (<https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPFDFWHTML/2019NSDUHFFR1PDFW090120.pdf>) (accessed Apr. 13, 2021).

pillars of work: revolutionizing the addiction treatment system, breaking down addiction-related stigmas and supporting and empowering our communities. To learn more visit www.Shatterproof.org.



Jeff Richardson, MBA, LCSW-C, Board Chair
Charles Ingoglia, MSW, President and CEO

**Statement for the Record Submitted by
Charles Ingoglia, President and CEO, National Council for Behavioral Health
Hearing of the House Committee on Energy and Commerce Subcommittee on Health
“An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America”
Wednesday, April 14, 2021**

The National Council for Behavioral Health (National Council) appreciates the opportunity to submit this statement for the record for the hearing entitled, “An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America.” National Council is the unifying voice for nearly 3,500 mental health and substance use disorder organizations serving over 10 million adults, children, and families living with serious mental illness and addictions. National Council applauds the Committee for holding this hearing to consider policy solutions aimed at reversing the growing substance use and overdose trends that have been made worse by the COVID-19 pandemic and its impact on the mental wellbeing of Americans.

The legislation being considered today will increase access to life-saving medications such as buprenorphine and create a necessary bridge in Medicaid coverage for those reentering society from the criminal justice system. These legislative proposals would also help prevent unnecessary prescribing of opioid medications, and ensure states and localities are able to meet the needs of both the COVID-19 pandemic and the overdose crises related to opioids. Overall, the legislation being considered today will strengthen integrated and coordinated care efforts for people who have mental health and substance use disorder needs, improve our mental health and substance use workforce, and move our care systems toward parity.

While the effects of the COVID-19 pandemic on Americans’ mental health will be long-standing, we can already see alarming trends. Increased isolation and job loss have resulted in staggering increases in both non-fatal and fatal overdoses and increased demand for services provided by mental health and substance use disorder treatment organizations. New research found that one-third of COVID-19 survivors developed a mental health condition they had not previously had.¹ In 2019, 11 percent of Americans identified as having anxiety and/or depression. In January 2021, that number had risen to 41 percent.²

The devastation of the COVID-19 pandemic is likely to continue to worsen as the full public health impact comes into focus. We must act swiftly to save American lives. We applaud the House Committee on Energy and Commerce Subcommittee on Health for its commitment to addressing the growing addiction crisis and for its thoughtful discussion about the legislation being considered today. National Council thanks the Subcommittee for its unwavering dedication to meaningful, evidence-based solutions to the ongoing substance use and overdose crises and strongly supports policies that provide more integrated care, increase the mental health and substance use disorder workforce, and promote parity.

¹ [https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(21\)00084-5/fulltext](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(21)00084-5/fulltext)

² <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>



Emmert/AFP via Getty Images

BIDEN LOOKS TO EXTEND TRUMP'S BOLSTERED MANDATORY MINIMUM DRUG SENTENCING

Over 100 advocacy groups sent a letter to Congress opposing the "hardline anti-science policy," which applies to a broad range of fentanyl-related substances.



[Akela Lacy](#)

April 12 2021, 4:56 p.m.

THE BIDEN ADMINISTRATION is expected to announce support this week for the temporary extension of a Trump-era policy expanding mandatory minimum sentencing to cover a range of fentanyl-related substances. More than 100 civil rights, public health, and criminal justice advocacy groups sent a [letter](#) last week urging Congress and President Joe Biden to oppose any extension of the Trump policy.

The administration can't extend the policy without congressional action, which it is expected to support during a Wednesday hearing on substance use before the House Energy and Commerce Committee, according to two groups on the letter and several Democratic aides. The aides note that the administration will likely request additional time to explore the policy's ramifications and has not yet decided whether it will adopt a full extension.

Biden ran on a platform that included criminal justice reform and an end to mandatory minimum sentencing, a practice he helped establish during his time as a senator in the 1980s and '90s. Criminal justice and drug policy advocates say extending the Trump policy would be an abandonment of those promises and a return to the kinds of strategies that escalated the war on drugs, mass incarceration, and the opioid epidemic. Current laws impose a five-year mandatory minimum sentence, and a 40-year maximum sentence, for selling substances with trace amounts of fentanyl analogues in a mixture weighing between 10 and 100 grams.

"Class-wide scheduling would exacerbate pretrial detention, mass incarceration and racial disparities in the prison system, doubling down on a fear-based, enforcement-first response to a public health challenge. As we approach the 50-year milestone of President Nixon's announcement of the War on Drugs, there is ample evidence that these unscientific policies destroy communities, entrench racial disparities, and do nothing to reduce drug supply or demand," the letter reads. "We must learn from the lessons of the past: It is time for Congress and the Biden administration to embrace a public health approach to drug use."

THE TRUMP ADMINISTRATION started classwide scheduling of fentanyl analogues in 2018. The policy put a wide range of substances with a chemical structure similar to fentanyl on Schedule I of the Controlled Substances Act, expanding the application of mandatory minimum sentencing laws to all fentanyl analogues. "But chemical structure alone cannot predict how a drug will affect the human brain," the letter claims, citing a neurobiologist's testimony before the House

Subcommittee on Crime, Terrorism, and Homeland Security, “and not all fentanyl analogues are harmful.”

The Trump policy, set to expire in May, gives the Drug Enforcement Administration unlimited power to determine the legality of substances while cutting scientists and public health experts out of the conversation. This limits their ability to study certain prohibited drugs, which can prove crucial for developing therapies. Spokespersons from the Justice Department “repeatedly, erroneously, have claimed that failure to enact class-wide scheduling would ‘legalize’ harmful fentanyl analogues,” the letter continues, citing a Washington Post [op-ed](#) by former Attorney General Bill Barr with the title, “Fentanyl could flood the country unless Congress passes this bill.” The sale of fentanyl analogues can be prosecuted whether or not they are scheduled, and the policy imposes harsher sentences for possession.

According to a [report](#) by the United States Sentencing Commission, prosecution of federal fentanyl offenses increased by close to 4,000 percent between 2015 and 2019, and prosecution of fentanyl analogues increased by well over 5,000 percent since 2016. As the letter points out, those prosecutions involved significant racial disparities, “with people of color comprising almost 75% of those sentenced in fentanyl cases in 2019.” The same was true of sentencing for fentanyl analogues, with people of color comprising 68 percent of people sentenced.

“Congress and the Biden administration should be wary of expanding the reach of these penalties by adopting a policy explicitly designed to expedite drug prosecutions and increase penalties,” the signatories wrote. “Any further extension of the Trump administration’s class-wide scheduling policy threatens to repeat past missteps with crack cocaine that policymakers are still working to rectify.”

Fentanyl has been back in the national spotlight alongside the trial of Derek Chauvin, the Minneapolis police officer who killed George Floyd, as conservative commentators and law enforcement point to the drug’s presence in Floyd’s system in their attempts to exculpate Chauvin for his death. “It’s been a very visible example of how mythology and fear around fentanyl and racism is playing out in the media right now,”

said Grant Smith, deputy director of national affairs at the Drug Policy Alliance, one of the letter's signatories. "Those are the exact same narratives that the Trump administration relied on to impose this policy. And if the Biden administration were to choose to extend this — which it sounds like they will — they're really just embracing that same rhetoric. That same racist thinking."

Advocates wonder why the Biden administration would go out of its way to extend a policy that would mark a return to the harsh drug sentencing laws from which the president has tried to distance himself, and even in some cases, [apologized for pursuing](#). A Government Accountability Office [report](#) released Monday on classwide scheduling of fentanyl-related substances explores potential impacts of altering the policy. In filings attached to the report, Biden's Department of Justice [argues](#) aggressively in favor of extending the policy, writing that "alternatives to class-wide scheduling are inadequate to address the opioid epidemic." A White House spokesperson did not immediately respond to The Intercept's request for comment.

"If the Biden administration were to come out and just flat out support the classwide scheduling, I think that would be very disappointing, because it wouldn't take into consideration the false premise that this started with," a Democratic aide told The Intercept. "Maybe it's understandable that they might need more time because it is a pretty fraught and dense issue. But I would hope that they would certainly look at it close enough to see that this is something that was requested based on an idea that isn't necessary."



X the X-Waiver: How Congress can facilitate treatment for opioid abuse

BY MIKE HUNTER AND JOSH STEIN, OPINION CONTRIBUTORS — 02/25/21 07:30 AM EST
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announces bid for New
York governor



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Next month will mark a full calendar year since the lives of millions of Americans were turned upside down as a result of the COVID-19 pandemic. However, even as the coronavirus continues to ravage communities across the country, another public health crisis is still devastating American families: our nation's fatal addiction to opioids. In 2019, nearly 50,000 Americans lost their lives to an opioid overdose — a 136 percent increase just since 2010.

There's alarming new evidence that overdose rates have jumped even further since the March 2020 COVID-19 emergency declaration. According to the most recent available data from the Centers for Disease Control and Prevention (CDC), both April and May saw the largest monthly increases in opioid deaths on record. It's easy to understand how the stress, dislocation and uncertainty caused by the pandemic would be devastating for those suffering from substance use disorders. People across the country are in pain and too many are dying.

The good news is that safe and effective treatment options exist, but Congress must act to ensure these options are more widely available. One type of medication for opioid use disorder, called buprenorphine, helps

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diminish the effects of physical dependence on opioids, such as withdrawal symptoms and cravings. Experts worldwide, including the National Institute on Drug Abuse, agree that buprenorphine is a safe, effective treatment for opioid use disorder.

In the United States, however, medical practitioners are limited in how they can prescribe this lifesaving treatment. The [Drug Addiction Treatment Act](#) of 2000 requires that practitioners apply for a waiver, commonly known as the [X-Waiver](#), in order to legally treat patients for opioid use disorder using buprenorphine. Practitioners must complete between eight and 24 hours of specialized training before they can apply for this waiver and, even after receiving it, are restricted in the number of patients they can treat.

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When it comes to the powerful opioids that have created this crisis of addiction, prescribers do not need any kind of waiver to prescribe these deadly drugs. Yet, the law demands that prescribers get a waiver to prescribe the safer medication that serves to treat opioid use disorder. In fact, buprenorphine is the only drug for which the law requires prescribers to provide proof of special training in order to prescribe. The law is, frankly, upside down.

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This X-Waiver requirement not only erects a barrier that limits the number of prescribers treating patients, but also creates a stigma against the use of buprenorphine for treatment. As a result, less than 6 percent of practitioners are certified to prescribe it. This has led to a significant treatment shortage across the country, especially in rural America. A 2020 Department of Health and Human Services (HHS) [report](#) found that 40 percent of counties did not have a single provider who could legally prescribe buprenorphine.

Budowsky: DeSantis medically, politically...

As the attorneys general of Oklahoma and North Carolina, we see the cost of addiction among our constituents every day. In North Carolina, 64 out of 100 counties are considered "high need for treatment services," and in Oklahoma, 59 of 77 counties have the same distinction. Unfortunately, only 1 in 5 individuals with an opioid use disorder is receiving the treatment they need. Clearly, despite all the attention paid to the opioid epidemic in recent years, more needs to be done, especially in the wake of the COVID-19 pandemic.

Hypocritical, hilarious AOC says calling...

In 2018 and 2019, we joined our colleagues at the [National Association of Attorneys General](#) (NAAG) in calling on Congress to eliminate these unnecessary burdens by supporting either the [Mainstreaming Addiction Treatment \(MAT\) Act](#) or the [Comprehensive Addiction and Recovery Act \(CARA\) 2.0](#). Both bills would have eliminated the X-Waiver requirement and had bipartisan support in the 116th Congress, as well as the support of a broad coalition of organizations.

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Tackling the Drug Enforcement Administration's X-Waiver also has received bipartisan support within the executive branch. Under the Trump

administration, HHS issued [guidelines](#) to create an exemption for certain X-Waiver requirements. Although those guidelines were recently set aside by the Biden administration for procedural reasons, the new administration has expressed its support to [“find ways to lift burdensome restrictions on medications for opioid use disorder treatment.”](#)

America's opioid crisis is worse than ever. The nation cannot wait any longer to expand access to lifesaving treatment and bring hope to millions of Americans who are working on their path to recovery. We must take decisive action on behalf of Americans' public health. By eliminating the X-Waiver for good, the 117th Congress can take a simple step that will save countless lives.

Mike Hunter, a Republican, is the attorney general of Oklahoma. Josh Stein, a Democrat, is the attorney general of North Carolina. Both serve on the [National Association of Attorneys General Executive Committee](#).

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**TESTIMONY OF TIMOTHY B. CONLEY AND DR. DEBBIE AKERMAN OF YESHIVA
UNIVERSITY'S WURZWEILER SCHOOL OF SOCIAL WORK
SUBMITTED TO THE HOUSE COMMITTEE ON ENERGY AND COMMERCE
HEARING ON "AN EPIDEMIC WITHIN A PANDEMIC: UNDERSTANDING
SUBSTANCE USE AND MISUSE IN AMERICA."**

APRIL 14, 2021

Chair Eshoo and Ranking Member Guthrie, thank you for affording us the opportunity to provide this testimony to the subcommittee on the important topic of understanding substance use and misuse in America in the midst of a pandemic.

My name is Timothy B. Conley and I have been a Certified Addiction Specialist (C.A.S.) with the American Academy of Health Care Providers in the Addictive Disorders since 1993. I have both a Master's degree (M.S.W.) and Ph.D. in Social Work - I have held a license to practice since 1990 and have treated people with substance use disorders since 1987. Initially I worked in the greater Boston area; I have been teaching and practicing in rural Montana since 2003, serving the entire state. After 11 years earning tenure as an Associate Professor at University of Montana, I moved on to become an Associate Clinical Professor at Yeshiva University in NY, NY teaching fully online - even before the pandemic. Yeshiva hired me to develop a graduate level program for social workers specializing in the treatment of addictions

(which we now have). My current educational mission is preparing the next generation of highly qualified and credentialed professionals to work with those afflicted by substance use disorders. I am writing to you in collaboration with my colleague Dr. Ackerman who will briefly introduce herself before we offer ideas and suggestions.

My name is Dr. Debbie Akerman. I earned my M.S.W. (2010) and Ph.D. (2019) in Social Welfare from Yeshiva University, Wurzweiler School of Social Work. I maintain a private practice where I specialize in treating addiction and I am a Clinical Assistant Professor at Wurzweiler where, along with Dr. Conley, I teach several graduate courses on addictions. My foray into the world of addiction, like many others, came from personal experience and devastation. It is no coincidence that one of the sayings in the 12-step recovery programs is that “Addiction starts with pain and ends with pain”. Addiction remains the most misunderstood, stigmatized, and moralized diagnosis in the professional world; current legislative proposals have an opportunity to change that.

Between us we have counseled thousands of individuals toward recovery while watching the treatment workforce gray and retire, with too few replacements to fill ranks as an epidemic descended on our country and our professional world. We have seen, in our own offices, the faces behind the statistics citing over eighty-eight thousand (88,000) individuals died of overdoses in a single 12 month period. This is why we are increasingly committed to training a next generation of counselors to address America’s most recent substance use epidemic: opioid use disorder.

The problem

We suggest that of all the text in all the bills under consideration by your subcommittee, the most important single sentence is in HR 2366, page 5, lines 19 and 20 “**...and expanding access to treatment.**” We take this to mean access to qualified and trained treatment providers. This assumes enough treatment providers exist: *they do not*.

The United States has effective evidence based treatment models for addiction; we have Federally Qualified Health Centers; we have state licensed and accredited inpatient and outpatient treatment programs and the ability to start more; we have a sympathetic wave of goodwill towards people suffering addiction the likes of which has not been seen since the 1970s but – these are carts without horses. Programs must be staffed and we desperately need more qualified addiction treatment providers. According to the current U.S bureau of Labor Statistics, Occupational Outlook Handbook

“Employment of substance abuse, behavioral disorder, and mental health counselors is projected to grow 25 percent from 2019 to 2029, much faster than the average for all occupations. Employment growth is expected as people continue to seek addiction and mental health counseling.”

This was *before the pandemic*. Given the adverse impact of Covid on mental health issues, particularly substance use disorders, we must assume the need for qualified treatment professional is even greater now.

Looking at this issue from a macro or educational level, Dr. Akerman’s research indicates 75% of behavioral health clinic administrators stated their clinicians could not diagnose or treat

addiction. In a country where addiction cases continue to rise, to cost this country where billions of dollars in forensics, health costs, and lost productivity are prevalent. It is imperative that the behavioral health workforce numbers change to meet the problem. Addiction and its sequelae cannot be addressed if there is not an adequate work force that understands this disease process from all fronts. Treatment centers cannot be effective if they do not have the adequate numbers of well-trained staff to implement evidence based treatment. Clients, their families and communities will all continue to suffer if there are not enough clinics and rehabs for those who seek treatment, if we do not have enough manpower to educate, and support the recovery community.

The 2019 National Survey on Drug Use and Health (NSDUH) states **“80% of individuals with a substance use disorder (SUD) do not get needed care”** (1). This was a conservative estimate, again made pre-pandemic. Most people suffering an opioid or other substance use disorder would choose to get the needed care were it available – but it is not, particularly in rural America (like Montana where Dr. Conley lives) because there are nowhere near enough addiction treatment service providers. Even those qualified to treat other mental illness are most often not trained to treat addiction. Therefore, re-training is in order. It takes about 100 hours of additional professional training for individuals with a Master’s degree or higher to become credentialed and proficient at treating addiction.

A well-intentioned pouring of support into the treatment system will result in unspent dollars if treatment settings cannot find qualified personnel to hire.

The following anecdote is informative. Dr. Ackerman has been treating a young man for about four years (early recovery may take 3-5 years) who had a fairly significant addiction issue. Luckily for this individual, he was able to get into recovery while still a teen and embraced the concepts of a higher power, gratitude and acceptance in relatively short time. From a teen who was unable to go to school, work or function in any meaningful capacity due to his addiction and mental health issues he has emerged a sensitive, cheerful young man who has started his own business and immersed in the 12 step world of daily prayer, humility and gratitude which includes sponsoring several newcomers with his “experience, strength and hope.” This young man is just one of millions of individuals who have had the benefit of workers trained with the principles of both social work and addiction.

The problem we see is making sure that this positive experience can be replicated and for that to happen we need workforce.

Solution

The United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) 2019 “Behavioral Health Workforce Report” concluded that the United States should:

- (Address) ...the need for behavioral health providers and encourage students to pursue careers in behavioral health.

- Provide funding to healthcare practitioner education programs to embed information on care and treatment of serious mental illness and substance use disorders into standard undergraduate curriculum.
- Encourage clinical placements/practicums in mental health and substance use disorder settings to increase the knowledge base of practitioners in behavioral health services.
- Increase loan forgiveness programs for all behavioral health specialties to encourage entry to the field.

At this point in time, a critical part of solving the opioid and other substance use disorder epidemic is incentivizing careers for qualified treatment professionals. This translates into tuition remission and loan forgiveness programs (going forward) for those completing formal education in social work, mental health and addiction counseling degrees. These must be specific to earning state-level addiction counseling credentials like the Joint Masters in Social Work / Credentialed Alcoholism and Substance abuse Counseling (MSW/CASAC) program we have built at Yeshiva University.

“Nothing changes if nothing changes” is a phrase persons in recovery from addiction are aware of, and we humbly testify that it is time to provide additional funding so that we may train more qualified workers to bring hope and recovery to a nation in desperate need of recovery.

References

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2. U.S bureau of Labor Statistics, Occupational Outlook Handbook <https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm> Retrieved 4-11-21



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February 9, 2021

The Honorable Paul Tonko
Member of Congress
2369 Rayburn House Office Building
Washington, DC 20515

Re: Support for the Mainstreaming Addiction Treatment Act

Dear Representative Tonko:

On behalf of the National Association of Boards of Pharmacy® (NABP®), I am writing in strong support of the Mainstreaming Addiction Treatment Act (MAT Act). Thank you for your continued leadership on this important legislation and for your long-standing commitment to ensuring that Americans with substance use disorder have access to much-needed medication-assisted treatment (MAT). The tireless work that you and your staff have done on this issue has made a significant difference to public health, and NABP appreciates the opportunity to work with you to advance the MAT Act in the 117th Congress.

NABP is a nonprofit association whose mission is to protect and promote public health by assisting its member state boards of pharmacy and offering programs to promote safe pharmacy practices for the benefit of patients. NABP is proud to support the boards in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, and 10 Canadian provinces. As an association, we provide a wide variety of programs and services all underscored by our vision statement – innovating and collaborating today for a safer public health tomorrow. From inspection support to licensure transfer, examinations, and accreditation, NABP is involved in every step of pharmacy compliance and health promotion across the country.

NABP is deeply troubled by reports of spikes in drug overdoses across the country as the opioid epidemic continues to be exacerbated by the coronavirus disease 2019 pandemic. Now more than ever, we must ensure that providers are equipped with the appropriate resources to combat the opioid crisis and are not burdened by unnecessary and unproven bureaucratic processes. Your bipartisan legislation, if enacted, will reduce barriers to care and improve patients' access to MAT by eliminating the redundant, outdated requirement that practitioners apply for a separate waiver through Drug Enforcement Administration to offer MAT to patients. Currently, only 7% of providers have taken the steps necessary to obtain the waiver and prescribe MAT. The rising demand for care coupled with an already dwindling substance use disorder workforce underscores how imperative it is for Congress to take purposeful steps to curb this epidemic by eliminating federal restrictions that are inhibiting evidence-based treatment options from being accessible to those in need.

The Honorable Paul Tonko
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With over 80,000 pharmacy locations across the country, pharmacists are uniquely positioned to expand access to this critical therapy. However, the current statute categorically prohibits pharmacists from using their medication expertise to help treat patients in need of MAT. Currently, pharmacists largely play a dispensing role in the provision of MAT; however, given their accessibility and expertise, pharmacists could easily take on the role of prescribing MAT, particularly to address gaps in care. Pharmacists can help develop treatment plans, communicate with patients, coordinate care, and monitor adherence and improvement, along with prescribing and dispensing buprenorphine medications. Pharmacists are accessible in nearly every community, including those that do not have convenient access to health care, much less providers who focus on treating opioid use disorder. Allowing pharmacists to prescribe MAT would have a significant impact on access to this important treatment. To do this, Congress must remove unnecessary federal restrictions and empower states to determine the appropriate provider requirements for their communities as states regulate providers' authority to prescribe. Pharmacists handle sensitive controlled substances every day, with little evidence of diversion or misuse. States across the country have also granted pharmacists authority to prescribe some drugs in specific situations and would likely consider allowing pharmacists to prescribe MAT if federal law did not prohibit it. Currently, federal law prevents this local decision making and prohibits pharmacists from providing access to critical MAT at a time of great need. The MAT Act proposes a sensible solution to amend the problematic statute that unreasonably limits the types of providers who can offer MAT, burdens the providers currently deemed qualified under the law, and preempts state regulatory authority.

Thank you for your continued leadership in Congress and for once again introducing the MAT Act. NABP looks forward to continuing to work with you and your staff to see the MAT Act advanced and ultimately enacted this Congress, finally removing the unnecessary waiver process that has created a barrier to care for too long. Please know that we stand ready to work with you to ensure that federal policies that safeguard public health, like the MAT Act, become law.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY



Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

cc: Representative Michael Turner
Representative Antonio Delgado
Representative Anthony Gonzalez

Questions for the Record

House Committee on Energy and Commerce, Subcommittee on Health

Hearing entitled, "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America"

April 14, 2021

Regina LaBelle, Acting Director, Office of National Drug Control Policy

The Honorable Frank Pallone, Jr.

1. There is a potential for drug identification laws like H.R. 2355 to prevent high-risk individuals, such as a homeless person without an ID, from having access to needed prescriptions. Has ONDCP itself, or in partnership with other federal agencies, done any research on the effectiveness of prescription drug identification policies in deterring opioid shopping or misuse?

Response

The Centers for Disease Control and Prevention (CDC) conducted a review of state prescription drug identification laws in 2013. At the time, CDC found that 25 states either explicitly required or allowed pharmacists to request identification at the time of dispensing.¹ A National Association of Model State Drug Laws review conducted under a contract with the Office of National Drug Control Policy (ONDCP) found that, as of March 2016, the majority of states and the District of Columbia had some form of controlled substance prescription ID requirement;² however, an assessment of the effectiveness of these laws in reducing opioid prescribing was beyond the scope of the effort. ONDCP has not itself, nor in partnership with other federal agencies, conducted research on the effectiveness of prescription drug identification policies in deterring opioid shopping or misuse.

2. Does ONDCP have insight on whether prescription drug identification laws should remain at the state level or if a national strategy is needed?

Response

With the exception of controlled substances, dispensing of prescription drugs and

¹ Centers for Disease Control and Prevention. Menu of State Prescription Drug Identification Laws. Public Health Law. Office for State, Local, and Territorial Support. 2013. Retrieved July 14, 2021 at <https://www.cdc.gov/phlp/docs/memu-pdil.pdf>

² National Association for Model State Drug Laws. States that Require ID Prior to Dispensing Controlled Substances or Non-Controlled Prescription Drugs. 2016. Retrieved July 14, 2021 at <https://namsdl.org/wp-content/uploads/States-that-Require-ID-Prior-to-Dispensing.pdf>

prescription drug monitoring programs are generally areas of state oversight and regulation, as is the operation of prescription drug monitoring programs. At this time, given the lack of research on the impact of various prescription drug identification requirement laws, the likelihood that a single approach would likely not be equally effective across states, and given the long history of state regulation in this area, ONDCP does not believe there is a basis for recommending a transfer of such authorities to the federal government.

The Honorable Richard Hudson (R-NC)

1. There remain concerns around the reporting requirements included in Section 202 of H.R. 2366, Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021. Section 202 requires a high level of reporting of highly sensitive information. This is further compounded by the directive for CMS to publish the information, with a sole exemption for “proprietary information.” It would seem that most information required to be reported may be considered proprietary information. From a policy perspective, I am concerned this could dissuade entrance into the naloxone space particularly, given the highly burdensome reporting requirements. Would you provide policy rationale and reasoning for the scope of the data requested? In addition, please provide any clarification around what information may be considered “proprietary information,” as used in Section 202.

Response:

The Office of National Drug Control Policy (ONDCP) is focused on increasing access to and expanding distribution of the opioid overdose reversal drug naloxone. In the midst of an overdose epidemic in which the estimated total number overdose deaths for 2020 surpassed 93,000—an all-time high that is nearly 30 percent above the 2019 figure³—increased access to naloxone is critical.

Naloxone should be affordable and easily accessible to anyone who needs it; to anyone who might encounter a person who could overdose, whether they are first responders, families, or friends of people who use drugs; and to those who are in treatment or receiving care through harm reduction services like syringe services programs.

As Section 202 of the “Support, Treatment, and Overdose Prevention of Fentanyl Act of 2021 was crafted by Congress, we are not aware of the specific rationale for its formulation.

³ Centers for Disease Control and Prevention. Vital Statistics Rapid Release: Provisional Overdose Death Counts. National Center for Health Statistics. Retrieved July 14, 2021 at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

The Honorable Earl L. “Buddy” Carter

1. Generic injectable overdose agents have been available for several years, and FDA is doing all it can to encourage additional entrants to the market, yet the FTC has previously said “too much transparency can harm competition in the market.” The FTC has expressed concern “when information disclosure allows competitors to figure out what their rivals are charging, which dampens each competitor’s incentive to offer a low price.” Wouldn’t requiring a whole host of new reporting requirements, particularly of sensitive business information that would impact competitive dynamics, impede companies from wanting to enter the market?

Response

Questions of market dynamics and associated regulatory incentives or disincentives are beyond the scope of the Office of National Drug Control Policy’s mission. We defer to Federal agencies that deal more directly with the market for pharmaceuticals on these questions.

Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
“An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America”
April 14, 2021

Geoffrey Laredo, MPA, Principal, Santa Cruz Strategies LLC

The Honorable Frank Pallone, Jr. (D-NJ)

Chairman Pallone, thank you very much for these questions. I base my answers on my personal experience, and in this instance, am also relying heavily on language provided to me by Dr. Sandra Comer of Columbia University and the College on Problems of Drug Dependence.

1. Drug overdose deaths are at an all-time high, and a key driver of this trend is illicitly manufactured fentanyl and fentanyl-related substances. One tool for preventing the supply of fentanyl related substances is to classify these substances as under Schedule I. Mr. Laredo, could you discuss further why you believe class wide scheduling of Fentanyl analogs does not reduce harm or risk associated with substance use?

There are many examples from past years where substances were placed into schedule 1 (or were already there) and that scheduling did not result in decreased morbidity or mortality. Once our field really started focusing on the opioid overdose and addiction crisis, we succeeded somewhat in reducing the amount of opioids prescribed by doctors. Morbidity and mortality did not decrease; rates of heroin use and addiction increased. As efforts shifted to deal with heroin, fentanyl emerged and developed into the problems we see today. During the past years, several fentanyl analogs were placed in schedule one, to no effect. Then the class-wide effort was initiated, and as you know, death and disease has continued to accelerate. If I was aware of a successful class-wide scheduling effort decreasing morbidity and mortality, I would focus on it and tell you we should double down on that strategy. I am unaware of any such success.

Whether or not you choose to support class-wide scheduling, I strongly recommend you implement a MUCH more robust role for HHS in that entire process. HHS must be relied upon to determine the pharmacological activity of compounds before putting them into Schedule I. Dr. Comer’s past testimony (in italics below) is illustrative of this point:

Etorphine is a very potent opioid used in veterinary medicine to tranquilize large animals and diprenorphine is an antagonist used as an antidote for etorphine. These examples illustrate how the antidote to a toxic substance and the toxic substance itself can share core chemical structures. However, the chemical structure of a compound alone cannot tell us whether it will have agonist or antagonist activity. Basic pharmacological studies must be performed in order to make this determination.

- *Science-based agencies, specifically the FDA and the National Institute on Drug Abuse (NIDA) at the Department of Health and Human Services (HHS), should review the pharmacological activity, not just the chemical structures, of these compounds.*
- *The role of HHS need not be as robust as the 8-factor analysis currently mandated by the Controlled Substances Act. Instead, the Committee should consider adding a role for HHS in subjecting compounds to more limited tests of pharmacological activity through animal models using a rapid process that could be undertaken by NIDA and a designated, pre-screened team of extramural scientists. In fact, NIDA, FDA, and the Drug Enforcement Administration (DEA) currently participate on the Interagency Committee for Drug Control, which reviews and prioritizes compounds that need analysis. NIDA issues grants and contracts for such analyses, as does the DEA.*

The current fentanyl crisis poses a formidable challenge to Congress and the DEA since there are literally thousands of (existing or potential) fentanyl analogues, some of which have high abuse and dependence potential. CPDD supports efforts to control the distribution, sales, and use of these synthetic fentanyls. In the face of the opioid crisis, it is tempting to globally put all compounds that are chemically similar to fentanyl in Schedule 1; however, such an action is likely to severely limit biomedical research and, in the long term, adversely impact public health. The opioid crisis is a very challenging public health issue and, arguably, we have yet to significantly turn the tide in this battle despite our current efforts. To restrict research by limiting access to potentially important compounds, based solely on chemical structure, is not likely to facilitate progress in this arena.

2. Mr. Laredo, will you discuss further how research requirements related to Schedule I substances could be streamlined and why you believe this is a meaningful policy solution?

While at NIDA, I spent several years trying to work with the DEA and FDA to agree upon and implement streamlined research requirements to enable researchers to work more efficiently with schedule 1 compounds. It was frustrating, slow work, and it is still ongoing. I am aware that the CPDD and other organizations are continuing those efforts, and I also assume that the federal agencies are part of this discussion.

In particular (again, language borrowed from Dr. Comer), these 6 suggestions could go a long way in helping the research community do more work, faster, and more efficiently. Taken together, this would be a meaningful policy solution because it allows professionals to be professional, to find answers to the problems we are facing, and to share and advance that work in an environment of scientific rigor and discovery rather than one of suspicion.

1. *Permit researchers holding a Schedule 2 license to conduct research on all Schedule 1 drugs. Specifically, treat the process for obtaining and modifying a Schedule 1 research registration the same as is currently in place for Schedule 2 (e.g., the DEA currently does not require FDA review of Schedule 2 substances for the purpose of obtaining a license.) NOTE: 1) FDA review will still be required for clinical studies of these substances during the Investigational New Drug application process, and 2) the security requirements are the same for Schedule 1 and 2 drugs so there are no implications for diversion.*
2. *Clarify that it is permissible for one individual to hold a Schedule 1 registration under which colleagues from the same institution may work even if those colleagues do not work directly for the registrant.*
3. *Eliminate the requirement to store each substance in a separate cabinet and for each individual researcher to have their own storage cabinet.*
4. *Allow registered researchers to store, administer, and otherwise work with any substances for which they hold a research registration at multiple practice sites on a single campus so long as the registrant notifies the Attorney General prior to conducting research at those sites.*
5. *Clarify that it is permissible for researchers to make limited modifications to the substances they are researching, such as processing them into extracts, solutions, or derivatives, without having to obtain a separate manufacturing license.*
6. *Allow individuals conducting research with a substance subsequently placed into Schedule 1 who hold a registration to conduct research with any other Schedule 1 or Schedule 2 substance to continue work on the newly scheduled substance until their new or amended registration application is approved or denied. These individuals will have to submit their new or amended registration application within 120 days of the substance being added to Schedule 1.*

Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
“An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America”
April 14, 2021

J. Deanna Wilson, M.D., M.P.H., Assistant Professor of Medicine and Pediatrics,
 University of Pittsburgh School of Medicine

The Honorable Frank Pallone, Jr. (D-NJ)

- 1. One approach to address substance use disorder is to reduce excess or unnecessary prescriptions for narcotics and to increase access to medication that can treat substance use disorder and prevent overdose death. However, per SAMHSA’s most recent report in 2019, 1.6 million people in the U.S. had Opioid Use Disorder yet only about 1 in 3 received evidence-based Medication Assisted Treatment from a certified treatment center. In addition, the rate of naloxone prescriptions has increased substantially, but prescribing rates for high-dose opioids still far exceed that of naloxone and naloxone dispensing varies substantially across the country. Dr. Wilson, as a physician, do you support additional training on safe opioid prescribing for health care professionals? If so, why do you believe that additional is necessary?**

We absolutely need additional training on safe opioid prescribing for health care professionals, but also, we need to broaden this type of training to better address the current opioid crisis. All health care professionals who prescribe opioids should receive training not only in how to safely prescribe and monitor opioids in individuals receiving them for pain, but also how to provide counseling and education in reducing overdose and misuse risks, and in how to identify and recognize those patients for whom opioid prescriptions have become problematic. Currently few health care professionals receive this kind of training as part of routine medical education. Current safe opioid prescribing lectures often solely focus on how to prescribe opioids for pain but fail to provide any information on how to manage suspected misuse or how to support and treat patients who have developed opioid use disorders. In response to suspected opioid misuse, many providers will then fail to recognize it or will recognize it and then abruptly discontinue or aggressively taper patients leading to severe withdrawal and increasing risk for illicit opioid use and potentially overdose. All providers able to prescribe opioids should receive mandatory training in a core curriculum recognizing how you prescribe and manage opioids safely for pain, and how you recognize, manage, and treat individuals who then develop side-effects to the medications, such as opioid use disorder.

- 2. Dr. Wilson, legislation before the Subcommittee today would require a minimum level of training related to treatment and management of patients with opioid or substance use disorders. Do you believe this approach would help to support safe opioid prescribing?**

Education requirements around safe opioid prescribing must be broader than how to safely prescribe opioids for pain, but also must provide training on how best to identify and manage those patients with pain who have developed an opioid use disorder or other substance use disorder. Providers currently receive little to no training in identifying and treating patients with opioid use disorder as part of routine medical education. For all providers able to prescribe opioids, they should also receive training in how to identify and treat opioid misuse and how to offer treatment for those who go on to develop an opioid use disorder. I all too often will see patients abruptly terminated from a pain clinic where their doctor was prescribing opioids and stopped because of appropriate or inappropriate concern for misuse. Patients are left in severe withdrawal and often then turn to illicit opioids, increasing their risk for possibly fatal overdose. It is irresponsible to prescribe opioids without also knowing how to monitor for misuse and opioid use disorder and then how to safely transition patients to medications to treat opioid use disorder. Safe opioid prescribing also means knowing how to safely treat and manage opioid use disorder.

- 3. Dr. Wilson, could you speak, as a provider in this field, to any consequences or barriers in an individual's recovery that might arise from the ID requirement set forth in H.R. 2355, the Opioid Prescription Verification Act of 2021?**

I have repeatedly seen that ID requirements serve as a large and potentially unforeseen barrier to treatment engagement and retention for patients. For example, currently many methadone opioid treatment programs still require that patients present with an ID prior to connecting with the program. I see patients in the hospital who are eager to get plugged into substance use treatment and want to be on methadone, but who lack an ID. It is a tragedy when we as healthcare providers are ready and able to start patients on medication to treat their opioid use disorder, when patients are ready and willing to start, and when we cannot get them plugged into treatment because of ID requirements.

Although not the intention of the Act, any addition regulation requiring that medications to treat opioid use disorder, such as buprenorphine or suboxone (as they are classified as opioids), would require an ID to be filled, would create an undue burden for vulnerable patients. The ID requirement would unintentionally serve as a barrier to treatment with potentially fatal consequences as stable patients would risk return to illicit use if unable to fill medications and patients eager to start treatment would be delayed. Any delay or any interruption in receiving the life-saving medication to treat opioid use disorder could be fatal.

Lacking an ID is a common experience for many of the patients for whom I provide care. These patients still provide their names and their date of birth to pharmacists when they pick up their medication. The medication is listed in our (PA) state PDMP under the individual patient's name. I can track their refills and see if they have filled any other opioids at other pharmacies. Adding an ID requirement would only serve as a barrier to my patients continuing or starting life-saving medication to treat their opioid use disorder without adding any additional clinical or regulatory benefits. An ID requirement would be a potentially tragic barrier interrupting and preventing care for an already vulnerable group of patients.

4. Is it correct that vulnerable patients (such as the homeless) may be unable to continue their recovery medications and experience relapse and overdose if they are required to provide an ID to get their medications from the pharmacy?

Patients with substance use disorders commonly struggle with having IDs (as they may be homeless, live lives with some chaos prior to connecting with treatment that may make it hard to keep an ID secure, and are at increased risk for victimization and theft causing their IDs to be taken). Replacing an ID is not an easy task: there is a financial burden to patients often with limited resources, patients often need other supporting documents, such as birth certificates they also lack, and even for patients who are able to start the process it can be a lengthy one. Any delay in care can be a deadly delay in care as patients risk return to use. A new pharmacy requirement would also threaten individuals who are already successfully receiving medications and engaged in treatment. The patients would experience acute opioid withdrawal and be at high risk for a relapse and possible overdose. Any new requirement stating patients would need to use an ID to pick up opioid medications to treat their opioid use disorder, such as to fill a buprenorphine or suboxone prescription, would lead to unnecessary deaths. ID requirements would create an undue burden for the most vulnerable patients.