LIVES WORTH LIVING: ADDRESSING THE FENTANYL CRISIS, PROTECTING CRITICAL LIFELINES, AND COMBATING DISCRIMINATION AGAINST THOSE WITH DISABILITIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

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C O N T E N T S

WITNESSES

[1] Mr. Chester and Mr. DeLena did not answer submitted questions for the record by the time of publication. Replies received after publication will be retained in committee files and made available at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=115361.

Page

LEGISLATION

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[2]The information has been retained in committee files and is available at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=115361.

LIVES WORTH LIVING: ADDRESSING THE FENTANYL CRISIS, PROTECTING CRITICAL LIFELINES, AND COMBATING DISCRIMINATION AGAINST THOSE WITH DISABILITIES

WEDNESDAY, FEBRUARY 1, 2023

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

The subcommittee met, pursuant to call, at 10:01 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Brett Guthrie (chairman of the subcommittee) presiding.

Members present: Representatives Guthrie, Bucshon, Burgess, Latta, Griffith, Bilirakis, Johnson, Hudson, Carter, Dunn, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Obernolte, Rodgers (ex officio), Eshoo (subcommittee ranking member), Sarbanes, Cárdenas, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Craig, Schrier, Trahan, and Pallone (ex officio).

Staff present: Alec Aramanda, Professional Staff Member, Health; Kate Arey, Content Manager and Digital Assistant; Jolie Brochin, Clerk, Health; Sarah Burke, Deputy Staff Director; Kristin Flukey, Professional Staff Member, Health; Theresa Gambo, Financial and Office Administrator; Seth Gold, Professional Staff Member, Health; Grace Graham, Chief Counsel, Health; Nate Hodson, Staff Director; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Clare Paoletta, Professional Staff Member, Health; Carla Rafael, Staff Assistant; Michael Taggart, Policy Director; Lydia Abma, Minority Policy Analyst; Jacquelyn Bolen, Minority Health Counsel; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Staff Director; Perry Hamilton, Minority Member Services and Outreach Manager; Saha Khaterzai, Minority Professional Staff Member; Una Lee, Minority Chief Health Counsel; Juan Negrete, Minority Professional Staff Member; Greg Pugh, Minority Staff Assistant; Andrew Rosario, Minority Health Fellow; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; Tristen Tellman, Minority Health Fellow; Rick Van Buren, Minority Senior Health Counsel; and C.J. Young, Minority Deputy Communications Director.

Mr. GUTHRIE. The Subcommittee on Health will now come to order.

The microphone is not on? It should be on. Yes, it is. Wow. I hit the button.

Anyway, things you have to learn, right?

Well, thanks a lot. I appreciate everybody being here today. And I appreciate working with Democrat Leader Eshoo. We enjoyed working together last Congress, and we will continue to do so. We have a lot of things before us.

But the subcommittee will come to order. And the Chair now recognizes himself for 5 minutes for an opening statement.

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

As we turn the page on both 2022 and the 117th Congress, thousands of Americans and their families are still reeling from failures by this administration and the last Congress to meaningfully address one of the greatest public health threats of our lifetimes, the fentanyl crisis.

Over the past several years, the United States has seen a historic rise of drug overdoses, driven by an increased supply of synthetic opioids such as illicit fentanyl analogs. In 2021 alone, there were over 107,000 drug overdoses reported, according to the Centers for Disease Control and Prevention, and over 60,000 of these were caused by synthetic opioids. My home State of Kentucky experienced a 14 percent jump in drug overdose deaths between 2020 and 2021, with over 70 percent of these deaths being caused by fentanyl alone.

Sadly, you cannot go a week without reading or hearing about the stories of mothers, sons, sisters, brothers, and cherished friends and even babies losing their lives to fentanyl overdoses.

How could this be possible? We don't have to look farther than the crisis right now at our southern border. Since last October, October of last year, our Border Patrol authorities have seized over 7,000 pounds of illicit fentanyl at our southwest border. This is on top of the over 14,000 pounds of illicit fentanyl seized the prior year. The dual crises, both the fentanyl and border crises, have effectively turned every community across the United States into a border community.

Fortunately, this very subcommittee has the ability to take action and do what we know will work to help keep illicit fentanyl out of our communities and save lives.

One of the bills before us today, H.R. 467, the Halt All Lethal Trafficking of Fentanyl Act, also known as the HALT Fentanyl Act, would take the critical step of permanently scheduling all fentanyl-related substances as Schedule I drugs under the Controlled Substances Act.

Congress has enacted temporary extensions several times over the last few years. These continued temporary solutions are not sustainable. We need a permanent solution and must pass the HALT Fentanyl Act now. Doing so will be my top priority as long as I am chairman of this Health Subcommittee.

I want to address the demand for illegal and dangerous drugs here in the United States while simultaneously focusing on support for recovery services for those who want help. We will have an opportunity later this year to reauthorize key parts of the SUPPORT

Act, and we will be able to examine how to get people into recovery and keep them safe.

But if we have learned anything over the past few years, it is that these illicit fentanyl analogs are an entirely different class of drugs than any other deadly substance that our country has faced thus far and has the ability to make other illegal drugs that much more lethal.

Further, the Block, Report, and Suspend Suspicious Shipments Act, introduced by one of our newest subcommittee members, Representative Harshbarger, would also address the overdose crisis. This bill would require drug manufacturers and distributors to report all suspicious shipments of controlled substances to the Drug Enforcement Agency and require these entities to decline to fill such orders.

Fighting the overdose epidemic necessitates a multipronged approach and a strong partnership between the public and private sectors, which this legislation accomplishes. I thank Representative Harshbarger for leading on this issue.

The other important pieces of legislation before us today are equally as focused on protecting the sanctity of life. The 988 Lifeline Cybersecurity Act would ensure that the lifesaving 988 Suicide and Crisis Hotline is protected from cyber vulnerabilities.

This comes after the lifeline suffered a cyber attack in early December which resulted in an hours-long outage of the lifeline. This cannot happen again, and I look forward to moving this bill through committee.

Finally, we are examining legislation to permanently ban the use of quality-adjusted life years in all publicly funded healthcare programs like Medicare and Medicaid. It is long overdue for Congress to take the necessary step of banning QALYs. With the Protecting Health Care for All Patients Act before us today, this would be finally achieved.

Such policies arbitrarily put a value on someone's life and are especially discriminatory towards those living with disabilities. A life worth living is always a life worth saving, regardless of someone's health status. I know this bill is personal and very important to our chair of the full committee, Chair McMorris Rodgers.

I urge all of my colleagues on this subcommittee to support these four bills before us today.

Thank you, and I yield back.

[The prepared statement of Mr. Guthrie follows:]

Opening Statement for the Honorable Brett Guthrie

As Prepared for Delivery

"Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"

February 1, 2023

As we turn the page on both 2022 and the 117th Congress, thousands of Americans and their families are still reeling from failures by this Administration and the last Congress to meaningfully address one of the greatest public health threats of our lifetimes: the fentanyl crisis.

Over the past several years, the United States has seen an historic rise of drug overdoses, driven by an increased supply of synthetic opioids, such as illicit fentanyl analogs. In 2021 alone, there were over 107,000 drug overdoses reported, according to the Centers for Disease Control and Prevention, and over 60,000 of these were caused by synthetic opioids. My home state of Kentucky experienced a 14 percent jumped in drug overdose deaths between 2020 and 2021, with over 70

percent of these deaths being caused by fentanyl alone. You sadly cannot go a week without reading or hearing about stories of mothers, sons, sisters, brothers, cherished friends, and even babies, losing their lives to a fentanyl overdose.

How could this be possible? Well don't have to look farther than the crisis right now at our southern border. Since October of last year, our border patrol authorities have already seized over 7,000 pounds of illicit fentanyl at our Southwest Border. This is on top of the over 14,000 pounds of illicit fentanyl seized the year prior. The dual crises, both the fentanyl and border crisis, have effectively turned every community across the United States into a border community.

Fortunately, this very subcommittee has the ability to take action and do what we know will work to help keep illicit fentanyl out of our communities and save lives. One of the bills before us here today, H.R. 467, the Halt All Lethal Trafficking of Fentanyl Act, also known as the HALT Fentanyl Act, would take the critical step of permanently scheduling all fentanyl-related substances as Schedule I drugs under the

Controlled Services Act. Congress has enacted temporary extensions several times over the last few years. These continued temporary solutions are not sustainable – we need a permanent solution and must pass the HALT Fentanyl Act now. Doing so will be my top priority for as long as I am Chair of the Health Subcommittee.

To be clear, I want to acknowledge that we must also address the demand for illegal and dangerous drugs here in the United States. We will have an opportunity later this year to reauthorize key parts of the SUPPORT Act, and be able to examine how to get people into recovery and keep them safe. But if we've learned anything over the past few years, it's that these illicit fentanyl analogs are an entirely different class of drugs than any other deadly substances that our country has faced thus far and have the ability to make other illegal drugs that much more lethal.

Further, *The Block, Report, and Suspend Suspicious Shipments Act*, introduced by one of our newest Subcommittee members Representative Harshbarger, would also address the overdose crisis. This bill would

require drug manufacturers and distributors to report all suspicious of controlled substances to the Drug Enforcement Agency and require these entities to decline to fill such orders. Fighting the overdose epidemic necessitates a multipronged approach and a strong partnership between the public and private sectors, which this legislation accomplishes. I thank Representative Harshbarger for leading on this issue.

The other important piece of legislation before us today are equally as focused on protecting the sanctity of life. The 9-8-8 Lifeline Cybersecurity Act would ensure that the lifesaving 9-8-8 suicide and crisis hotline is protected from cyber vulnerabilities. This comes after the lifeline suffered a cyber-attack, in early December, which resulted in an hours-long outage of the lifeline. This cannot happen again, and I look forward to moving this bill through committee.

Finally, we are examining legislation to permanently ban the use of quality-adjusted life years in all publicly funded health care programs, like Medicare and Medicaid. It is long overdue for Congress to take the necessary step of banning QALYs, which the Protecting Health Care for

All Patients Act that's before us today would finally achieve. Such policies arbitrarily put a value on someone's life and are especially discriminatory toward those living with disabilities. A life worth living is always a life worth saving, regardless of someone's health status. I know this bill is personally very important to Chair Rodgers.

I urge all of my colleagues on the subcommittee to support these four bills before us today.

Thank you, and I yield back.

Mr. GUTHRIE. The Chair now recognizes the subcommittee ranking member, Ms. Eshoo, for 5 minutes for an opening statement.

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

Ms. ESHOO. Well, good morning, everyone.

And thank you, Mr. Chairman. And, first of all, my warmest congratulations to you on becoming the chairman of this, what I think is an extraordinary Health Subcommittee.

And welcome to the new members of this subcommittee. You are going to love serving here. And I know, from this side of the aisle, that we look forward to working with you for the benefit of the American people.

Our first hearing today focuses on an issue this subcommittee has been struggling with for nearly 25 years, the opioid crisis.

Over 900,000 Americans have died from opioids since 1999, including more than 107,000 deaths in just the last year. The country has had three waves of opioid deaths: prescription opioids, heroin opioids, and now fentanyl.

Fentanyl is a synthetic opioid that is up to 50 times stronger than heroin and 100 times stronger than morphine. According to the CDC, over 66 percent of the overdose deaths in 2021 were caused by fentanyl.

Today, our subcommittee considers H.R. 467, the HALT Fentanyl Act, to address this epidemic.

What is unfortunate is that the HALT Fentanyl Act does nothing to change the status quo. For the past 5 years, all fentanyl-related substances have been considered Schedule I drugs. The HALT Fentanyl Act would continue that scheduling.

Scheduling doesn't stop deaths. Since 2018, when fentanyl-related substances first became Schedule I, fentanyl deaths have risen by over 50 percent. So we have to do much more to save lives.

First, I think we need to stop the supply of illicit fentanyl. We are making progress through record-breaking DEA seizures. For example, last year the DEA seized 10,000 pounds of illicit fentanyl powder—10,000 pounds. I mean, it is so difficult to get your head wrapped around these figures.

There is another part of this, though, and it isn't really very often spoken about. I believe that we have broken gun laws. In this case, Mexican cartels are trading—they are trading illicit fentanyl for readily available American guns. We need to stop this so-called "iron river" of death between our two countries.

Another major contributing factor to overdoses is the difficulty finding treatment. According to SAMHSA, only 11 percent of people—only 11 percent, so 89 percent of people with opioid addiction do not receive medication-assisted treatment.

Importantly, in December, Congressman Tonko's MAT Act became law. The new law eliminates bureaucratic guardrails that limit the availability of medication-assisted treatment. Medication-assisted treatment is proven to reduce overdose deaths and curb illicit drug use.

Naloxone is another miracle medicine that saves lives. Anyone can use it to rapidly reverse opioid overdose. And I commend the

FDA's recent work to make naloxone available over the counter. And I urge all the makers of this drug, including Emergent and Kaleo, to begin switching their product labels from prescription to over-the-counter.

I look forward to hearing from ONDCP, SAMHSA, and the DEA today about what else Congress should do to change the status quo and save lives.

We will also hear two other bills unrelated to fentanyl. H.R. 498, the 988 Lifeline Cybersecurity Responsibility Act, is a commonsense bill that requires the 988 network administrator to report potential cybersecurity threats to SAMHSA immediately upon discovery. I support that bill.

H.R. 485 is focused on ending the Federal Government's use of quality-adjusted life years metrics, also known as QALYs. I support ending the use of discriminatory QALYs, because the metric devalues the lives of people with disabilities.

So I look forward to learning more about the bill and its impact, Mr. Chairman, during today's hearing.

So congratulations once again. It is your opening day. And, again, look forward to working with you.

And I yield back.

[The prepared statement of Ms. Eshoo follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

Hearing on "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"

February 1, 2023

Good morning everyone and thank you Mr. Chairman. First of all, my warmest congratulations to you on becoming the Chairman of what I think is an extraordinary Health Subcommittee, and welcome to the new members of this Subcommittee. You are going to love serving here, and I know from this side of the aisle that we look forward to working with you for the benefit of the American people.

Our hearing today focuses on an issue this Subcommittee has been struggling with for nearly 25 years – the opioid crisis. Over 900,000 Americans have died from opioids since 1999, including more than 107,000 deaths in just the last year. The country has had three waves of opioid deaths – prescription opioids, heroin, opioids, and now fentanyl. Fentanyl is a synthetic opioid that is up to 50 times stronger than heroin and 100 times stronger than morphine. According to the CDC, over 66% of the overdose deaths in 2021 were caused by fentanyl.

Today, our Subcommittee considers H.R. 467, the *HALT Fentanyl Act* to address this epidemic. What's unfortunate is that the *HALT Fentanyl Act* does nothing to change the status quo. For the past five years, all fentanyl-related substances have been considered schedule 1 drugs. The *HALT Fentanyl Act* would continue that scheduling. Scheduling doesn't stop deaths. Since 2018, when fentanyl-related substances first became Schedule 1, fentanyl deaths have risen by over 50 percent. So we have to do much more to save lives. First, I think we need to stop the supply of illicit fentanyl. We are making progress through record-breaking DEA seizures. For example, last year, the DEA seized 10,000 pounds of illicit fentanyl powder. 10,000 pounds, I mean it's so difficult to get your head wrapped around these figures. There's another part of this though and it isn't very often spoken about. I believe that we have broken gun laws, in this case Mexican cartels are trading illicit fentanyl for readily-available American guns. We need to stop this so-called iron river of death between our two countries. Another major contributing factor to overdoses is the difficulty finding treatment. According to SAMHSA, only 11% of people, only 11%, so 89% of people with opioid addiction do not receive medication-assisted treatment. Importantly, in December, Rep. Tonko's MAT Act became law. The new law eliminates bureaucratic guardrails that limit the availability of medication-assisted treatment. Medication-assisted treatment is proven to reduce overdose deaths and curb illicit drug use.

Naloxone is another miracle medicine that saves lives. Anyone can use it to rapidly reverse opioid overdose, and I commend the FDA's recent work to make naloxone available over the counter, and I urge all naloxone makers, including Emergent and Kaleo, to begin switching their products' labels from prescription to over the counter. I look forward to hearing from

ONDCP, SAMHSA, and the DEA today about what else Congress should do to change the status quo and save lives. We will also hear two other bills unrelated to fentanyl.

H.R. 498, the *9-8-8 Lifeline Cybersecurity Responsibility Act* is a commonsense bill that requires the 9-8-8 network administrator to report potential cybersecurity threats to SAMHSA immediately upon discovery. I support that bill. H.R. 485, is focused on ending the federal government's use of Quality Adjusted Life Years metrics also known as "QALYs." I support ending the use of discriminatory QALYs because the metric devalues the lives of people with disabilities. So I look forward to learning more about the bill and its impact Mr. Chairman during today's hearing.

So congratulations once again, it's your opening day and again I look forward to working with you

I yield back.

Mr. GUTHRIE. Thank you very—I thank the gentlelady for yielding back.

And the Chair will now recognize the chair of the full committee, Mrs. McMorris Rodgers, for 5 minutes for an opening statement.

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

Mrs. RODGERS. Thank you, Mr. Chair.

Welcome, everyone, to the legislative hearing titled "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combating Discrimination Against Those with Disabilities." We will hear from a diverse panel on how we can advance solutions that will help people in need of hope and healing in our communities.

Last month, the Energy and Commerce Republicans held a roundtable on the fentanyl crisis, and we heard from Deb and Ray Cullen, who had lost their son, Zach. They told us they will never forget the moment that the police showed up at their door asking if they were Zach's parents. He was just 9 days past his 23rd birthday, and he was targeted and poisoned by a drug dealer.

Today, we will hear from Molly Cain from my hometown of Spokane, Washington. She lost her son, Carson, to fentanyl poisoning when he was also 23 years old.

Deb, Ray, and Molly have experienced immeasurable pain from losing their children, and they deserve justice. That is why Reps Griffith and Latta are working on the HALT Fentanyl Act. This bill would permanently place fentanyl-related substances into Schedule I of the Controlled Substances Act and make sure that our law enforcement can keep these weapons-grade poisons off the streets.

Unfortunately, the administration is proposing to treat these deadly poisons differently from fentanyl and other currently scheduled fentanyl-related substances. The administration supports exempting the entire class from mandatory minimums that are typically imposed upon drug dealers, drug traffickers, preventing law enforcement from stopping those who would bring deadly substances into our communities.

If the temporary legislation were to expire, it would mean the criminals who kill people like Zach and Carson could keep trafficking these lethal substances with little consequences. So let's make it permanent.

And I am hopeful that we can work together, both sides of the aisle, to make sure that we take action that will punish those who make and import and distribute these poisons to our children.

I also want to recognize Mrs. Harshbarger's bill in introducing the Block, Report, and Suspend Suspicious Shipments Act.

The opioid epidemic is fueled in part by suspiciously large shipments of pain medication being delivered across the country, especially in places like Tennessee and West Virginia. This bill would stop this practice and save lives by requiring drug manufacturers and distributors that discover a suspicious order for controlled substances to halt the order and report the information to DEA.

Additionally, just last month we learned about a cyber attack on the 988 Suicide and Crisis Lifeline. This lifeline is a network of

local crisis centers that promotes emotional support to people in suicidal crisis or emotional distress. It is a critical tool that was established by the bipartisan work of this committee, and we must ensure that it is protected from future cyber threats.

Representative Obernolte's 988 Lifeline Cybersecurity Responsibility Act would do just that. It requires coordination and reporting to improve cybersecurity protections for the 988 Lifeline.

Finally, we will discuss why it is important to take action to protect people with disabilities with the Protecting Health Care for All Patients Act. It would ban quality-adjusted life years, or QALYs, that discriminate against people with disabilities and patients with debilitating or life-threatening health conditions.

QALYs undervalue treatments for patients who have shorter lifespans than others. In countries with QALYs, the most vulnerable get pushed to the back of the line for treatment. People like those with cystic fibrosis, ALS, or people like my son with Down syndrome, the government says that their lives don't matter as much. They are not valuable enough.

In America, where we have led the world in amazing medical breakthroughs and innovation, we must ban QALYs and strongly affirm that every life is worth living. It is my sincere hope that we can move forward on this bill with bipartisan support.

Families need hope. And there is inherent dignity in every human life. And that is why we are coming together today in our first legislative hearing this Congress, and I look forward to hearing more.

I appreciate everyone being here to testify as we work together to promote life, liberty, and the pursuit of happiness for all.

Thank you, and I yield back.

[The prepared statement of Mrs. Rodgers follows:]

Congresswoman Cathy McMorris Rodgers
Health Subcommittee Hearing
February 1, 2023
Opening Statement
As Prepared for Delivery

INTRO

Welcome to our legislative hearing titled, "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

We will hear from a diverse panel on how we can advance solutions that will help people in need of hope and healing in our communities.

FRS / HALT / BLOCK

Last month, Energy & Commerce Republicans held a roundtable on the fentanyl crisis.

We heard from Deb and Ray Cullen who lost their son, Zach.

They told us they will never forget the moment the police showed up to their door asking if they were Zach's parents.

He was just 9 days past his 23rd birthday when he was targeted and poisoned by a drug dealer.

Today, we'll hear from Molly Cain from my hometown of Spokane, Washington.

She lost her son Carson to a fentanyl poisoning when he was also 23 years old.

Deb, Ray, and Molly have experienced immeasurable pain from losing their children...

… and they deserve justice.

That is why Reps. Griffith and Latta are leading on the HALT Fentanyl Act.

This bill would permanently place fentanyl-related substances into Schedule I of the Controlled Substances Act… and make sure our law enforcement can keep these weapons-grade poisons off our streets.

Unfortunately, the Biden administration is proposing to treat these deadly poisons differently from fentanyl and other currently scheduled fentanyl related substances.

The administration supports exempting the entire class from mandatory minimums that are typically imposed upon drug traffickers, preventing law enforcement from stopping those who bring deadly substances into our communities.

If the temporary legislation were to expire, it would mean the **criminals** who killed people like Zach and Carson could keep trafficking these lethal substances with little consequences. So let's make it permanent.

I am hopeful that my colleagues on the other side of the aisle will work with us to punish those who make, import, and distribute these poisons to our children.

I also want to recognize Rep. Harshbarger's leadership in introducing the Block, Report, And Suspend Suspicious Shipments Act.

The opioid epidemic is fueled, in part, by suspiciously large shipments of pain medication being delivered across the country – particularly in places like Tennessee and West Virginia.

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988

Additionally, just last month, we learned about a cyber-attack on the 9-8-8 Suicide & Crisis Lifeline.

This lifeline is a network of local crisis centers that provides emotional support to people in suicidal crisis or emotional distress.

It's a critical tool that was established by the bipartisan work of this Committee, and we must ensure that it is protected from future cyber threats.

Rep. Obernolte's 9-8-8 Lifeline Cybersecurity Responsibility Act would do just that – it requires coordination and reporting to improve cybersecurity protections for the 988 lifeline.

QALY

Finally, we will discuss why we must take action to protect people with disabilities with the Protecting Health Care for All Patients Act.

It would ban Quality Adjusted Life Years or QALYs that discriminate against people with disabilities and patients with debilitating or life-threatening health conditions.

QALYs undervalue treatments for patients who have shorter life spans than others.

In countries with QALY's, the most vulnerable get pushed to the back of the line for treatment...

.... People like those with cystic fibrosis, ALS, and people like my son with Down syndrome.

The government says their lives don't matter. They aren't valuable enough.

In America—where we have led the world in amazing medical breakthroughs and innovation—we must ban QALY's and strongly affirm that every life is worth living.

It is my sincere hope we can move forward on this bill in a bipartisan way.

Families need hope—not a government that has power over life and death.

CLOSING

There is inherent dignity in every human life.

That is what we are coming together around today in our first legislative hearing this Congress...

… and I look forward to learning more today on how we can work together to promote life, liberty, and the pursuit of happiness for all.

Thank you and I yield back.

Mr. GUTHRIE. I thank the chair for yielding back.

The Chair recognizes the ranking member of the full committee, Mr. Pallone, for 5 minutes.

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

Mr. PALLONE. Thank you, Chairman Guthrie.

And I believe the top priority of this subcommittee is ensuring all Americans have access to quality and affordable health coverage so they can live long and healthy lives.

And I am also proud of this subcommittee's work in the last Congress, which is a testament to the life-changing and lifesaving policies we can achieve if we work together.

Last Congress, we passed landmark laws that make healthcare and prescription drugs more affordable; we expanded access to healthcare, including to children and mothers, through CHIP and Medicaid; we equipped the Food and Drug Administration and the Centers for Disease Control and Prevention with critical tools and resources to maintain and enhance our Nation's public health; and we made significant investments to address the mental health and substance use disorder crisis, including implementing historic policy reforms to address the overdose crisis. Specifically, we included the MAT Act, which will increase access to lifesaving treatments for those experiencing substance use disorders.

We accomplished a tremendous amount, and I commend every member of the subcommittee for their dedication and hard work.

Now, today, we will discuss the scourge that is illicit fentanyl and fentanyl-related substances, which have caused so much harm and death to our families, friends, and constituents.

The policies passed in the fiscal year 2023 omnibus in December, some of which I just mentioned, are concrete examples of the work we are doing to save lives.

I am disappointed that our first hearing in the Health Subcommittee does not build on the successes of last Congress but, rather, that my Republican colleagues have chosen to take a different route with the partisan HALT Fentanyl Act.

We have learned time and time again that we cannot incarcerate our way out of a public health crisis and that a broader public health approach is needed to address what is at its root a health problem.

Moreover, my Republican colleagues were unwilling to consider any Democratic bills to address the overdose crisis for inclusion in this hearing, and that is disappointing. If Republicans are serious about finding a long-term solution, then they should be willing to discuss bipartisan, evidence-based policies to address the substance use and overdose crisis.

One such bill is the bipartisan Save Americans from the Fentanyl Emergency Act, which was introduced by Representatives Pappas, Newhouse, and Gonzales. This legislation reflects the administration's comprehensive approach to address the fentanyl crisis. Our Nation's law enforcement and public health agencies both agreed to this approach.

I am disappointed that this bill was not included in the hearing, as well as many other bipartisan bills that would help us address the overdose crisis. Representative Tonko's bipartisan Reentry Act would ensure that individuals transitioning out of the justice system and into our communities have access to treatment for substance use disorders.

We are also considering a bill today to ban the use of quality-adjusted life years, often referred to as QALYs, in value measurements and price determinations set by Federal agencies and States.

While I appreciate and respect the perspective of those in the disability community about any economic metrics that value certain lives differently, I fear this bill is a solution in search of a problem. Federal law already prohibits the use of QALYs in Medicare, and Medicaid is required to cover, with limited exceptions, every outpatient drug covered by the program if a manufacturer has a rebate agreement in place.

As I mentioned earlier, Democrats delivered on our promise to lower drug prices last year with the enactment of the Inflation Reduction Act. That new landmark law provides the Secretary of Health and Human Services with the authority to negotiate lower drug prices for Medicare beneficiaries for the first time, while also explicitly prohibiting the use of QALYs in this process.

I fear this bill would be a Trojan horse that goes far beyond just banning QALYs by potentially banning all other kinds of ways of measuring a drug's value. This would result in artificially keeping drug prices and healthcare costs high while also tying the hands of the Federal Government in determining the value of healthcare services and treatments.

So, again, if my Republican colleagues want to discuss how to best protect the disability community, we should consider the impacts of proposed cuts that the Republican majority wants to make in exchange for a debt ceiling increase.

The Republican Study Committee's budget for fiscal year 2023 calls for cutting Medicaid and CHIP by $3.6 trillion and cutting Medicare by $2.8 trillion. These drastic cuts will be devastating for the millions of people with disabilities who rely on Medicaid for their health and well-being.

The Republican plan to slash and burn Medicaid is an existential threat to a major source of health insurance for individuals with disabilities, and Democrats will aggressively oppose these cuts.

As for today's hearing, I welcome the discussion on how we move forward to address the fentanyl crisis, and I hope that in the coming weeks the subcommittee can discuss bipartisan solutions that were unfortunately not included in this hearing today.

And, with that, I yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

Health Subcommittee Hearing on "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"

February 1, 2023

Thank you, Chairman Guthrie. I believe the top priority of this Subcommittee is ensuring all Americans have access to quality and affordable health coverage so they can live long and healthy lives. I am also proud of this Subcommittee's work in the last Congress, which is a testament to the life-changing and life-saving policies we can achieve if we work together.

Last Congress, we passed landmark laws that make health care and prescription drugs more affordable. We expanded access to health care, including to children and mothers through CHIP and Medicaid. We equipped the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) with critical tools and resources to maintain and enhance our nation's public health. And we made significant investments to address the mental health and substance use disorder crises, including implementing historic policy reforms to address the overdose crisis. Specifically, we included the MAT Act, which will increase access to life-saving treatments for those experiencing substance use disorders. We accomplished a tremendous amount and I commend every member of the Subcommittee for their dedication and hard work.

Today, we will discuss the scourge that is illicit fentanyl and fentanyl-related substances (FRS), which have caused so much harm and death to our families, friends, and constituents. The policies passed in the fiscal year 2023 omnibus in December, some of which I just mentioned, are concrete examples of the work we are doing to save lives.

I am disappointed that our first hearing in the Health Subcommittee does not build on the successes of last Congress, but rather, that my Republican colleagues have chosen to take a different route with the partisan HALT Fentanyl Act. We have learned time and time again that we cannot incarcerate our way out of a public health crisis, and that a broader public health approach is needed to address what is at its root a health problem. Moreover, my Republican colleagues were unwilling to consider any Democratic bills to address the overdose crisis for inclusion in this hearing. That is disappointing.

If Republicans are serious about finding a long-term solution, then they should be willing to discuss bipartisan, evidence-based policies to address the substance use and overdose crisis. One such bill is the bipartisan Save Americans from the Fentanyl Emergency Act, which was introduced by Representatives Pappas, Newhouse, and Gonzalez. This legislation reflects the Administration's comprehensive approach to address the fentanyl crisis. Our nation's law enforcement and public health agencies both agreed to this approach.

I'm disappointed that this bill was not included in the hearing, as well as many other bipartisan bills that would help us address the overdose crisis. Representative Tonko's bipartisan Reentry Act would ensure that individuals transitioning out of the justice system and into our communities have access to treatment for substance use disorders.

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If my Republican colleagues want to discuss how best to protect the disability community, we should consider the impacts of proposed cuts that the Republican majority wants to make in exchange for a debt ceiling increase. The Republican Study Committee's budget for fiscal year 2023 calls for cutting Medicaid and CHIP by $3.6 trillion and cutting Medicare by $2.8 trillion. These drastic cuts would be devastating for the millions of people with disabilities who rely on Medicaid for their health and well-being. The Republican plan to slash and burn Medicaid is an existential threat to a major source of health insurance for individuals with disabilities, and Democrats will aggressively oppose these cuts.

As for today's hearing, I welcome the discussion on how we move forward to address the fentanyl crisis, and hope that, in the coming weeks, the Subcommittee can discuss bipartisan solutions that were unfortunately not included in this hearing.

Thank you.

Mr. GUTHRIE. The gentleman yields back. And I do look forward to working together as we move forward on reauthorizing the SUPPORT Act this year.

We now conclude with Member opening statements. The Chair would like to remind Members that, pursuant to the committee rules, all Members' opening statements will be made part of the record.

We will now move to our witnesses. We want to thank all of our witnesses for being here today and taking the time to testify before the subcommittee.

Each witness will have the opportunity to give an opening statement, followed by a round of questions from Members.

Our witnesses today are Mr. Kemp Chester, a senior advisor at the Office of National Drug Control Policy with expertise in international relations and supply reduction. Then we will have Dr. Neeraj Gandotra, the Chief Medical Officer for the Substance Abuse and Mental Health Services Administration. And, finally, we will be joined Mr. Jon DeLena, the Associate Administrator at the Drug Enforcement Administration.

We appreciate you being here today. We will recognize each for 5 minutes. I think you have all testified before and know the lighting system. You will have a yellow light just to give you a warning, and then a red light means to wrap up.

So we appreciate that, and we appreciate you being here.

I will now recognize our first witness to give 5 minutes for an opening statement. Mr. Chester, you are recognized for 5 minutes.

STATEMENTS OF KEMP CHESTER, SENIOR ADVISOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; NEERAJ GANDOTRA, M.D., CHIEF MEDICAL OFFICER, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JON DELENA, ASSOCIATE ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

STATEMENT OF KEMP CHESTER

Mr. CHESTER. Chairman Guthrie, Ranking Member Eshoo, members of the subcommittee, thank you for inviting me to testify today on the illicit drug environment we face in the United States and our efforts to address it.

The administration is taking a number of tangible steps to reduce drug-related deaths, expand access to treatment for substance use disorder, and target the global production and trafficking of synthetic opioids like illicit fentanyl which currently kill more than 107,000 Americans every year.

The administration's National Drug Control Strategy focuses on attacking the two drivers of the opioid epidemic: untreated addiction and the drug-trafficking profits that fuel this crisis.

In terms of public health, we are expanding access to substance use prevention, harm reduction in addiction treatment, and recovery support services.

And I want to thank the Congress for including key provisions of the MAT Act in the bipartisan omnibus government funding bill, which will allow prescribers across the country to treat their pa-

tients who have opioid use disorder with buprenorphine without additional Federal licensing.

We are also working to remove barriers to naloxone, make permanent the COVID–19 flexibilities that expanded access to treatment, address emerging threats like xylazine being added into illicit fentanyl. And we look forward to working with the Congress to make permanent the 2-year extension of the scheduling of all fentanyl-related substances as a class.

But while the opioid epidemic is a daunting public health issue, it presents a serious national security and economic prosperity challenge for the United States as well. The vast majority of the substances harming Americans are produced outside the United States and brought across our borders through a variety of means.

To address this very real threat, we have taken a new and more comprehensive approach to this problem: to commercially disrupt the global business of illicit synthetic drug production and trafficking.

We will target not only the finished drugs themselves and those who sell them but also the raw materials and machinery used to produce them, the commercial shipping that moves these items around the world, and the illicit financial structure that allows this global business to operate and allows drug traffickers to profit from the suffering of others.

Using new authorities provided by Executive order, the Department of the Treasury has imposed sanctions against dozens of individuals and entities involved in the illicit drug trade, including illicitly manufactured fentanyl.

In 2022 alone, Customs and Border Protection seized nearly 262,000 pounds of illicit narcotics, including 15,000 pounds of fentanyl. And our HIDTA task forces seized more than 737,000 pounds of drugs, including 26,000 pounds of illicit fentanyl in the United States.

These are drugs permanently removed from the illicit supply chain, not killing our citizens. And domestic seizures alone denied $9 billion in profits and critical operating capital to drug traffickers.

And the President has asked for increased funding for both Customs and Border Protection and the Drug Enforcement Administration to enable their vital work in keeping our Nation safe from these dangerous drugs.

However, this problem does not begin or end at the United States border. This is a global problem that has negative effects not only in the United States but also the rest of the world. And American leadership at the global level is absolutely essential.

These deadly drugs are manufactured using precursor chemicals made available by criminal elements, often in the People's Republic of China, that are shipped to Mexico, where they are used to produce illicit fentanyl or one of its analogs and often pressed into the counterfeit pills that have poisoned so many Americans.

The administration is working bilaterally with our international partners, particularly Mexico, the People's Republic of China, India, and others, and multilaterally to address the global threat of illicit synthetic opioid production and trafficking.

I am pleased to say that, as a result of our work in the public health and law enforcement domains, we are beginning to see some progress, with 5 straight months of decreased drug-involved deaths.

Together, the administration and the Congress are changing the trajectory of a complex national security, criminal justice, and public health challenge that has vexed the Nation for the better part of three decades. There are signs of hope, but we have a very long way to go.

On behalf of Dr. Gupta and the men and women of the Office of National Drug Control Policy, thank you for your foresight and leadership on this difficult issue, and we look forward to continuing our work with you in the months and the years ahead.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Chester follows:]

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

"Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"

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

Wednesday, February 1, 2023
10:00 a.m.

Statement of
Mr. Kemp Chester
Senior Advisor
Office of National Drug Control Policy

For Release Upon Delivery

Introduction

Chairman Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, thank you for inviting me to testify today on the ever-changing illicit drug environment we face in the United States, which in the last year has claimed more than 107,000[1] lives and torn families and communities apart, as well as the Biden-Harris Administration's work to reduce the availability of illicit fentanyl in the United States, expand access to addiction treatment, and save American lives.

The Administration's Approach

Over the past two years, the Biden-Harris Administration has undertaken a comprehensive evidence-based approach to reduce drug-related deaths, expand access to treatment for substance use disorder, and target the global production and trafficking of synthetic opioids, like illicit fentanyl, which kill tens of thousands of Americans each year.

President Biden's inaugural *National Drug Control Strategy*, released in 2022, relies on the best evidence and data we have available, and sets out a whole-of-government approach to attack the two drivers of the opioid overdose epidemic: untreated addiction, and the drug trafficking profits that fuel this crisis. The Administration's approach addresses both the public health aspects of this crisis as

well as its national security, law enforcement, and economic dimensions, because addressing this problem holistically is the best approach to prevent overdose deaths and achieve long term and sustainable success against a problem that has vexed the nation for three decades.

In terms of public health, we are working to greatly expand access to addiction treatment, harm reduction, youth substance use prevention, and recovery support services. Much of this work is being done in partnership with the Congress, and I want to thank the members of this Committee and the Congress at large for your support of numerous pieces of legislation helping to address this crisis, including the Bipartisan Infrastructure Law and the bipartisan omnibus government funding bill, the latter of which included key provisions to help lower barriers to treatment and deliver necessary tools and resources to our communities to address the overdose crisis, such as the bipartisan Mainstreaming Addiction Treatment Act, or MAT Act, and the bipartisan Medication Access and Training Expansion Act, or MATE Act. Thanks to the MAT Act, prescribers across the country will be able to treat their patients who have opioid use disorder with buprenorphine, a medication proven to help people achieve recovery, without obtaining additional federal licensing. I also commend the Committee for beginning this Congress by focusing on the fentanyl threat, both with last month's roundtables featuring families affected by it and with today's hearing.

The Office of National Drug Control Policy has also funded the development of a number of model state laws to help local jurisdictions across the country expand access to naloxone, improve treatment in jails and prisons, and deploy settlement funds from the various opioid lawsuits effectively, among others. Similarly, ONDCP has worked with our partners across the government to remove barriers to accessing naloxone, make permanent the COVID-19 related flexibilities that expanded access to treatment, and support people in recovery.

And as much as this is a public health challenge, it is also a national security issue that directly affects the public safety and economic prosperity of the United States. It is a fact that the vast majority of the substances harming Americans are produced outside the United States and brought across our borders and into our communities through a variety of means, affecting the health, safety, and prosperity of the nation as a whole.

To address this very real threat, we have taken a new and more comprehensive approach to disrupt the production of these substances in other countries, interdict their global movement, and target the trafficker profits and operating capital that sustains this global illicit enterprise.

Disrupting the flow of drugs into the United States is important not only to keep them from harming our citizens, but it is especially important as the means to

allow our historic investments in public health interventions to take hold. The simple truth is, if it is easier to get illicit drugs in America than it is to get treatment, we will not be able to bring this crisis to a close.

To address the various facets of the illicit drug challenge and undercut the threat *before* it reaches our communities, we have broadened our approach to focus on Commercial Disruption. In this context, we are pursuing Commercial Disruption through a deliberate and coordinated whole-of-government effort that focuses and synchronizes all the national policy levers to disrupt the global illicit synthetic drug production and trafficking enterprise. This includes strategically targeting criminal facilitators and enablers, and the targeting of key vulnerabilities in the illicit fentanyl supply chain to maximize our impact across the drug producers' and traffickers' spectrum of capabilities.

Through Commercial Disruption, we are targeting not only the finished drugs themselves and those who sell them, but also the raw materials and machinery used to produce them, the commercial shipping that moves these items around the world, and the illicit financial structures that allow this global business to operate and allows drug producers and traffickers the ability to enjoy the profits and benefits of their illicit business.

In December 2021, President Biden signed two Executive Orders to provide the Federal Government with expanded tools and capabilities to go after traffickers, criminal facilitators, and their illicit profits. Thus far the Department of the Treasury has used the expanded counter narcotics sanctions authority to impose sanctions on dozens of targets around the globe involved in the illicit drug trade, including illicitly manufactured fentanyl.[2]

We are also continuing the necessary and difficult work of interdicting illicit drugs at our borders and within communities across the country. Thanks to the hard work and dedication of our U.S. Customs and Border Protection (CBP) officers and agents, as well as the 33 High Intensity Drug Trafficking Areas (HIDTAs) covering all 50 states, seizures of illicit fentanyl, methamphetamine, and cocaine are all up significantly compared to 2021.

In fiscal year 2022, CBP seized nearly 15,000 pounds of fentanyl, nearly 2,000 pounds of heroin, 175,000 pounds of methamphetamine, and more than 70,000 pounds of cocaine.[3] And during the same period within the United States, our HIDTA Task Forces seized more than 26,000 pounds of illicit fentanyl, nearly 6,500 pounds of heroin, more than 335,000 pounds of meth, and nearly 370,000 pounds of cocaine, representing nearly $9 billion of profits denied to drug traffickers.[4]

These seizures permanently removed these drugs from the illicit supply chain, thereby saving lives and denying profits and critical operating capital to drug trafficking organizations.

In last year's Budget request, President Biden called for a funding increase to support the work of CBP and the Drug Enforcement Administration so they can continue their vital work in keeping our nation safe from these dangerous drugs.[5]

Our CBP officials, and our 33 HIDTAs nationwide, deserve our thanks and appreciation for all their hard work in preventing drug poisoning deaths and holding traffickers accountable. I also want to thank the Congress and the members of this Committee for your long history of strong support for our HIDTA program. HIDTA has played a critical role in our success thus far and will continue to be a critical part of our work going forward.

In December, the Congress passed a two-year extension of the scheduling of fentanyl-related substances, which controls these substances as a class and provides the necessary authorities for our law enforcement entities to prevent the production and trafficking of all potential fentanyl analogues. Thank you for your leadership and partnership on extending this authority, and we look forward to working with you in making this class scheduling action permanent.

While seizures and arrests are critically important, this problem does not begin or end at a United States border. The production and trafficking of these drugs is a global problem, and United States leadership at the global level is absolutely essential to saving lives. While drug trafficking is harmful in its own right, and imperils the health and well-being of our citizens, it is also part of a larger complex of criminal behaviors that have negative effects not only in the United States but in this hemisphere and the rest of the world.

In Fall 2021, in coordination with the U.S. interagency, Secretary of State Blinken requested that the United Nations consider placing international controls on three fentanyl precursors. As a result of U.S. leadership, the March 2022 UN Commission on Narcotic Drugs decided unanimously to internationally control these three chemicals used by drug traffickers to produce illicit fentanyl, thereby reducing their presence in the illicit supply chain.[6]

As you are all well aware, synthetic opioids like fentanyl and its analogues are produced using precursor chemicals made available by criminal elements, often in The People's Republic of China, that are shipped to Mexico where they are used to produce illicit fentanyl or one of its analogues. This fentanyl is either sold in powder form or pressed into the counterfeit pills that have poisoned so many Americans. These drugs are then either smuggled across our southern border,

typically through the existing ports of entry, or shipped into the United States through the mail or through express consignment carriers.

The Administration is working bilaterally with our international partners, particularly Mexico, The People's Republic of China, India, and others, and internationally through forums such as the North American Drug Dialogue and the United Nations Office of Drugs and Crime, to address the global challenge of illicit synthetic opioid production and trafficking. The President placed fentanyl as a key topic on his agenda at the recent North American Leaders Summit, and the United States, Mexico, and Canada agreed to increase information sharing and actionable intelligence on chemicals used in the illicit manufacture of fentanyl and other synthetic drugs.

Conclusion

I am pleased to say that as a result of our work thus far, in preventing illicit fentanyl from reaching our communities, preventing the harm caused by these dangerous drugs, and expanding access to the treatment so many Americans need, there are signs of progress.

We have now seen five straight months where overdose numbers have decreased, a 2.57% overall decrease from its high point in March 2022[7]. It is a sign

of hope, and at the very least is sparing some families from going through the devastating loss of loved ones. However, we still have a very long way to go.

The Administration's leadership on this critical issue, the close collaboration among Federal departments and agencies, and the work the members of this Committee and your colleagues in Congress have kept this issue at the forefront of our national consciousness and are changing the trajectory of this particularly complex national security, criminal justice, and public health challenge. We have much work ahead of us, and your partnership will be as critical in the months ahead as it has been thus far.

On behalf of Dr. Gupta and the men and women of the Office of National Drug Control Policy, I would like to thank the subcommittee and your Congressional colleagues for your foresight and leadership on this incredibly difficult issue. Ending the opioid crisis demands the best efforts of us all: the entirety of the federal government; states, tribes, and local communities; private sector partners and stakeholders; and the Congress, in the spirit of bipartisanship.

The Office of National Drug Control Policy looks forward to continuing its work with this Committee, the Congress, and our other partners to disrupt the production and trafficking of these dangerous drugs, prevent drug overdoses and poisonings, and save American lives.

[1] Centers for Disease Control and Prevention, NCHS. "Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts." January 11, 2023. Accessed January 11, 2023. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

[2] Office of National Drug Control Policy. "Press Release: Dr. Rahul Gupta Statement on New Sanctions Announced by Treasury Department to Counter Transnational Criminal Organizations and Illicit Drug Trafficking of Fentanyl." November 15, 2022. https://www.whitehouse.gov/ondcp/briefing-room/2022/11/15/dr-rahul-gupta-statement-on-new-sanctions-announced-by-treasury-department-to-counter-transnational-criminal-organizations-and-illicit-drug-trafficking-of-fentanyl/#_ftn1

[3] Customs and Border Protection. "CBP Drug Seizure Statistics Dashboard, FY2023." (Dashboard filtered for FY2022 only.) Accessed January 22, 2023. https://www.cbp.gov/newsroom/stats/drug-seizure-statistics

[4] Office of National Drug Control Policy. "Press Release: Dr. Gupta and Law Enforcement Officials Announce New Domestic Seizure Data from ONDCP'S High Intensity Drug Trafficking Areas." January 23, 2022. https://www.whitehouse.gov/ondcp/briefing-room/2023/01/23/dr-gupta-and-law-enforcement-officials-announce-new-domestic-seizure-data-from-ondcps-high-intensity-drug-trafficking-areas/

[5] Office of National Drug Control Policy. "FY 2023 Budget Highlights." March 22, 2022. https://www.whitehouse.gov/wp-content/uploads/2022/03/FY-2023-Budget-Highlights.pdf

[6] Office of National Drug Control Policy. "Press Release: At Urging of U.S., UN Commission Acts Against 'Precursor' Chemicals Used to Produce Illicit Fentanyl." March 16, 2022. Accessed January 22, 2023. https://www.whitehouse.gov/ondcp/briefing-room/2022/03/16/at-urging-of-u-s-un-commission-acts-against-precursor-chemicals-used-to-produce-illicit-fentanyl/

[7] Centers for Disease Control and Prevention, NCHS. "Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts." January 11, 2023. Accessed January 11, 2023. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Mr. GUTHRIE. Thank you.

The gentleman yields back.

And I will now recognize Dr. Gandotra for 5 minutes for your opening statement.

STATEMENT OF NEERAJ GANDOTRA, M.D.

Dr. GANDOTRA. Good morning. Thank you, Chair Guthrie, Ranking Member Eshoo, Chair McMorris Rodgers, Ranking Member Pallone, and members of the subcommittee, for inviting me to testify at this hearing covering fentanyl and the 988 Suicide and Crisis Lifeline, among other topics.

My name is Dr. Neeraj Gandotra, and I am Chief Medical Officer for the Substance Abuse and Mental Health Services Administration, also known as SAMHSA. SAMHSA leads public health efforts to improve behavioral health of our Nation.

I am pleased to be here along with my colleagues from the White House Office of National Drug Control Policy and the Drug Enforcement Administration.

I look forward to discussing our work at SAMHSA, which aims to support all aspects of the care continuum, from prevention and harm reduction to treatment, crisis care, and sustained recovery services.

Ultimately, SAMHSA envisions people with, affected by, or at risk for mental health and substance use conditions receive care, thrive, and achieve well-being.

Over the past few years, we have seen the opioid overdose epidemic evolve. We are now faced with the reality that fentanyl and substances laced with fentanyl are far more deadly than other opioids or stimulants alone.

That is why addressing addiction and the overdose epidemic are one of the four pillars of the Unity Agenda that the President outlined in last year's State of the Union Address.

Additionally, at the beginning of the Biden-Harris administration, Secretary Becerra released the comprehensive HHS Overdose Prevention Strategy, which is designed to increase both access to primary substance use prevention activities and access to the full range of services for individuals at risk for overdose as well as services for their families. This strategy prioritizes four key areas: primary prevention, harm reduction, evidence-based treatment, and recovery support.

SAMHSA's substance abuse prevention programs target at-risk populations and specific age groups to stop substance use before it starts. We work with State and local partners to reach people where they are and to reduce the impacts of substance misuse. For example, SAMHSA's First Responders-CARA program trains first responders on how to respond to overdose-related incidents and provides training on naloxone administration.

SAMHSA also provides funding and support for evidence-based harm-reduction services. Our harm-reduction grants support activities such as expanded distribution of overdose-reversal medications and fentanyl test strips. It also provides overdose education and counseling and works to stop the spread of infectious diseases.

Fentanyl test strips are an important component of harm-reduction programs, education and awareness-building toolkits, and low-

threshold, on-demand treatment programs. All of these are efforts that help save lives.

Because of Congress' commitment to treatment programs and thanks to December's omnibus, SAMHSA is actively working with Federal partners to implement the removal of the DATA 2000 waiver and related policies so that more Americans can access this lifesaving medication.

In addition to preventing and treating substance use, we also ensure that patients in mental health and substance use crisis are quickly directed to the appropriate level of care. This work includes helping States and localities coordinate crisis services through the 988 Suicide and Crisis Lifeline. The lifeline helps connect individuals with trained counselors and, if needed, crisis intervention and stabilization services. It may also include warm handoffs to treatment providers.

Thanks to the support from Congress, the lifeline is serving more Americans in crisis. For example, when comparing December 2021 with December 2022, the 988 Lifeline answered 434,000 contacts, which is 172,000 more calls, chats, and texts versus 2021, and it has also significantly improved how quickly these contacts were answered. Additionally, when comparing December 2022 to December 2021, calls, chats, and texts answered all increased—48 percent, 263 percent, and 1,443 percent, respectively.

In closing, on behalf of my colleagues at SAMHSA, thank you for supporting our programs and for working to improve our Nation's behavioral health. I would be pleased to answer any questions that you might have.

[The prepared statement of Dr. Gandotra follows:]

SAMHSA
Substance Abuse and Mental Health Services Administration
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Testimony Before the
House Committee on Energy and Commerce Subcommittee on Health
Hearing entitled: *Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities*
February 1, 2023

Written Statement of Neeraj Gandotra, M.D.
Chief Medical Officer

Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Good morning. Thank you, Chair Guthrie, Ranking Member Eshoo, and members of the Energy and Commerce Health Subcommittee for inviting me to testify during this hearing focused on fentanyl.

My name is Dr. Neeraj Gandotra, and I serve as the Chief Medical Officer for the Substance Abuse and Mental Health Services Administration, also known as SAMHSA. SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes. SAMHSA envisions that people with, affected by, or at risk for mental health and substance use conditions receive care, thrive, and achieve wellbeing.

I am pleased to be here, along with my colleagues from the White House Office of National Drug Control Policy and the United States Drug Enforcement Administration to discuss fentanyl and rising overdose deaths.

We are here today because rising overdoses continue to be a challenge for this country. Synthetic opioids like illicitly manufactured fentanyl, and the use of other substances, particularly stimulants such as cocaine and methamphetamine, have led to significant increases in overdose deaths.[1] Over the past few years, we have seen the opioid overdose epidemic evolve. We are now faced with the reality that illicitly manufactured fentanyl, and substances contaminated with illicitly manufactured fentanyl, are far more deadly than other opioids or stimulants alone.

Our country faces an unprecedented crisis among people of all ages and backgrounds. The COVID-19 pandemic has exacerbated an already tragic situation, with drug overdose deaths reaching a historic high, devastating families and communities.[2] The 2021 National Survey on Drug Use and Health found that among people who used prescription fentanyl products for any reason in the past year, 20.9 percent misused them.[3] Moreover, findings from SAMHSA's analysis of 2021 data from drug-related emergency department visits show that fentanyl-related emergency department visits rose throughout 2021.[4] Provisional data from the CDC

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[1] Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001–2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://dx.doi.org/10.15620/cdc:122556

[2] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data

[3] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data

[4] Substance Abuse and Mental Health Services Administration. (2022). Drug Abuse Warning Network: Findings from Drug-Related Emergency Department Visits, 2021 (HHS Publication No. PEP22-07-03-002). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

predicts that more than 107,000 Americans died due to a drug overdose in the 12-month period ending in August 2022. Of these drug overdoses, the same source predicts that 81,231 of these fatalities involved opioids, and approximately 73,102 were attributable to fentanyl and other synthetic opioids (excluding methadone).[5]

Addressing addiction and the overdose epidemic was one of the four pillars of the Unity Agenda the President outlined in last year's State of the Union Address. Building on the Unity Agenda, the Biden-Harris Administration thanks Congress for its partnership in the work being done to address the overdose epidemic head-on. This bipartisan, bicameral work includes last year's Bipartisan Safer Communities Act (P.L. 117-159) as well as significant behavioral health investments included in the Consolidated Appropriations Act, 2023 (P.L. 117-328).

At the beginning of the Biden-Harris Administration, U.S. Department of Health and Human Services Secretary Xavier Becerra released the comprehensive HHS Overdose Prevention Strategy (Strategy), which is designed to increase access to primary substance use prevention activities for at-risk populations as well as increasing access to the full range of care and services for individuals who use substances that cause overdose, and their families. The Strategy prioritizes four key areas: primary prevention, harm reduction, evidence-based treatment, and recovery support.

Throughout this testimony, I will expand on what SAMHSA is doing to implement the Strategy and how we are working to advance the President's goal of reducing both fatal and non-fatal overdoses.

SUPPORTING THE SUBSTANCE USE CARE CONTINUUM

Two of SAMHSA's largest formula-based substance use programs, both of which were recently reauthorized through the Consolidated Appropriations Act, 2023 (P.L. 117-328), allow funding to be tailored to the specific state, territory, or Tribal Nation to be used for activities related to prevention, treatment and recovery. These programs, the State and Tribal Opioid Response Grants and the Block Grants for Substance Use Prevention, Treatment, and Recovery Services, are detailed below.

State and Tribal Opioid Response Grants

SAMHSA would like to thank Congress for investing $1.575 billion in the State Opioid Response Grants to states and territories to help address the Nation's addiction and overdose crisis. To assist states, territories, Tribes and Tribal Nations in addressing the nation's overdose crisis, SAMHSA administers the State Opioid Response (SOR) and Tribal Opioid Response (TOR) grant programs. Recognizing that illicitly manufactured fentanyl is driving overdose deaths across much of the country, often in combination with stimulants, both programs focus on opioids and stimulants. As such, the core aims of the SOR and TOR grant programs continue to involve: increasing access to the three Food and Drug Administration (FDA)-approved medications for the treatment of opioid use disorder, reducing unmet treatment need, and reducing opioid-

[5] Id.

related overdose deaths by supporting the full continuum of prevention, harm reduction, treatment, and recovery support services. These programs also support the continuum of care for those states and communities across the country that are dealing with rising rates of stimulant use, in addition to opioids, and the associated negative health, social and economic consequences of substance misuse. Like the SOR program, the TOR grant program provides dedicated resources for these activities to Tribes and Tribal Nations.

As an example, in partnership with the Seattle Indian Health Board, Washington State provided low barrier treatment with medications for opioid use disorder and related services to urban American Indian and Alaskan Native individuals who are experiencing homelessness with opioid use disorder (OUD). Low Barrier Treatment is a model of providing care to patients with OUD that increases access to treatment by creating patient-centered programs that are easy to access, offer a high quality of care, and eliminate hurdles to access or stay in care for OUD. Low Barrier Treatment achieves this by providing treatment in non-traditional settings (jails, SSPs, etc.), same-day treatment, and other flexibilities.

Block Grants for Substance Use Prevention, Treatment, and Recovery Services
SAMHSA would also like to thank Congress for appropriating $2.0 billion for the Block Grants for Substance Use Prevention, Treatment, and Recovery Services (BGSU). BGSU funds help all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, 6 Pacific jurisdictions, and 1 tribal entity in addressing substance use disorder (SUD) treatment and prevention needs. States use BGSU funds to support activities including prevention, treatment, and recovery systems' infrastructure and capacity building, thereby increasing availability of services and development and implementation of evidence-based practices. States use this funding for services not covered by public or private insurance, as well as for non-clinical activities and services that address the critical needs of state substance use service systems and treatment needs.

Primary Prevention
Prevention is critical to reducing overdoses and overdose deaths. SAMHSA's activities in this area are designed to invest in the vital community infrastructure necessary to prevent harms related to substance use. In addition to the twenty percent set-aside in the BGSU, examples of SAMHSA's activities in support of the Strategy's primary prevention goal are below.

First Responder Training for Opioid Overdose-Related Drugs
SAMHSA's First Responders – Comprehensive Addiction and Recovery Act (FR-CARA) program is an important part of our response to the overdose crisis. The FR-CARA program trains and equips firefighters, law enforcement officers, paramedics, emergency medical technicians, and volunteers in other organizations to respond to adverse overdose-related incidents, including how to administer naloxone. This program also establishes processes, protocols, and mechanisms for referral to appropriate treatment services and recovery communities. FR-CARA's broader eligibility and rural-set asides ensure that vital services reach rural and tribal areas. During the program's recent project period, each state developed a strategic action plan for combatting opioid misuse and deaths related to heroin and illicit fentanyl.

As of January 19, 2023, FR-CARA grantees have distributed 339,964 naloxone kits with grant funds and administered naloxone 157,361 times. Also as of last month, FR-CARA grantees have conducted 41,150 trainings and trained 188,076 individuals on how to respond to overdose-related incidents.

Strategic Prevention Framework for Prescription Drugs Grant Program
The Strategic Prevention Framework for Prescription Drugs (SPF-Rx) program focuses on bringing prescription drug use prevention activities and education to schools, communities, parents, prescribers, and their patients. Grantees have also worked with the pharmaceutical and medical communities to raise awareness about the dangers of sharing medications and to ensure that prescribers understand the risks of overprescribing opioids to young adults. SAMHSA's SPF-Rx also assists grantees in developing capacity and expertise in the use of data from state run prescription drug monitoring programs (PDMPs). SAMHSA notes positive trends in reductions in opioid overdoses and the incorporation of prescription drug monitoring data into needs assessments, as well as strategic plans, as indicators of program success.

Data from the evaluation of the first cohort of SPF-Rx grantees show that grantees implemented 565 prevention activities in communities across the country. These SPF-Rx grantee prevention activities include support for media campaigns, webinars, disposal lockboxes, and direct training of health care professionals. Our first cohort of grantees, which took place from FY17-FY19, reached an estimated 33 million persons indirectly (through media channels, etc.) and 122,000 persons directly through trainings, educational programs, events, and screenings.

Additional findings showed that while there were over 95 million opioid prescriptions written across all grantees in 2017; that number dropped to just over 80 million in 2019. Among the grantees reporting, the number of prescribers registered for their state's PDMP rose from 378 in 2017 to 499 in 2019.

Harm Reduction
Evidence-based harm reduction strategies minimize the negative consequences of drug use for both individuals and communities. Therefore, providing funding and support for innovative harm reduction services is a key pillar of the Strategy. The activities below highlight the substantial steps that SAMHSA has taken to advance the adoption and use of evidence-based harm reduction approaches where not prohibited by law.

Harm Reduction Grant Programs
Last year, SAMHSA launched its first-ever Harm Reduction grant program and issued $30 million in grant awards to organizations working to expand access to harm reduction strategies where not prohibited by law. This grant opportunity, authorized and funded by the American Rescue Plan Act, aims to help increase access to a range of community harm reduction services and supports harm reduction service providers as they work to help prevent overdose deaths and reduce health risks often associated with drug use. This funding is allowing organizations to

expand their distribution of overdose-reversal medications and fentanyl test strips, provide overdose education and counseling, and manage or expand syringe services programs (SSP), which help prevent transmission of HIV, hepatitis C virus, and other causes of infectious disease.

As summarized by our colleagues at the Centers for Disease Control and Prevention (CDC)[6], SSPs are supported by almost 30 years of research indicating that they are safe, effective and produce cost-savings.[7,8] In addition to being highly evidence-based, data also show that SSPs reduce the transmission of infections like viral hepatitis and HIV, and do not increase use of illegal drugs or contribute to a rise in crime.[9,10] Finally, data on SSPs also show that users of these services are five times more likely to start treatment for their SUD and about three times more likely to cease use of illegal substances than their counterparts who do not participate in SSPs.[11]

In October 2022, Impact Life, the recipient of a 3-year SAMHSA Harm Reduction grant based in Delaware, partnered with Walgreens to offer harm reduction services to underserved and high-risk communities across the state. Their partnership allows the Impact Life team to occupy space at 11 Walgreens locations throughout the state. These locations are in areas that have high rates of fatal overdose and high substance use activity.

This partnership works with the Delaware Department of Health and Social Services' Divisions of Public Health Substance Abuse and Mental Health to identify "hot spots" to tailor outreach schedules to provide services in the highest-need areas. At each location, the Impact Life team offers harm reduction resources such as risk reduction screenings, distribution of naloxone and drug deactivation and disposal pouches, and fentanyl test strips. Impact Life also distributes wound care kits, provides linkages to behavioral health services including medication treatment for OUD, physical health services and social service organizations.

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[6] Summary of information on the safety and effectiveness of syringe service programs (SSPs). (2023, January 11). Cdc.gov. https://www.cdc.gov/ssp/syringe-services-programs-summary.html

[7] Martin, N. K., Hickman, M., Hutchinson, S. J., Goldberg, D. J., & Vickerman, P. (2013). Combination interventions to prevent HCV transmission among people who inject drugs: modeling the impact of antiviral treatment, needle and syringe programs, and opiate substitution therapy. Clin Infect Dis, 57 Suppl 2, S39-45. doi:10.1093/cid/cit29

[8] Aspinall, E. J., Nambiar, D., Goldberg, D. J., Hickman, M., Weir, A., Van Velzen, E., . . . Hutchinson, S. J. (2014). Are needle and syringe programs associated with a reduction in HIV transmission among people who inject drugs: a systematic review and meta-analysis. Int J Epidemiol, 43(1), 235- 248. doi:10.1093/ije/dyt243

[9] Id.

[10] Bernard, C. L., Owens, D. K., Goldhaber-Fiebert, J. D., & Brandeau, M. L. (2017). Estimation of the cost-effectiveness of HIV prevention portfolios for people who inject drugs in the United States: A model-based analysis. PLoS Med, 14(5). doi:10.1371/journal.pmed.1002312

[11] Hagan H, McGough JP, Thiede H, Hopkins S, Duchin J, Alexander ER, "Reduced injection frequency and increased entry and retention in drug treatment associated with needle-exchange participation in Seattle drug injectors", Journal of Substance Abuse Treatment, 2000; 19:247–252.

Fentanyl Test Strips
HHS announced in April 2021 that grantees in certain programs, such as SOR grants and the BGSU program, may use grant funds to purchase rapid fentanyl test strips to help curb the dramatic spike in drug overdose deaths largely driven by strong synthetic opioids, including illicitly manufactured fentanyl, in jurisdictions where they are not prohibited by law.[12,13]

Reports from states such as California, Arizona, Nevada, and Alaska note that fentanyl test strips funded through SOR have become an important component of syringe service programs; education and awareness building toolkits; and innovative, low-threshold, on-demand treatment programs. As of January 28, 2023, 49 states have reported distributing 824,048 fentanyl test strips.

Evidence-based Treatment
Evidence-based treatments for SUD can reduce substance use, related health harms, and overdose deaths, as well as increase positive outcomes for long-term recovery. Beyond improving public health outcomes, they also enhance public safety outcomes. In addition to SAMHSA's SOR/TOR and BGSU programs, below are examples of other SAMHSA efforts and programs that support evidence-based treatment.

Flexibilities to Increase Access to Medications for Opioid Use Disorder
The Consolidated Appropriations Act, 2023 (P.L. 117-328) included provisions that amended the Controlled Substances Act (P.L. 91-513) to eliminate the requirement for qualified practitioners to first obtain a special waiver (also referred to as the X-waiver) to prescribe schedule III-V controlled medications, namely buprenorphine, for the treatment of OUD. This action, which we are currently working with our colleagues at the DEA to implement, ends a decades-long requirement that impeded access to vital lifesaving treatment for OUD. In addition to removing the X-waiver requirement, the new law also removed associated patient limits. It is important to note that though Congress removed the X-waiver via the Consolidated Appropriations Act, 2023 (P.L. 117-328), some states currently maintain additional requirements for providers to prescribe buprenorphine. The removal of both requirements, obtainment of the federal X-waiver and patient limits, will make it easier for practitioners to prescribe buprenorphine to more patients. This builds on the HHS Overdose Prevention Strategy and delivers on the call to action in President Biden's Unity Agenda to address the overdose and addiction crisis.

Removal of X-waiver requirements will expand access to a lifesaving medication. SAMHSA saw this with release of the updated buprenorphine practice guidelines in April 2021. Indeed, prior to implementation, training and certification requirements were often cited as a barrier to

[12] Centers for Disease Control and Prevention, "Federal Grantees May Now Use Funds to Purchase Fentanyl Test Strips", (April 7, 2021).
[13] SAMHSA 2021 Report to Congress on the State Opioid Response Grants (SOR).
https://www.samhsa.gov/sites/default/files/2021-state-opioid-response-grants-report.pdf

treating more people.[14] We know that treatment with buprenorphine decreases opioid-related overdose mortality by over 50 percent,[15,16] and that the revision to the Practice Guidelines for the Administration of Buprenorphine[17] saw an increase in the number of practitioners submitting a Notice of Intent to prescribe buprenorphine.[18] These Notices of Intent are no longer required for practitioners to prescribe the medication. Removal of X-waiver requirements may further reduce geographic disparity in access to buprenorphine and provides opportunities to fully integrate this important intervention into routine medical care.

SAMHSA has also learned from the substance use disorder-related treatment flexibilities that were implemented at the beginning of the COVID-19 pandemic. For example, we have seen how telehealth can expand access to care in certain populations, overcome geographic inequality in the provision of services, and reduce stigma associated with accessing life-saving medications such as buprenorphine.[19] Providers and patients have overwhelmingly supported integration of telehealth into the care of those with OUD, since it offers: flexibility in delivery and receipt of treatment; a means for those living in rural or remote areas to better access care; improvement in the provider-client relationship through flexible scheduling; greater care coordination activities; maximization of workforce productivity; reduction in burnout; and a reduction in service delivery costs by allowing remote work and provision of care.[20] The COVID-19 pandemic also necessitated flexibilities in how patients accessed methadone in opioid treatment programs (OTPs) for take-home administration. SAMHSA's regulatory flexibilities related to methadone take home medication implemented at the beginning of the pandemic have been met with positive feedback from patients, providers, and researchers. Recent

[14] Substance Abuse and Mental Health Services Administration, "HHS Releases New Buprenorphine Practice Guidelines, Expanding Access to Treatment for Opioid Use Disorder" (April 27, 2021). https://www.samhsa.gov/newsroom/press-announcements/202104270930

[15] Substance Abuse and Mental Health Services Administration Results From the 2018 National Survey on Drug Use and Health (2019) https://www.samhsa.gov/data/

[16] Sordo, Barrio, Bravo, Indave, Degenhardt, Wiessing, Ferri, Pastor-Barriuso, Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-analysis of Cohort Studies (Apr. 2017), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5421454/

[17] Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder; Health and Human Services Department Notice, 86 Fed. Reg. 22439 (April 28, 2021).

[18] United States Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. (2022, December 2). Early Changes in Waivered Clinicians and Utilization of Buprenorphine for Opioid Use Disorder After Implementation of the 2021 HHS Buprenorphine Practice Guidelines. https://aspe.hhs.gov/reports/early-changes-after-2021-hhs-buprenorphine-practice-guidelines

[19] Guille, C., Simpson, A. N., Douglas, E., Boyars, L., Cristaldi, K., McElligott, J., Johnson, D., & Brady, K. (2020). Treatment of opioid use disorder in pregnant women via telemedicine: A nonrandomized controlled trial. JAMA Network Open, 3(1), e1920177-e1920177.

[20] King, V. L., Brooner, R. K., Peirce, J. M., Kolodner, K., & Kidorf, M. S. (2014). A randomized trial of web-based videoconferencing for substance abuse counseling. Journal of Substance Abuse Treatment, 46(1), 36-42.

research has found that these increases in methadone take-home doses have not been associated with increases in overdoses or other negative impacts.[21,22]

For these reasons, on December 16th of last year, SAMHSA published a Notice of Proposed Rulemaking (NPRM) to update 42 CFR Part 8, the federal regulation that governs opioid use disorder treatment standards, as well as OTP accreditation and certification standards. Through the NPRM, SAMHSA proposes action to improve Americans' access to and experiences with OUD treatment, with a specific focus on OTPs. The proposed changes reflect over 20 years of evidence, as well as stakeholder feedback, that supports (1) greater autonomy among OTP practitioners to provide patient-centered care, (2) a positive and productive recovery, and (3) making telehealth and take-home related flexibilities that were implemented at the start of the nation's COVID-19 Public Health Emergency permanent.

In 2022, SAMHSA certified 151 new OTPs, new brick and mortar medication units, as well as new mobile units to expand treatment access across the nation. As of December 2022, there were 1,994 active OTPs with 80 having affiliated brick and mortar medication units, and 24 with mobile locations.

Medication-Assisted Treatment for Prescription Drug and Opioid Addiction
The Medication-Assisted Treatment for Prescription Drug and Opioid Addiction (MAT-PDOA) program addresses treatment needs of individuals who have an OUD by expanding/enhancing treatment system capacity to provide accessible, effective, comprehensive, coordinated/integrated, and evidence-based medications for opioid use disorder (MOUD) and recovery support services. With support from MAT-PDOA funding, some grantees have provided outreach to faith-based communities through radio programming. Utilizing community outreach teams, these grantees connect with faith-based leaders to ensure that they are supported, and that information regarding treatment and recovery services is appropriately communicated to congregations. These grantees have also provided recommendations to religious leaders on effective methods of conveying information to congregants on the array of services that are available for persons with an opioid use disorder either virtually (during COVID) or through the distribution of flyers and pamphlets (provided by the grantee) to their parishioners and members of their local communities. The latest Notice of Funding Opportunity for the next five-year MAT-PDOA grant program was released last month along with four other SUD-related SAMHSA grants. We expect to be able to fund about 24 MAT-PDOA grantees in our next cohort starting later this year. SAMHSA thanks Congress for increasing funding for this effective program by providing $111.0 million through the Consolidated Appropriations Act, 2023 (P.L. 117-328).

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[21] Jones CM, Compton WM, Han B, Baldwin G, Volkow ND. Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. JAMA Psychiatry. 2022;79(9):932–934. Available at: doi:10.1001/jamapsychiatry.2022.1776.
[22] Mary C. Figgatt, Zach Salazar, Elizabeth Day, Louise Vincent, Nabarun Dasgupta, (2021). Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. Journal of Substance Abuse Treatment, (123) e. 108276. Available at: https://doi.org/10.1016/j.jsat.2021.108276.

Comprehensive Opioid Recovery Centers
The Comprehensive Opioid Recovery Center (CORC) program provides grants to nonprofit substance use disorder treatment organizations to operate comprehensive centers which provide a full spectrum of treatment and recovery support services for opioid use disorders. Grantees are required to provide outreach and the full continuum of treatment services including MOUD; counseling; treatment for mental health disorders; testing for infectious diseases, residential treatment, and intensive outpatient services; recovery housing; peer recovery support services; job training, job placement assistance, continuing education; and family support services such as childcare, family counseling, and parenting interventions. CORC grantees have been utilizing funding in a variety of ways. They have used their grant funding for improving systems of comprehensive MOUD care at the county level; improving follow up with clients who have experienced overdose reversals; and removing barriers to MOUD in residential treatment. Other ways CORC grantees have used their funding include engaging with special populations, such as homeless persons, people on probation, and LGBTQ+ persons, and meeting the needs of underserved areas.

Certified Community Behavioral Health Clinics Expansion Grants
The Certified Community Behavioral Health Clinic (CCBHC) Expansion program includes CCBHC Planning, Development, and Implementation (PDI) grants and Improvement and Advancement (IA) grants. CCBHC PDI grants support organizations in planning, developing, and implementing a CCBHC that meets the CCBHC Certification Criteria, while the CCBHC IA grants support current CCBHCs that already meet the Criteria to increase access to and improve the quality of community mental health and SUD treatment services. CCBHCs funded under this program must provide access to services for individuals with serious mental illness or SUD, including OUD; children and adolescents with serious emotional disturbance; and individuals with co-occurring mental health and SUDs. This program improves the mental health of individuals by providing comprehensive community-based mental health and SUD services; improving treatment of co-occurring disorders; advancing the integration of mental health/SUD treatment with physical health care; utilizing evidence-based practices on a more consistent basis; and promoting improved access to high quality care.

Data from intake of most recent reassessments for individuals served in the CCBHC program demonstrate that as of January 2023, enrollees have achieved a 74-percent reduction in hospitalization and a 69-percent reduction in emergency department visits, as well as a 31-percent increase in mental health functioning in everyday life. Additionally, the data demonstrated a 15-percent increase in employment or school enrollment. SAMHSA appreciates Congress including support for CCBHC planning grants and technical assistance in the Bipartisan Safer Communities Act (P.L. 117-159) and the Consolidated Appropriations Act, 2023 (P.L. 117-328).

Pregnant and Postpartum Women Program
The Pregnant and Postpartum Women program (PPW) uses a family-centered approach to provide comprehensive residential SUD treatment, prevention, and recovery support services for pregnant and postpartum individuals, their minor children, and for other family members.

The family-centered approach includes partnering with others to leverage diverse funding streams, encouraging the use of evidence-based practices, supporting innovation, and developing workforce capacity to meet the needs of these families. The PPW program provides services not covered under most public and private insurance. SAMHSA continues to prioritize states that support best-practice collaborative models for treatment, as well as provide support to pregnant individuals with OUD. The Comprehensive Addiction and Recovery Act (P.L. 114-198) increased accessibility and availability of services for pregnant individuals by expanding the authorized purposes of the program to include the provision of outpatient and intensive outpatient services.

Recovery

SAMHSA has a long history of advancing recovery supports dating back to the 1980s with the Community Support Program and the 1990s, when the first Recovery Community Support Programs were funded. SAMHSA defines recovery as a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.

Establishing an Office of Recovery and Advancing Peer Supports

Recovery support is a key pillar of the HHS Overdose Prevention Strategy. That is why, during Recovery Month in the fall of 2021, SAMHSA announced that it would be establishing a new Office of Recovery. This office promotes the involvement of people with lived experience throughout agency and stakeholder activities, fosters relationships with internal and external organizations in the mental health and addiction recovery fields, and identifies health disparities in high-risk and vulnerable populations to ensure equity for support services across the nation.

We know that recovery is enhanced by peer-delivered support services. These services have proven to be effective in sustaining recovery over the long term.[23,24] Investing in peer support services is critical, given the significant workforce shortage throughout the continuum of behavioral health clinicians and providers. That is why, as part of the President's Strategy to Address Our National Mental Health Crisis, SAMHSA is updating and expanding existing compendia[25] of state-by-state peer specialist certifications and is convening stakeholders to create a new set of model national standards for peer specialist certification.

BGSU Recovery Set-Aside

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[23] Mental Health America. (2018). *Evidence for Peer Support.* May 2018. Retrieved January 25, 2023, from https://mhanational.org/sites/default/files/Evidence%20for%20Peer%20Support%20May%202018.pdf

[24] Substance Abuse and Mental Health Services Administration. (n.d.). *Value of Peers Infographic: General Peer support. Resource Details.* Retrieved January 25, 2023, from https://peerrecoverynow.org/resources/resourceDetails.aspx?resourceID=10

[25] Peer Recovery Center of Excellence, Comparative Analysis of State Requirements for Peer Support Specialist Training and Certification in the United States, January 2022 https://www.peerrecoverynow.org/documents/Comparative%20Analysis_Jan.31.2022%20(003).pdf

Though not included in the Consolidated Appropriations Act. 2023 (P.L. 117-328), the 2023 Budget proposed a ten percent set-aside within the BGSU for recovery support services aimed at significantly investing in the continuum of care both upstream and downstream. This proposed set-aside would support the development of local recovery community support institutions such as recovery community centers, recovery homes and recovery schools. In addition, the funding from this set-aside would be used by states to develop strategies and educational campaigns, trainings, and events to reduce addiction/recovery-related stigma and discrimination at the local level. Further, the recovery set-aside would require states to provide addiction recovery resources and support system navigation; make accessible peer recovery support services that support diverse populations and that are inclusive of all pathways to recovery; and collaborate and coordinate with local private and non-profit clinical health care providers, the faith community, city, county, state, and federal public health agencies, and criminal justice response efforts.

CONCLUSION

On behalf of my colleagues at HHS and SAMHSA, thank you for your interest in, and support for, our programs, and for supporting the nation's behavioral health. I would be pleased to answer any questions that you may have.

Mr. GUTHRIE. I appreciate your testimony.

The gentleman yields back.

And I will recognize Mr. DeLena for 5 minutes for an opening statement.

STATEMENT OF JON DELENA

Mr. DELENA. Good morning, Subcommittee Chairman Guthrie, Ranking Member Eshoo, Committee Chair McMorris Rodgers, Ranking Member Pallone, and distinguished members of this subcommittee.

On behalf of the Department of Justice and, in particular, the approximately 10,000 employees of the Drug Enforcement Administration, it is my honor to appear before you today. I thank the committee for bringing attention to this important topic.

Today's hearing comes at a critical moment in our country's history. Our Nation is in the midst of a devastating drug poisoning epidemic that claimed the lives of over 107,000 people this past year. An estimated 294 people die every day from drug poisoning, and countless more overdose and survive.

I have had the privilege of being a DEA special agent for nearly 27 years. I have worked in Colorado, Florida, Virginia, and my home region, New England. The current drug poisoning epidemic is like nothing I have ever experienced in my career.

In 2022, DEA seized more than 50 million fake pills and 10,000 pounds of fentanyl powder. That is approximately 379 million deadly doses of fentanyl taken off of American streets. That is enough fentanyl to supply a potentially lethal dose to every member of the U.S. population.

As a country, we must do everything we can to stop this national crisis. For our part, the men and women of the DEA are relentlessly focused, day in and day out, on combating the deadly drug poisoning epidemic and on saving lives.

DEA leads and coordinates the whole-of-government response to defeat the two Mexican drug cartels, the Sinaloa Cartel and the Jalisco Cartel, that are responsible for driving the drug poisoning epidemic in all of our communities.

A unified response, with DEA in the lead, ensures that the whole of government is moving in one direction. Through this unified response, we can protect the safety and health of Americans.

The Sinaloa and Jalisco cartels pose the greatest criminal drug threat the United States has ever faced. These ruthless, violent criminal organizations have associates, facilitators, and brokers in all 50 States as well as in more than 40 countries around the world.

The Sinaloa and Jalisco cartels control the supply chain for illicit fentanyl. They obtain precursors from China and use these precursor chemicals to manufacture fentanyl and other synthetic drugs in clandestine laboratories in Mexico. The cartels take that fentanyl and press it into fake prescription pills and other drugs. The cartels then transport fentanyl in pill and powder form, as well as other drugs like methamphetamine, heroin, and cocaine, into the United States.

I have seen firsthand what the Mexican cartels have done to our great country. The cartels are destroying families and communities with callous indifference and greed.

The DEA is working across its global operations to defeat these two cartels and protect our communities. I would like to briefly highlight three initiatives in particular.

First are the counter-threat teams. DEA launched two cross-agency counterthreat teams that focus exclusively on defeating the Sinaloa Cartel and Jalisco Cartel. The teams use a network-focused approach. They are mapping, analyzing, and targeting the cartels' entire operations. The teams will use all of the resources at their disposal to defeat these two cartels.

The second initiative is Operation Overdrive, which targets drug-trafficking organizations and gangs that are responsible for the greatest number of deaths and violence. Operation Overdrive is a data-driven approach that is currently in 57 locations across the country, and we will expand.

The final initiative I would like to highlight are DEA's family summits. In June and November of 2022, DEA brought together families from across the country who have lost loved ones to drug poisoning. The summits were incredibly impactful. They were an opportunity for DEA to explain what we are doing to combat the drug poisoning epidemic, but, more importantly, it was an opportunity for families to share their stories with one another and with us.

Throughout my career, I have partnered with families, local groups, prevention specialists, and community outreach organizations for events big and small, and I appreciate the great work that they do and feel very strongly that the connections we have made with these people and these families will help educate, spread awareness, and save lives.

Congress, of course, has an important role to play. I personally want to thank and extend my sincere thanks to the Members of Congress who have worked so hard to ensure the temporary classwide scheduling of fentanyl-related substances does not expire. Classwide scheduling is critical to DEA's ability to seize FRS when they are encountered and to investigate and prosecute those that manufacture and traffic in these deadly drugs. I urge Congress to make the temporary scheduling permanent. This is critical to the safety and health of Americans.

Thank you for the opportunity to testify before your subcommittee on this important issue, and I look forward to your questions.

[The prepared statement of Mr. DeLena follows:]

Department of Justice

STATEMENT OF
JON DELENA
ASSOCIATE ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION
U.S. DEPARTMENT OF JUSTICE

BEFORE THE

House Committee on Energy and Commerce
Subcommittee on Health

FOR A HEARING ENTITLED

"LIVES WORTH LIVING: ADDRESSING THE FENTANYL CRISIS, PROTECTING CRITICAL LIFELINES, AND COMBATTING DISCRIMINATION AGAINST THOSE WITH DISABILITIES"

PRESENTED

February 1, 2023

Statement of Jon DeLena
Associate Administrator
Drug Enforcement Administration
U.S. Department of Justice

At a Hearing Entitled,
"Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"

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

February 1, 2023

* * *

Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the committee: On behalf of the Department of Justice (Department), and in particular the over 10,000 employees working at the Drug Enforcement Administration (DEA), thank you for the opportunity to appear before you today to discuss DEA's work to save lives and to combat the deadly drug poisoning epidemic in our country.

From September 2021 through August 2022, an estimated 107,477 people lost their lives to drug poisonings in the United States. Every day, 294 people die from drug poisonings. Countless more people are poisoned and survive. These drug poisonings are a national crisis.

The DEA's top operational priority is to defeat the two Mexican drug cartels – the Sinaloa cartel and Jalisco New Generation (Jalisco) cartel – that are responsible for driving the drug poisoning epidemic in the United States. DEA is focusing its resources to counter this worldwide threat, and has launched a number of key initiatives to meet the moment.

The Drug Poisoning Epidemic

According to the Centers for Disease Control and Prevention (CDC), a majority of the drug poisoning deaths in the United States involve synthetic opioids, such as fentanyl, that are being distributed in new forms. Fentanyl is being hidden in and being mixed with other illicit drugs such as cocaine, heroin, and methamphetamine. Drug traffickers are also flooding our communities with fentanyl disguised in the form of fake prescription pills. These fake pills are made and marketed by drug traffickers to deceive Americans into thinking that they are real, diverted prescription medications. In reality, these fake prescription pills are highly addictive and are potentially deadly. DEA lab testing reveals that 6 out of 10 of these fentanyl-laced fake prescription pills contain a potentially lethal dose.

The availability of fentanyl throughout the United States has reached unprecedented heights. In 2022, DEA seized more than 50 million fake pills and 10,000 pounds of fentanyl powder equating to approximately 379 million deadly doses of fentanyl. This is enough fentanyl to supply a potentially

lethal dose to every member of the U.S. population. These seizures occurred in every state in the country.

The Drug Enforcement Administration

As the single mission agency tasked with enforcing our nation's drug laws, DEA's top operational priority is to relentlessly pursue and defeat the Sinaloa and Jalisco Cartels that are responsible for the current fentanyl and drug poisoning epidemic.

DEA is the lead agency on the law enforcement elements in the Biden-Harris Administration's whole of government response to defeat the cartels and combat the drug poisoning epidemic in our communities. DEA's role in leading the law enforcement response to the fentanyl epidemic protects the safety of agents, officers, and sources. Importantly, a unified response to the fentanyl epidemic ensures that the whole of government is moving in one direction that protects the safety and health of Americans.

DEA operates 23 domestic field divisions with 239 domestic offices and nine forensic labs. Internationally, DEA has 92 foreign offices in 69 countries. DEA's robust domestic and international presence allows it to map and target the entire Sinaloa Cartel and Jalisco Cartel networks.

In addition, DEA has launched two cross-agency counterthreat teams to execute a network-focused operational strategy. The two teams are mapping, analyzing, and targeting the cartels' entire criminal networks. The teams are composed of special agents, intelligence analysts, targeters, program analysts, data scientists, and digital specialists. This network-focused strategy is critical to defeating the Sinaloa and Jalisco Cartels.

DEA is simultaneously focused on protecting American communities. We are targeting the drug trafficking organizations and gangs located in the United States that are responsible for the greatest number of drug-related deaths and violence. DEA's Operation Overdrive uses a data-driven, intelligence-led approach to identify and dismantle criminal drug networks operating in areas with the highest rates of violence and drug poisoning deaths. In each of these locations, DEA is working with local and state law enforcement officials to conduct threat assessments identifying the criminal networks and individuals that are causing the most harm. DEA works with state, local, and federal law enforcement and prosecutorial partners to pursue investigations and prosecutions that will reduce drug-related violence and drug poisonings. Phase one of Operation Overdrive took place in 34 locations across the United States, and phase two is currently occurring in 57 locations.

In 2021, DEA launched the "One Pill Can Kill" enforcement effort and public awareness campaign. As part of the first two phases of the enforcement effort, DEA and our law enforcement partners seized more than 20 million fake, fentanyl-laced prescription pills. In phase three of the enforcement effort, which was conducted between May and September 2022, DEA seized more than 10 million fake, fentanyl-laced prescription pills and approximately 980 pounds of fentanyl powder. This equates to roughly 36 million potential lethal doses of fentanyl, which could have entered our communities. Additionally, this enforcement effort resulted in 390 investigated cases, including 35 cases with a direct link to one or both of the primary Mexican cartels responsible for the majority of fentanyl in the United States: the Sinaloa Cartel and the Jalisco Cartel. Moreover, DEA investigated 129 cases directly linked to the sale of fake pills containing fentanyl on social media.

DEA is working closely with our local, state, tribal, territorial, federal, and international counterparts to target every part of the illegal drug supply chain and every level of the drug trafficking organizations that threaten the health and safety of our communities. To succeed, we must use every tool to combat this substantial threat that is being driven by the cartels, as well as the Chinese-sourced precursor chemicals and Chinese money laundering operations that facilitate the cartels' operations.

Mexican Cartels and Drug Trafficking

The Sinaloa and Jalisco Cartels pose the greatest criminal drug threat the United States has ever faced. These ruthless, violent, criminal organizations have associates, facilitators, and brokers in all 50 states in the United States, as well as in more than 40 countries around the world.

The Sinaloa Cartel and the Jalisco Cartel and their affiliates control the vast majority of the fentanyl global supply chain, from manufacture to distribution. The cartels are buying precursor chemicals in the People's Republic of China (PRC); transporting the precursor chemicals from the PRC to Mexico; using the precursor chemicals to mass produce fentanyl; pressing the fentanyl into fake prescription pills; and using cars, trucks, and other routes to transport the drugs from Mexico into the United States for distribution. It costs the cartels as little as 10 cents to produce a fentanyl-laced fake prescription pill that is sold in the United States for $10 to $30 per pill.

Drugs manufactured by the Sinaloa Cartel and the Jalisco Cartel often end up being marketed by dealers using social media platforms to relentlessly expand their business and deceptively sell fake prescription pills directly to young people and teenagers. Drug traffickers operate on multiple platforms simultaneously, and often drive traffic between platforms.

The business model used by the Sinaloa and Jalisco Cartels is to grow at all costs, no matter how many people die in the process. The cartels are engaging in deliberate, calculated treachery to deceive Americans and drive addiction to achieve higher profits.

The Sinaloa Cartel

The Sinaloa Cartel, based in the Mexican State of Sinaloa, is one of the oldest drug trafficking organizations in Mexico. The Sinaloa Cartel controls drug trafficking activity in various regions in Mexico, particularly along the Pacific Coast. Additionally, it maintains the most expansive international footprint of the Mexican cartels. The Sinaloa Cartel exports and distributes wholesale amounts of methamphetamine, marijuana, cocaine, heroin, and fentanyl in the United States by maintaining distribution hubs in cities that include Phoenix, Los Angeles, Denver, and Chicago. Illicit drugs distributed by the Sinaloa Cartel are primarily smuggled into the United States through crossing points located along Mexico's border with California, Arizona, New Mexico, and Texas. Sinaloa reportedly has a presence in 15 of the 32 Mexican states.

The Jalisco Cartel

The Jalisco Cartel is based in the city of Guadalajara in the Mexican state of Jalisco, and was originally formed as a spin off from the Milenio Cartel, a subordinate to the Sinaloa Cartel. The Jalisco Cartel maintains illicit drug distribution hubs in Los Angeles, Seattle, Charlotte, Chicago, and Atlanta. Internationally, the Jalisco Cartel has a presence and influence through associates, facilitators, and brokers on every continent except Antarctica. The Jalisco Cartel smuggles illicit drugs such as

methamphetamine, heroin, cocaine, and fentanyl into the United States by accessing various trafficking corridors along the southwest border that include Tijuana, Mexicali, Ciudad Juarez, Matamoros, and Nuevo Laredo. The Jalisco Cartel's rapid expansion of its drug trafficking activities is characterized by the organization's willingness to engage in violent confrontations with Mexican Government security forces and rival cartels. The Jalisco Cartel reportedly has a presence in 21 of the 32 Mexican states.

People's Republic of China and Precursor Chemicals

Chemical companies within the PRC produce and sell the majority of precursor chemicals that are used today by the Sinaloa and Jalisco Cartels to manufacture fentanyl and methamphetamine. These precursor chemicals from companies within the PRC are the foundation of the fentanyl and methamphetamine that is manufactured and transported from Mexico into the United States, and is causing hundreds of thousands of drug-related deaths in our country.

According to the State Department's 2021 International Narcotics Control Strategy Report, there are approximately 160,000 chemical companies in the PRC. Chemical companies within the PRC distribute and sell precursor chemicals that are used in fentanyl and methamphetamine production around the world. Some companies within the PRC, for example, engage in false cargo labeling and ship chemicals to Mexico without tracking the customers purchasing the chemicals.

DEA has been and remains willing to engage the PRC government on fentanyl related substances and fentanyl precursor chemicals. However, due to diplomatic tensions between the United States and the PRC, the government has suspended all counter-narcotics cooperation with the United States. Moreover, since 2019, the PRC government has repeatedly declined diplomatic and congressional requests to stop precursor chemicals from going to Mexico for the production of illicit fentanyl and methamphetamine.

Chinese Money Laundering Operations and the Cartels

The Sinaloa and Jalisco Cartels utilize U.S.-based Chinese Money Laundering Organizations (CMLOs) around the world to facilitate laundering drug proceeds. CMLOs use trade-based money laundering and bulk cash movement to facilitate the exchange of foreign currency. The use of CMLOs by the cartels simplifies the money laundering process and streamlines the purchase of precursor chemicals utilized in manufacturing drugs.

These money laundering schemes are designed to remedy two separate issues: (1) the desire of Mexican cartels to repatriate drug proceeds into the Mexican banking system, and (2) wealthy Chinese nationals who are restricted by the PRC's capital flight laws from transferring large sums of money held in Chinese bank accounts for use abroad. To address these issues, CMLOs acquire U.S. dollars held by Mexican cartels as a means to supply their customers in China.

Scheduling of Fentanyl-Related Substances

Drug traffickers are continuously manufacturing and trafficking new and novel fentanyl-related substances (FRS) that are poisoning Americans. The DEA strongly supports the permanent scheduling and control of FRS as a class.

Cartel associated chemists are continually utilizing different precursor and pre-precursor chemicals, as well as new synthesis techniques and methods, to evade detection and make new highly potent and lethal fentanyl analogues. These FRS are structurally similar to fentanyl in ways that would be expected to have psychoactive effects and toxicity with potentially deadly outcomes. FRS are not permanently controlled in any schedule. Drug traffickers develop FRS to, at least in part, avoid regulatory controls, and thus circumvent detection and prosecution.

Prior to the emergency class-wide scheduling of FRS in 2018, the DEA had to reactively schedule new fentanyl analogues on a case-by-case basis, as they were encountered. The scheduling process involves multiple federal agencies, to include the DEA, and the Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Prior to 2018, DEA and its interagency partners were racing to keep pace with the cartel chemists who were manufacturing and trafficking in new fentanyl analogs outside the existing laws and regulations. The continual scheduling of new fentanyl analogues in reaction to innovations by cartel chemists was unworkable.

Since the DEA's emergency class-wide scheduling in 2018, Congress has extended the temporary scheduling order 8 times. The most recent extension is set to expire on December 31, 2024. DEA remains appreciative of Congress for extending the scheduling of FRS. Since class-wide scheduling, the identification of new FRS has dramatically slowed.

The permanent class-wide scheduling and control of FRS is critical to the safety and health of Americans. Permanent class-wide scheduling would deter the Sinaloa and Jalisco Cartels and other traffickers from developing new deadly substances. It will also send a strong message to foreign partners. Moreover, it would permit law enforcement to respond to the illicit manufacturing, importation, and trafficking of fentanyl analogues before they are distributed and before they can cause harm to Americans.

The DEA looks forward to working with Congress to permanently schedule FRS consistent with the Administration's legislative proposal.

Conclusion

DEA will continue our relentless pursuit to dismantle the Sinaloa Cartel and Jalisco Cartel that are driving drug poisonings and threatening the safety and health of our communities. Thank you again for the opportunity to appear before the committee today. I look forward to answering your questions.

Mr. GUTHRIE. Thank you.

The gentleman yields back.

I thank the witnesses for their testimony.

And we will begin—we will now move into the Q&A portion of the hearing. I will begin the questioning and recognize myself for 5 minutes.

So, Mr. Chester, first, we had Dr. Gupta in Bowling Green, Kentucky, my hometown, with Leader McConnell. And a lot of my law enforcement guys were real concerned. And it goes back to a comment that you made in a hearing in December 2021. And you were defending the context of—what they were upset about is that—and a lot of us are concerned about—is the administration's position to schedule fentanyl-related substances as a Schedule I but exempt it from the mandatory minimums.

And in defending that policy before, you made this statement, and I will quote it to you. It says: The administration, quote, "has gathered up an entire class of substances uncreated that, within the class of substance, there may be substances that either have medical merit or are not the least bit harmful. They are not any more harmful than water," unquote. That was a direct quote.

I just can't imagine anywhere that a cartel would smuggle fentanyl analogs into our country that is not as harmful as water. Would you clarify that statement?

Mr. CHESTER. Thank you for your question, Congressman. Yes. And I remember that. I remember that very clearly——

Mr. GUTHRIE. I do, too.

Mr. CHESTER [continuing]. When we were talking about two sides of the same coin, with gathering up an entire class of substances that have not been subjected to testing. And so it is chemically possible that there are alterations to the fentanyl molecule that have no effect on the body.

The question is, we don't know that. And so, not until they are subjected to the three- and the eight-factor analysis that the FDA does that the effect on the body of these substances can be determined.

Traffickers often create new substances based upon their chemical structure and then move them in and then ask for customer feedback afterwards. And this is something that we see quite often. They experiment with substances by sending them out and then hear what the users provide in terms of feedback.

So there is a possibility that a trafficker creates a substance based upon the fentanyl molecule, maybe a deletion of the fentanyl molecule, sends it out, and it winds up having no effect on the body at all.

Mr. GUTHRIE. That just seems—maybe that—I just can't imagine a cartel—maybe they do send some of this.

But, anyway, you have illegal cartels smuggling drugs into our country. Say they have no effect, somebody takes them and complains, "I took this pill. It has no effect." That is still an illegal cartel moving drugs into this country.

The other one you said may have medical merit. You know, fentanyl in itself has medical merit, except it is illegal and is subject to mandatory minimums if you illegally traffic fentanyl.

So I just—it is concerning the administration has that position and—it is concerning to me.

So, Mr. DeLena, you are in the DEA. Do you believe that we should permanently—you said in your testimony that permanently scheduling illicit fentanyl analogs has an effect and you have the ability to—it gives you more authority. Would you care to just talk about how important it is for your administration to have this bill in place?

Mr. DELENA. Thank you for the question, Congressman.

It is the top legislative priority for DEA to permanently schedule fentanyl as a classwide substance. We have never seen a deadlier drug, and we have seen the impact throughout the entire United States.

Mr. GUTHRIE. Have you ever seen a cartel smuggle a harmless drug into the country?

Mr. DELENA. I can't speak to every single thing that has ever been smuggled, but what I can tell you——

Mr. GUTHRIE. But have you ever seen a harmless drug smuggled into the country?

Mr. DELENA [continuing]. The two cartels that we are laser focused on, the Sinaloa Cartel and the Jalisco Cartel, are producing fentanyl and methamphetamine at epic rates. And it is fentanyl and methamphetamine that is ending up in our communities and causing the devastation and harm that we have seen play out: 107,735 Americans died between August 2021 and August 2022. It has to stop.

Mr. GUTHRIE. You do see drugs that have medical merit, that are prescription drugs that have been diverted, that are smuggled into our country. That should be a crime and subject to the same as well.

I mean, the administration says, "It could have medical merit. We need to test it first." But if a cartel is smuggling even prescription drugs that have been diverted, it still should be punished and subject to mandatory minimums. Do you agree?

Mr. DELENA. Thank you for the question, Congressman.

DEA is a law enforcement agency. We conduct investigations, and we bring these cases forward to prosecutors. It is the prosecutors and the judges who ultimately make those decisions.

Mr. GUTHRIE. So, if we permanently schedule fentanyl analogs subject to Schedule I and some do come in that have medical merit, they will be treated just like any other drug that has medical merit? And if for some reason a cartel decides to send some that are harmless, you still want to have the ability to disrupt those cartels, correct?

Mr. DELENA. Thank you for the question, Congressman.

We are laser focused on disrupting and defeating the two cartels, Sinaloa and Jalisco, that are causing the damage and destruction throughout all of our communities.

Mr. GUTHRIE. Thank you.

My time has expired, and I recognize Ms. Eshoo from California for 5 minutes to ask questions.

Ms. ESHOO. Thank you, Mr. Chairman.

And thank you to the witnesses for your testimony.

First, I want to go to Mr. DeLena.

Thank you for being here. A lot of passion in your voice and in your testimony. A career that spans decades.

I think you have answered my first question: Do Mexican cartels fuel the supply of illicit fentanyl in the United States? That is a definite "yes."

So just "yes" or "no" to the following: Do the Mexican cartels benefit from the availability of American guns?

Mr. DELENA. Thank you for the question, Congresswoman.

As I stated, the two cartels, Sinaloa and Jalisco Cartel, are driven by greed. They are producing methamphetamine and fentanyl at catastrophic rates and bringing those drugs into all of our communities——

Ms. ESHOO. So it is "yes"?

Mr. DELENA. They are fueled by any type of greed, and they are paid and repatriated in any way possible.

Ms. ESHOO. Do they benefit from the guns, though, the trafficking of them?

Mr. DELENA. Thank you for the question.

These are ruthless, violent criminal organizations——

Ms. ESHOO. But is it "yes"——

Mr. DELENA [continuing]. That are involved in——

Ms. ESHOO. We know they are ruthless. I mean, my God. But is it "yes" or "no"?

Mr. DELENA. They use violence, guns of all——

Ms. ESHOO. So it is "yes"?

Mr. DELENA. Yes.

Ms. ESHOO. OK.

If the cartels had less access to American guns, would that diminish their strength and their firepower?

Mr. DELENA. Anything that we provide them——

Ms. ESHOO. I think it is obvious, but I want to hear what you think.

Mr. DELENA [continuing]. Less access to—exactly. Thank you.

Ms. ESHOO. Uh-huh.

If the cartels were weakened, would that reduce the amount of illicit fentanyl coming into the United States from Mexico?

Mr. DELENA. Our focus is to defeat them, not just weaken them, but——

Ms. ESHOO. But is it "yes"——

Mr. DELENA [continuing]. Defeat those two cartels.

Ms. ESHOO [continuing]. Or "no"?

Mr. DELENA. Yes. Yes.

Ms. ESHOO. OK.

To Dr. Gandotra, as I said in my opening statement, only 11 percent of people who need substance use treatment receive it. So that is a very small number of people in our country.

Hopefully the number is going to grow soon, given the MAT Act that we passed that was signed into law. It is going to allow more doctors to prescribe medication-assisted treatment.

As quickly as you can, what are both SAMHSA and ONDCP doing to educate the providers about the MAT Act so that we can expand the access to medication-assisted treatment?

And if you can give us a specific, so that we have a clearer handle on what you are doing.

Dr. GANDOTRA. Thank you for the question.

Certainly SAMHSA, HHS, and our Federal partners at ONDCP and DEA are working together quickly to provide providers with education and direction.

Ms. ESHOO. Yes, but what are you doing? Give us an example. When you say we are working to provide, what does that mean?

Dr. GANDOTRA. Well, we are having regular meetings to coordinate frequently asked questions. There has been a letter that has been sent out to DEA registrants. Certainly we are working with the professional societies to perform a framework of educational priorities and competencies for providers.

We have been reaching out to all of our stakeholders—States, the State opioid treatment authorities, as well as providers themselves—so that they can have the education. There are updates on our web pages, both for ourselves as well as for our colleagues at the DEA.

Mr. CHESTER. Ma'am, I think my colleague from SAMHSA has summed it up well in terms of implementation, but let me just add that it is critically important that the elimination of the X waiver created the opportunity for physicians to be able to do this. Through greater education through SAMHSA and others, they are creating the willingness of physicians to be able to prescribe this very necessary drug as well. And SAMHSA is doing great work in that regard.

Ms. ESHOO. I think it is important to note here, as we talk about the need for medication-assisted treatment, how few in our country receive it today; what our goal is, certainly, with the new law; that Medicare currently covers an estimated 1.7 million beneficiaries with substance use disorder. That is Medicare, which may be surprising to some people. You think of older people, there is addiction there that—it is a disappointment and a surprise. And Medicaid—Medicaid covers about 6 million people with substance use disorder.

So I would say to my Republican friends that, as there is a nexus between debt ceiling and cutting Medicare, watch it. Because these are people that need, absolutely have to have this coverage.

With that, I yield back, Mr. Chairman.

Mr. GUTHRIE. The gentlelady yields back.

Mr. Burgess from Texas is recognized for 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

I wasn't going to bring this up, but the ranking member and the ranking member of the full committee have provoked me on this.

Look, cuts to Medicare over the past 2 years have been staggering. And you talk to any practicing physician out in the country and ask them, "Have you felt the effect of Medicare cuts in the last 2 years?" and the answer will be, "Absolutely, yes."

Now, the American Rescue Plan—actually, one of the pay-fors of the American Rescue Plan was a sequester on Medicare. Yes, Congress has put a stay on that sequester, but that looms out there as a budget item in the future. The Inflation Reduction Act—$300 billion of Medicare cuts to pay for money to go to insurance companies.

So, please, let's be careful about our language here, because it does matter.

But we have a very important issue at hand.

And, Mr. DeLena, thank you so much. Your testimony was very powerful. Your written testimony is some of the most disturbing that I have read since I have been on this committee, and that goes back to 2005.

I am grateful that you are working with the State Department. You referenced the State Department's International Narcotics Control Strategy Report. So I am encouraged by that.

What is concerning to me is the next paragraph. You say, "DEA has been willing to engage the People's Republic on fentanyl-related substances and precursors. However, due to diplomatic tensions between the United States, the People's Republic of China, the government"—I assume that is the PRC Government—"has suspended all counter-narcotics cooperation with the United States."

Is that an accurate statement?

Mr. DELENA. Congressman, thank you for your question.

DEA is working in China to stop the illicit flow of those precursor chemicals that are ending up in the hands of the two cartels, the Sinaloa Cartel and the Jalisco Cartel. We know that, every day, chemicals, precursor chemicals, are leaving China. China doesn't have a know-your-customer rule, or there is no oversight of any of that stuff that is ending up in Mexico.

And we also know that in China and throughout China there has been a dramatic increase in money-laundering activities as another way to get back involved with those two cartels, essentially undercutting all the other traditional forms of money laundering that had occurred up until now.

But the relationship right now, we know that China needs to do more to get more engaged.

Mr. BURGESS. Yes. There is the understatement of the year: "China needs to do more."

I mean, these are chemical weapons that are being dispatched into our country to kill our young people at a rate greater than 100,000 a year. Is that a fair statement that I have just made?

Mr. DELENA. Thank you for the question.

The chemicals, the precursor chemicals, that are essentially leaving China are ending up in Mexico, where those two cartels are mixing them in these clandestine laboratories into the synthetic drugs. And it has become a limitless supply now that we have, you know, switched to synthetics versus plant-based drugs.

Mr. BURGESS. So a terrorist organization producing weapons of mass destruction that are coming into our country, it seems like we would do everything within our power to disrupt them financially under tools that are already in existence probably dating back to the PATRIOT Act after 2001.

So are we disrupting the financial instruments that are available to chemical precursors in China and the cartels in Mexico?

Mr. DELENA. Thank you for the question.

As a law enforcement agency, DEA has taken a network approach to try to fully map and analyze and identify where these cartels are operating. They are operating throughout the entire

United States, obviously, and throughout Mexico but also in 40 countries around the world.

It is our goal to absolutely infiltrate and defeat those cartels as they exist.

Mr. BURGESS. Well, let me give you a mission statement, then: Follow the money. Because I think, in this case, it is extremely important. And, further, disrupt the ability to continue to fund this operation.

I mean, it is great we are doing harm reduction. And I would go back to Nancy Reagan's "Just say no." I think that was the greatest harm reduction that was made available to the country, back in the 1980s. But if we do not disrupt the financial instruments that allow this warfare to continue, we can't win. You can't—you can't harm reduction your way out of this problem.

And let me just ask you this as one last thing. We hear over and over again, "Well, it is not—you know, people coming over the border is really not the problem. It is points of entry." But it is the removal of Customs and Border Protection and even some of your agents, having to handle these vast numbers of people that are coming across the border illegally, and deflecting them from other activities that might be used to interdict fentanyl and even agricultural products that shouldn't be coming into this country. Is that something that concerns you?

Mr. DELENA. Thank you, Congressman.

I think, specific to your question, it is probably best served for the Department of Homeland Security and their components who actually control the border and those points of entry.

Mr. BURGESS. They don't control the border is precisely the point.

Thank you, Mr. Chairman. I will yield back.

Mr. GUTHRIE. Thank you.

The gentleman yields back.

We are going to try to stick to 5 minutes. We have two panels today. So I know we had a couple run over. I want to try to get on to sticking to the 5 minutes.

So next up is Mr. Sarbanes from Maryland. You are recognized for 5 minutes.

Mr. SARBANES. Thanks very much, Mr. Chairman. And congratulations on taking up the leadership of this subcommittee.

I want to thank all of you for your testimony today. You have responsibility for a broad set of initiatives. And, in particular, I want to thank your agencies for their work to combat the mental health and behavioral health crises that we see. We know that there is an intersection of those crises with the addiction crisis across this country, so that is a very important part of our response.

Last Congress, I was proud to work with colleagues on our committee to enact legislation that provided increased funding for mental health programs and reauthorize several key mental health and substance use disorder programs, including legislation I helped sponsor to bolster two programs that provide care for children and adolescents.

Both of these programs—the first one, the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Program—and let me break that down, because that is a mouthful. Comprehensive community mental health serv-

ices—so the idea that we have to take a holistic approach to this and make sure that it is a full community response—with children who have serious emotional disturbances, so that is the particular audience that it is being addressed to. The other program, the Youth and Family TREE Program. These are administered by SAMHSA, which has been working closely with the Biden administration to implement evidence-based policies and programs that save lives.

Dr. Gandotra, in your testimony, you note that many of the recent actions taken by Congress and the Biden administration have had a measurable impact on mental and behavioral health outcomes.

For example—and this is pretty remarkable—you note that the recent expansions in care through Certified Community Behavioral Health Clinics, which is an important part of the infrastructure in this area, have achieved a 74 percent reduction in hospitalizations and a 69 percent reduction in emergency department visits, not to mention a 31 percent increase in individuals' mental health functioning in everyday life.

So there has definitely been a very positive response to these programs. It is remarkable progress. We have to keep building on the success.

I do want to say that in Maryland we are working very hard to combat an acute crisis we face in pediatric mental health access, which has left far too many families struggling to find mental health care for their children, many of whom have been forced to remain in emergency departments or were turned away from care when they need it most.

Governor Moore, recently inaugurated in Maryland, has deemed addressing health issues as a core priority of his administration and proposed an investment of almost $1.5 billion in mental health care services in Maryland this year.

Dr. Gandotra, can you further explain how the recent investments in mental health through the Bipartisan Safer Communities Act and the bipartisan mental health package that I referred to are making a real difference in communities and why it is so important that we continue to invest in these programs?

Dr. GANDOTRA. Thank you, Congressman, for your question.

And, certainly, investing in children's mental health pays dividends for the community, for services throughout not just Maryland but throughout the country. We have seen investments really pay dividends with regard to improved functioning in school, decreased criminal justice involvement, decreased hospitalizations, decreased emergency department use.

As far as resources, SAMHSA's resources really do leverage a number of educational activities in terms of providing schools, counselors, teachers, as well as community organizations with the tools they need to help identify mental illness, prevent conditions before they worsen, and provide them with resources to link patients to treatment.

Also, we like to enhance the services we already have, by providing culturally competent workforce educational products as well as an ensuring individuals who are identified early are not only

linked to the right treatment but the appropriate level of care. That is also done with crisis management services as well.

Mr. SARBANES. Thanks very much.

I am out of time. I was going to ask you about telehealth also being a means of expanding access. I know that is very important. We want to continue to explore the opportunities there.

With that, Mr. Chairman, I yield back. Thank you.

Mr. GUTHRIE. I thank the gentleman for yielding back.

The Chair now recognizes Chair McMorris Rodgers for 5 minutes.

Mrs. RODGERS. Thank you, Mr. Chairman.

In 2019, China permanently scheduled all fentanyl-related substances. They were the first country in the world to do so. So far, the United States has stopped short of doing the same. A permanent American solution, like passing the HALT Fentanyl Act, is necessary.

Mr. Chester, can you discuss our working relationship with China to prevent the entry and sale of fentanyl and its analogs?

Mr. CHESTER. Thank you for the question, Congresswoman. Our relationship with the PRC doesn't move in a straight line, but as you point out, we have, in the past, had success in dealing with the PRC, specifically the class scheduling of fentanyl that we asked them to do that they announced in 2019, and a couple of things happened when that occurred.

The first one was, shipments of finished fentanyl directly from the PRC to the United States, principally through mail and express consignment, dropped to almost zero where they remain today.

Traffickers moved from the business of finished fentanyl to the precursor chemicals that they supply to manufacturers within Mexico, and Mexico became the locus of illicit fentanyl production.

We have worked with the PRC on a number of issues in terms of accountability and the prevention of the diversion of illicit chemicals, pill presses, better oversight over the shipping companies.

And while it is true that within an environment of competition, there are some areas of cooperation and that the PRC stepped back last summer from many of them, we continue to have contact with the government of the PRC, and we continue to call upon them to partner with the United States on a global level because they share a large portion of the task in dealing with this issue.

Mrs. RODGERS. Would you speak to how they are enforcing this ban on fentanyl and fentanyl-related substances in China, and what mechanisms do we have to hold China accountable to its commitment to ban the export of fentanyl in its analogs?

Mr. CHESTER. Within the PRC, their Ministry of Public Security and their law enforcement organizations take the issue of fentanyl trafficking very, very seriously, and in fact, when they announced in May 2019 that they were scheduling all fentanyl-related substances as a class, that September they invited members of our embassy over to witness the sentencing of 10 fentanyl traffickers.

And this was remarkable because, not just a year before, the government of the PRC had told me that no fentanyl was coming from the PRC. So what that tells us is, they take it very seriously.

We do have the opportunity to have progress, and when the government of PRC takes this issue seriously, they can do very, very good things. What we are asking them to do now is exert more oversight over their shipping industries and their chemical industries——

Mrs. RODGERS. Yes.

Mr. CHESTER [continuing]. That divert these chemicals for production.

Mrs. RODGERS. Right. It is frightening how many plants in China are producing the chemicals.

Mr. CHESTER. Yes, ma'am. There are about, we are told about 160,000 chemical plants, but the issue is that they are diverted on their way out of the country, destined for unknown and undeclared customers in Mexico who use them to produce the fentanyl-related substances.

Mrs. RODGERS. Have any other countries permanently scheduled all fentanyl-related substances?

Mr. CHESTER. I believe not, but I will get you that definite answer, ma'am.

Mrs. RODGERS. OK. Mr. DeLena, offenses prosecuted under classwide scheduling can trigger a mandatory minimum of 5 years for 10 grams or 10 years for 100 grams of a drug mixture containing a detectable amount of fentanyl analogs.

To put it into perspective, how many grams are fentanyl are lethal?

Mr. DELENA. Congresswoman, thank you for the question. DEA estimates about 2 milligrams is a potentially lethal dose. That is about enough to fit on the tip of a pencil.

Mrs. RODGERS. And then what is a lethal dose of carfentanil, which is a fentanyl analog?

Mr. DELENA. Thank you, Congresswoman. I would have to defer to some of the scientists and lab folks at DEA, but I can get you that exact, specific answer.

Mrs. RODGERS. Well, bottom line—bottom line—we know that there is enough fentanyl now in the United States to kill every person seven times over, and so it is a huge amount of fentanyl that has come into the United States.

And it is lethal, and it is impacting those that are addicted, but it is also impacting people who don't know even what they are doing or what they are taking, some of these pills that are laced with fentanyl.

And so I really just appreciate all you being here. We are committed to taking action to ensure that we are doing everything we can to keep fentanyl and fentanyl-related substances off our streets. It is destroying families, individuals, and communities all across this country, so thank you. I yield back.

Mr. GUTHRIE. I thank—the Chair yields back. The ranking member, Mr. Pallone from New Jersey, is now recognized.

Mr. PALLONE. Thank you, Chairman.

One bill that would have been a great addition to this hearing today is the Medicaid Reentry Act, and this bipartisan legislation would extend Medicaid eligibility to incarcerated individuals back to 30 days prior to their release. So let me start with Dr. Gandotra.

It is my understanding that individuals newly released from incarceration are at a much higher risk of overdose than suicide. Can you describe some of the reasons for that?

Dr. GANDOTRA. Thank you for the question. And as you accurately describe, individuals who are reentering society from incarceration are at higher risk for overdose, in particular, because during their incarceration, their tolerance levels have changed, and when they reenter society and they use again, they are much more likely to overdose if they previously—amounts that they had previously used that they were tolerant to.

So it is vitally important that these individuals engage in treatment, both prevention and recovery services as well as evidence-based treatment, well before they are actually released.

The most important aspect of that is the transition planning. There are certainly models that have been successful, such as the sequential intercept model, which not only encourages transitional planning by jail and end-reach providers but also can facilitate other resources that are necessary for success—social determinants of health, case management, resources that will be needed.

Sometimes a warm handoff and actual conversations with the service providers in the communities can really go a long way towards reducing mortality for those reentering society.

Mr. PALLONE. And the problem now, Doctor, is that they are not eligible for Medicaid under the law now until they leave prison, and then oftentimes we can't even find them to tell them to sign up or whatever, correct?

Dr. GANDOTRA. So certainly there are treatment gaps that need to be addressed, particular coverage gaps with regard to remuneration of services, but the prescriptions themselves, having those before they leave, having a contact, peer recovery support specialist in the community that can help connect them and keep them connected to treatment, because we know the treatment retention yields better outcomes.

Mr. PALLONE. All right. Now, I wanted to shift to Mr. Chester. In order to conduct quality research, investigators need access to fentanyl analogs as they might be useful in enhancing current treatments or developing new ones.

A key component of the administration's proposal involves how FRS are classified, or subsequently reclassified if found to have a lower risk profile. Can you explain the importance of the provision for off ramping and FRS?

Mr. CHESTER. Thank you, Congressman. That was a key component of the administration's proposal when it comes to fentanyl-related substances. So the first step is to scoop these substances up and make sure that Americans don't have access to them, that they can't be harmed.

But the second one is what you say, to determine two things: if those substances may have some medical merit, and what their qualitative effect is on the body. And it is critically important for researchers to be able to, even though they are in Schedule I, to have access to them.

And part of the proposal for FRS was not only FRS, but all Schedule I drugs, actually reworking the process by which re-

searchers can have access to Schedule I drugs for the purposes of research.

Mr. PALLONE. All right. Now, I am just going to rush through this because there is only about a minute left. What is your understanding of how the current administration's proposal differs from the HALT Fentanyl approach, and is the administration's approach evidence based? Why is it important to use evidence-based approaches when it comes to scheduling of FRS?

Mr. CHESTER. So on the first part, I apologize, I can't take a position on a specific piece of legislation, but what I can say is, the administration's proposal was comprehensive, and it was a consensus-based proposal that came across the interagency, and it is evidence based. It is based on what we know about access to research, what we know about criminal justice outcomes, and also what we know about the trafficking of these substances.

Mr. PALLONE. All right. I appreciate that. Thank you, Mr. Chester, for helping us understand some of the differences, if you will, from what the current administration is proposing.

And I just want to say appropriately studying and categorizing substances is key to addressing the opioid and fentanyl crisis. So it is important that we understand the differences between these various approaches.

And with that, I will yield back, Mr. Chairman.

Mr. GUTHRIE. Thank you. The gentleman yields back. The Chair recognizes Mr. Latta for 5 minutes for the purpose of asking questions.

Mr. LATTA. Well, thank you, Mr. Chairman, and thanks to our witnesses for being here. First, I would just like to, once again, show people—well, this is from the DEA website that I have used back in our district.

This is the amount of fentanyl that will kill you when you are looking at it next to a penny, and I think it is really important to see that because, again, what everyone is up against in this country and how we are going to have to stop this, because—and the testimony again being today that 107,477 Americans that lost their lives last year.

And, Mr. DeLena, I really appreciate something you are saying. You are saying "poisoning" now. We are not talking about overdose deaths, we are talking about poisoning.

And that is something that came up in the roundtable that we had with family members and law enforcement. It is no longer overdose. This is poisoning.

And when you think about the—you mentioned 294 people died from drug poisoning every day in this country, and that, you know, what was interdicted, that we know of, is 7.5 million tons of fentanyl that came into this country—7½ tons, not millions, excuse me—7½ tons of fentanyl that came into the country. So I think it is really important that we keep that in line.

And something else I think is really important, I think, in your testimony. It is costing—it says in your testimony, you say, it costs the cartels as little as 10 cents to produce a fentanyl-laced fake prescription pill sold in the United States. That is what we are saying, then, is they can kill us for 10 cents—10 cents.

So when we talk about do we got a crisis on our hands, we are past a crisis in this country, and I know my friend from Texas asked some of the questions especially dealing with the PRC, but—and the paragraph before because, again, it is where these chemicals be coming in, when you talk about 160,000 chemical companies in the PRC and those that are distributing the precursor chemicals for use in fentanyl and meth.

The question, you know, right now is that since they are faking these labels as they are going from China to Mexico, we are talking to our Mexican counterparts, is there anything that they are—being done within Mexico to try to find these fake labeled shipments as they come through?

Mr. DELENA. Congressman, thank you for your question, and to address the first part of it with drug poisonings, DEA—and I have been a part of it—has met with family members that have lost loved ones. We had 22 family summits, where we met with families who have lost loved ones, and, you know, we hear from them every day, you know, the pain and suffering that is caused by this drug, fentanyl.

And it truly is a poisoning, that is how we look at it now, that it is Americans that are being poisoned across the country.

To talk about the chemicals that you ask about, these Chinese chemical supply companies, there is no oversight or know-your-customer rule, and as you said, they are shipping these precursor chemicals into Mexico all the time.

We know, on one side, China needs to do a lot more, and we know the same has to happen in Mexico. The Mexican Government needs to do a lot more to enforce what is coming into that country and work with us to try to defeat these two cartels.

Mr. LATTA. Great. Let me follow up on, because, again, when you look at the, prior to 2018 with fentanyl, and what we want to do, my good friend from Virginia and I and our legislation on HALT Fentanyl, again, what will having it permanent because, again, you know, you always—you talk in your testimony about the temporary scheduling order 8 times. How will this bill help you on the crisis that we have with fentanyl?

Mr. DELENA. Thank you again for the question. The permanent scheduling will allow DEA to arrest and seize when we encounter fentanyl-related substances wherever that happens.

We also know that with classwide scheduling, there has been less production of different analogs. It is just not worth the chemical brokers and chemists in Mexico when they are making this substance, when they know it is a classwide, you know—it is illegal classwide, there is no benefit for them to try to create new substances.

Mr. LATTA. Well, again, I appreciate, you know, the work that you are doing because, again, we need to get this legislation across the finish line because we want to stop this horrendous rise in deaths across this country. And it has got to happen now.

So, Mr. Chairman, I yield back the balance of my time.

Mr. GUTHRIE. Thank you. The gentleman yields back.

The Chair now recognizes Mr. Cárdenas of California for 5 minutes for asking questions.

Mr. CÁRDENAS. Thank you very much, and congratulations, Chairman Guthrie. I have always enjoyed working with you and looking forward to working with you as the chairman of this very important committee.

And also to Ranking Member Eshoo, thank you so much for your diligent work, and I have enjoyed working with you, and this committee is going to hopefully do much, much good work over these next 2 years.

Before I ask my questions, I just want to mention a few words—Purdue, the Sackler family, and crime pays. Still one of the richest families in the world. Where did all this start and who was a big part of where we are today.

Dr. Gandotra, thank you for joining us today and for sharing your informative and valuable expertise on mental health policy.

As you are aware, HHS recently implemented the 988 hotline, a potentially life-saving service for individuals experiencing mental health crises, spearheaded by my colleague here, Congressman Sarbanes.

Thank you so much for everything you do in the space of mental health.

While there is much work to be done, I believe that the promise of 988 and the momentum—excuse me—the continuum of crisis care built around it, offers some much-needed hope for those struggling with their mental health.

However, in December the 988 hotline experienced a service interruption after a suspected cyber attack on Intrado, a large telecommunications company that provides services to Vibrant, the administrator of the 988 hotline.

The bill before us today, which I am co-leading, aims to prevent this from happening again. In the wake of the December Intrado service outage, how is SAMHSA mitigating the risk of similar incidents and hoping to keep that from happening again? Can you put your microphone just a little closer? Thank you.

Dr. GANDOTRA. Sure. Thank you, Congressman, for your question, and also for the ongoing support for the 988 program. And I would like to first state that our highest priorities are to develop additional redundancies in the event of any future outages.

While minimizing the likelihood of such events, we want to continue to protect personal information and be sure that there is clear communication protocols among the partners and the public. We certainly owe the public trust when it comes to their personal information.

We also want to be able to continue to expand services and understanding that when these problems arise, we want to quickly resolve them and provide clear guidance on where and how to seek help. Certainly, clear communication and protocols between the partners and public is going to be paramount.

Mr. CÁRDENAS. Are more resources needed, and do you appreciate Congress actually providing more resources in the future?

Dr. GANDOTRA. Well, we thank Congress for the investment certainly as we recognize that mental health crisis services are always needed. As there has been a growing need recognized, not just in the past years, but throughout the past decade, we would appreciate all the support the Congress has given us.

Mr. CÁRDENAS. Thank you. I look forward to working with you and SAMHSA on improving 988 and getting it to where it should be in the future.

I also want to take a moment to discuss our policy around fentanyl and fentanyl-related substances. Overdose deaths are skyrocketing in this country, and I share my colleagues' horror at the devastation we have seen at the hands of the fentanyl crisis.

But among other things, this is a complex, multifaceted public health crisis that requires a robust public health response. And candidly, I am concerned that this class-wide scheduling approach sets a precedent of guilty until proven innocent.

The proposal put forth by my Republican colleagues goes all in on applying harsh Federal penalties, but lays almost no groundwork to test for the potential harmlessness of these fentanyl-related substances, or even their potential therapeutic value.

We could be overlooking the next naloxone, which has saved countless lives from opioid overdose because our focus is solely punitive, and I think that is a grave error with immense consequences. The responses are usually multifaceted, but not simple.

Mr. DeLena, under the current classification system, what kind of resources have you allocated toward testing the effects of Schedule I compounds which may have medicinal purposes?

Mr. DELENA. Congressman, thank you for the question. DEA is open to the testing of Schedule I substances. It is our partners at HHS that conduct those type of tests, and as I said, we are open to Schedule I testing and research for any scientific need, and for any medical evaluation that could come out of it.

Mr. CÁRDENAS. OK. Thank you so much. My time having expired, I yield back.

Mr. GUTHRIE. Thank you. The gentleman yields back, and now Mr. Griffith is recognized for 5 minutes for the purpose of asking questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

There is some confusion about the HALT Fentanyl Act that I am hearing in some of the questioning and in some of the statements that have been made. The Act does, in fact, include the ability to do research and makes it easier to get through the pathways to get research done.

On some of those—and to our colleagues on the other side of the aisle, they held a great hearing earlier, last year, sometime last year. If memory serves me correct, there are approximately 48,000 potential analogs to fentanyl, of which, we have looked at somewhere between 30 and 40.

But that is a—you know, if you want more research, this makes it easier, and we probably need to get the appropriators to appropriate money to go in that direction, if that is the intent.

But we are—the bill does allow for more research. I have been a big advocate for researching substances and their potential medical use since I came to Congress.

Also, Mr. Chairman, I would request unanimous consent for the introduction of a letter for the record from the Peace Officers Research Association of California, representing 75,000 public safety members and 930 public safety associations which expressed their support for the HALT Fentanyl Act.

Mr. GUTHRIE. Any objections?

Seeing none, so ordered.

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

Mr. GRIFFITH. And from that letter, Mr. Chairman, they say, as the law enforcement community continues working to reverse these trends, the HALT Fentanyl Act would help to bolster the efforts by ensuring current Schedule I classification of fentanyl under the Controlled Substances Act does not expire. So there is that.

Let me ask a couple other things that I thought was interesting. Mr. DeLena, you indicated that because of the temporary ban, it is not worth it to the cartels to work on the analogs. That implies, and I believe it was happening, is that when there wasn't—when the analogs were not illegal, they were looking for analogs that would be legal, that they could get around the laws and not face criminal punishment in the United States by importing these poisons into our country. And this has actually helped stop that.

It may not have stopped the fentanyl deaths, and certainly this is only one part of a complex answer. But I am I correct that they were looking for other ways so they could avoid criminal punishment, yes or no?

Mr. DELENA. Thank you for the question. We have actually seen that play out before where they can flip one molecule and keep moving it along. With the class-wide scheduling, it is just not beneficial for them to do that.

Mr. GRIFFITH. And I appreciate that. I am going to switch gears for a second, Doctor, and I hope I am saying it right, Gandota, Gandotta?

Dr. GANDOTRA. Gandotra.

Mr. GRIFFITH. Gandotra. In a recent study published in the Journal of the American Medical Association, they said there was no evidence that telemedicine has actually expanded access to care for opioid use disorder.

They also found that telemedicine opioid use disorder patients tended to be more concentrated in higher income metro areas. And I am a big believer in telemedicine, so what do you think we can do to expand access to more rural areas like mine?

Dr. GANDOTRA. Thank you, Congressman, for the question. Certainly SAMHSA is committed to expanding treatment access for medications for opioid use disorder. We have heard from numerous stakeholders, in particular, from rural areas or from our State opioid treatment authorities.

Mr. GRIFFITH. So you are going to work with us on that?

Dr. GANDOTRA. Yes, sir.

Mr. GRIFFITH. All right, I appreciate that.

Buprenorphine. Now there is no limit on the number of doctors prescribing, but even before that—or the number of patients that a doctor can have to prescribe, but even before that, it was starting to become used as a street drug in a couple of my counties.

Are we monitoring to see if this is going to be a national trend? Are you all looking at that as a possibility? Because apparently, it is happening, according to some of my law enforcement folks.

Dr. GANDOTRA. Certainly expanding medications for opioid use disorder including buprenorphine is one of our goals for——

Mr. GRIFFITH. Well, I want to know if we are looking to make sure that we are not creating a new street drug.

Dr. GANDOTRA. We are certainly—we are certainly educating providers——

Mr. GRIFFITH. Mr. DeLena, you too? You are all looking at this?

Mr. DELENA. Thank you, Congressman. Absolutely. Any threat that is posed to the American public, DEA will continue to monitor.

Mr. GRIFFITH. And have you seen any uptick in buprenorphine being used as a street drug?

Mr. DELENA. Again, thank you for the question. I can't speak to that. I have not seen that in the area that I came from. My last assignment in New England, we did not see that trend.

Mr. GRIFFITH. All right. And I am running out of time, so last question. Got all these cartels in Mexico. Is the Mexican Government capable of defeating those cartels on their side of the border?

Mr. DELENA. Thank you for the question. Those two specific cartels, Jalisco and Sinaloa, that are causing all of this harm are operating virtually with impunity. We need the Mexican Government to lean in and do a lot more.

Mr. GRIFFITH. But right now, they can't do it, can they?

I yield back.

Mr. GUTHRIE. Thank you. The gentleman yields back.

The Chair now recognizes Dr. Ruiz for 5 minutes for questions.

Mr. RUIZ. Thank you. As an emergency physician, I have seen time and time again the devastating and often fatal effects of drug overdose. Fentanyl, in particular, continues to wreak havoc on our communities.

The most recent data from CDC shows that 67 percent of all overdose deaths in the U.S. involve synthetic opioids like fentanyl, and DEA Administrator Ann Milgram called fentanyl, quote, "the single deadliest drug threat our Nation has ever encountered," unquote.

Over the past several years, this Congress adopted many policies to try to stem the tide of the substance use crisis and increase access to prevention, treatment, and recovery services.

However, still more needs to be done. I think it is critical to remind everyone that substance use disorder is a disease, and it needs to be treated as such. This means we need to focus on greater access to harm reduction programs and increase efforts towards prevention.

I approach this disease like I would any other, addressing how to get someone well after they are sick, but also how to prevent them from getting sick in the first place.

Our healthcare system is good at healing the sick, but often too frequently ignores or undervalues prevention so that people don't get sick in the first place.

So on that note, I would like to talk about the HHS overdose prevention strategy and what it is accomplishing in this regard. The strategy involves four priorities: primary prevention, evidence-based treatment, harm reduction, and recovery support.

This is especially important among youth as recent data from the nonprofit group Families Against Fentanyl suggested children under 14 are dying a faster rate than any other age group.

So we know you can't incarcerate a public health problem from ending, and you also got to think through how—that, you know, the focus is on the drug cartels moving drugs over, but how about those who have the disease of addiction who are also fueling that through the enormous demand on our side?

So, Dr. Gandotra, what are the interventions and early prevention strategies used in the overdose prevention strategy to address opioid use, particularly among youth.

Dr. GANDOTRA. Thank you, Congressman, for that question. Certainly the prevention pillar is important in terms of the overdose prevention strategy. Our strategic prevention framework is one of our major grant programs that allows for community organizations, States themselves, and local jurisdictions, to identify the problem, also identify then the resources they have in terms of capacity.

Mr. RUIZ. Well, identifying a problem is not necessarily prevention because there is already a problem. So how do you prevent it from becoming a problem?

Let's say a school wants to start a program. Where can they go to get information or resources and moneys to create education outreach to prevent this from happening?

Dr. GANDOTRA. So SAMHSA's Block Grant Program—substance use Prevention Block Grant, has a 20 percent set-aside where the local jurisdictions can determine what is best suiting their needs. That 20 percent set-aside has been incredibly effective for schools and community organizations.

Mr. RUIZ. Can you explain the concept of harm reduction and what that means in practice?

Dr. GANDOTRA. Certainly. Harm reduction is a practice that utilizes the principle to meet the patient where they are, to reduce the morbidities, or negative aspects of use.

This may mean that individuals who may not be necessarily ready to engage in full treatment can still mitigate some of the effects of their use. In particular, harm reduction can involve naloxone administration for preventing overdose, as well as fentanyl test strips for drug testing to allow for individuals to determine how safe the product is that they have in their hand.

Those are just two examples, and there is a number of other harm reduction interventions that can be utilized.

Mr. RUIZ. Thank you. And how does the strategy address helping people after they receive treatment for SUD? Or how important is it to facilitate a safe recovery environment?

Dr. GANDOTRA. So thank you for that question, and for really highlighting the part that individuals who engage in harm reduction are much more likely to later engage in treatment, and be retained in treatment.

You have to reach patients where they are, where they are willing to actually engage with you. That means that if they are able to stay alive, you can treat them later. If you can't keep them alive, then there is no way that they can be engaged in treatment. So, certainly, the naloxone administration is a big aspect to that.

Mr. RUIZ. You know, I got to also mention that this illness of addiction is not just for the individual, but it is for their family, for their neighborhood as well, and treatment needs to go toward a family-based, home-based, community-based treatment programs

for prevention and also harm reduction. Thank you. I yield back my time.

Mr. GUTHRIE. Thank you. The gentleman yields back.

The Chair now recognizes Mr. Johnson for 5 minutes.

Mr. JOHNSON. Well, thank you, Mr. Chairman. First I want to say how excited I am to have been selected to serve on the Health Subcommittee. Healthcare is such an important issue in my rural Appalachian district, everything from cost to quality to availability, and I look forward to working on these important issues under your leadership, with all of our colleagues.

For today, however, I want to read some excerpts of a letter I received from a constituent yesterday right near my home in Washington County, Ohio. The letter is from a grieving mother of a young man named Jason who tragically died exactly 2 years ago yesterday, January 31st, 2021.

Jason's mom wrote to me and said, Jason was prescribed Vicodin by our family doctor after a car accident. Why wouldn't we trust it? Our doctor prescribed it. Our son had a couple of relapses after a stint in the Marines and some college, but we had good insurance and a medication-assisted treatment helped him pick up the pieces.

His relapse in September 2019 set the stage for a terrible, 15-month battle to save our son's life. By the time we were in the throes of COVID in March 2020, our son was in the worst of his disease.

She then went on to say, his drug of choice was heroin, and now that drug is laced with fentanyl. It was the first time I realized he was most likely going to die.

Fentanyl is a game-changer, she said. She closed with this. Jason was so much more than simply addicted. He was loved by so many, especially his own son, who we are now raising.

My friends and colleagues, this grieving mother is right—fentanyl is a game-changer. We are in entirely new territory now compared to when we started confronting what we called at the time the opioid epidemic, particularly in rural areas, like where I live.

So, Mr. Chester, let me start with you. Thank you for being here. The 2021 Drug Free Communities report highlights that close to 98 percent of Drug Free Communities coalitions address prescription opioids.

But only just over half address fentanyl, fentanyl analogs, or other synthetic opioids. And as we know, an increasing number of overdose deaths are attributed to synthetic opioids like the situation I highlighted.

The victim started with prescription opioids but moved on to heroin and then an accidental, extremely potent, and fatal fentanyl overdose.

Why does this disparity exist within the Drug Free Communities program? Does ONDCP plan to revisit their efforts and strengthen its response to synthetic opioids?

Mr. CHESTER. Thank you very much for the question, and we all are incredibly sorry for your constituent and the many others——

Mr. JOHNSON. I got another question so if you could answer that one.

Mr. CHESTER. Yes, sir. The Drug Free Communities program, the more than 700 grantees, their programs are locally designed based upon local conditions, and there is not a single Drug Free Communities overlay over all of them.

Mr. JOHNSON. Yes, but the fentanyl crisis and synthetic opioids is a nationwide problem. How can only half of them be digging into that area?

Mr. CHESTER. And the Drug Free Communities grantees decide based upon their local conditions what they want. Now, we do manage the program in cooperation with others, and we will absolutely be glad to address that. But the Drug Free Communities Program is centered at the community level.

Mr. JOHNSON. OK. I have got one question for you, Mr. DeLena. Some say the problem with class wide bans is that potentially thousands of compounds are defined solely by their chemical structures without regard for their pharmacological activity.

It is my understanding that the DEA looked at more than structural similarity when arriving at the definition of fentanyl-related substances. Can you explain to our committee what structure activity relationships are?

Mr. DELENA. Congressman, thank you for the question. Unfortunately, I am focused on the enforcement side. That is my background and where I come from, but we do have scientists and experts that handle that. I would be happy to take that question back.

Mr. JOHNSON. Are you happy—my time has run out, Mr. DeLena. Can you get back to your organization and those scientists and get us some information on that?

Mr. DELENA. We would be happy to. Thank you.

Mr. JOHNSON. OK. Thank you.

Mr. Chairman, I yield back.

Mr. GUTHRIE. The gentleman yields back.

The Chair now recognizes Ms. Kuster from New Hampshire for 5 minutes.

Ms. KUSTER. Thank you, Mr. Chairman, and thank you to the witnesses joining us today for your testimony. In particular, I want to thank Mr. DeLena who has been such a great resource for us in New England. I really appreciate our work together.

I am cochair of the bipartisan Task Force on Mental Health and Substance Use Disorder with my Republican colleague, Brian Fitzpatrick, and David Trone of Maryland.

And we are all grateful for the progress that this committee made in the 117th Congress, passing important mental health and substance use disorder legislation and, in particular, the Restoring Hope for Mental Health and Well-Being that I might add passed the House with 402 votes. I think it was probably the most bipartisan bill in the 117th Congress.

But as we all know, there is much more to be done. I am working closely with my colleague from Delaware, Congresswoman Blunt Rochester, to reintroduce our legislation, the STOP Fentanyl Act, and I hope that the Chair will bring that up in a subcommittee on a future date.

This bipartisan bill was introduced in the 117th to invest in fentanyl detection and data collection, stem the supply of fentanyl,

and address demand for synthetics through overdose prevention and substance use disorder treatments.

As Mr. Chester's testimony stated, fentanyl is a complex national security, criminal justice, and public health challenge that requires a multifaceted approach, and that is why the STOP Fentanyl Act devotes resources to enhance fentanyl surveillance, empowering officials at the State, local, and Federal level, to support detection and reporting.

We must continue to aggressively pursue the sources of fentanyl that have been described here today, stopping the flow of materials for synthetic drugs into this country, and cutting off the paths that bring these harmful substance into our communities.

This bill supports efforts to hold bad actors accountable both at the international governance level and with the social media companies that our families and friends use every day.

As the experts in this room know, a public health approach much be complemented by a well-resourced, data-driven plan to stem the supply of fentanyl. STOP Fentanyl is the path forward to respond to the challenges before us.

I look forward to hearing from my colleagues on this committee who are interested in a comprehensive approach to protect our companies from fentanyl—our communities. I ask for your partnership and support.

In order to best craft solutions, it is essential to definitively understand the problems. Mr. DeLena, it is great to be with you, and I wanted to ask you—you have seen how these issues affect communities like my district in New Hampshire, and the DEA has worked to prevent shipment through the postal system and crack down on chemists overseas as you describe—what is the top way that fentanyl enters the country, and where should congressional efforts be focused to complement your agency's work?

Mr. DELENA. Congresswoman, thank you for the question and for your work when it comes to fentanyl.

A majority of the fentanyl that is coming into our communities crosses the southwest border, predominantly through the ports of entry, but they use any possible way to get it across.

Ms. KUSTER. And, Mr. Chester, what role can HIDTAs play in expanding our surveillance and data collection efforts moving forward?

Mr. CHESTER. Our HIDTAs play a vital role because they are in all 50 States. They cover the vast majority of the population of the United States, and 99 of 100 major metropolitan areas. They are the one that can provide us the bottom's up information of what is actually happening in their communities, and they provide this information nationwide. They are an extremely valuable resource.

Ms. KUSTER. And is there coordination and sufficient resources for data collection and surveillance to know—I heard a reference to a new substance today that I wasn't even aware of, but to know when they are emerging threats?

Mr. CHESTER. Yes, ma'am. In fact, the HIDTAs are very valuable, not only do they work effectively in their own right, but they are networked together very well, particularly through their drug intelligence officers, who are able to share that information, and be

able to determine nationwide trends, based upon the local data that they are seeing from their particular HIDTAs.

Ms. KUSTER. I think that data collection and surveillance is going to be really important.

Dr. Gandotra, I am going to probably have to leave this question for the record, but once fentanyl enters our borders, how does SAMHSA work with first responders to educate on interacting with fentanyl?

Dr. GANDOTRA. Thank you for that question. I will point to our grant program, the First Responders—Comprehensive Addiction and Recovery Act that educates first responders, firemen, police officers, on how to administer fentanyl, how to recognize the signs for overdose, and how to link to care.

Ms. KUSTER. Great. Thank you. And with that, I yield back.

Mr. GUTHRIE. Thank you. The gentlelady yields back.

The Chair recognizes Mr. Bilirakis for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I appreciate it. Thanks for convening this hearing today.

I would like to start by briefly sharing a news story from my district in Florida, the Tampa Bay area, and also the nature coast.

Just last week, the Citrus County Sheriff's Office apprehended a long-time drug dealer who, as he attempted to flee arrest in his vehicle, threw a bag of drugs from his vehicle.

Having ruptured upon impact, the contents of this baggy were scattered throughout the grass shoulder. HAZMAT teams were deployed, and approximately 51 grams of fentanyl was collected, enough fentanyl to kill more than 25,000 people, believe it or not.

This, once again, highlights that we are in a crisis situation that deserves the highest amount of attention and response at every level of government, starting with the Biden administration.

It is clear they are not doing enough, and I am disheartened by the tragedies we are seeing on a daily basis. Headlines of toddlers, adolescents, young adults that have died already just 1 month into 2023.

Mr. Chairman, thank you for making this a priority.

Fentanyl coming into the country from Mexican cartels; fentanyl created with chemicals imported from China and India; enough fentanyl to kill every American in the country multiple times over.

Now I know there is no silver bullet as we all know that will solve this crisis right away, but Republicans on this committee are taking this threat seriously, and there should be serious doubts—zero doubts though—zero doubts or opposition permanently scheduling fentanyl-related substances to the Schedule I, again permanently.

And thank you for taking this on again, Mr. Chairman.

My question is to Mr. DeLena. You talk about the way these cartels are aggressively lacing other fake pills and distributing via social media networks. Can you tell us what your coordination is with social media companies, if any? How can you better improve communication to quickly respond to drug sales on these platforms?

Mr. DELENA. Congressman, thank you for the question. It is very clear that social media has become a superhighway for drugs. The role of these drug cartels and the drug trafficking organizations that work on behalf of them, they are advertising, actually com-

pleting sales and effectuating payment using these types of applications.

And we know that the social media companies who control the algorithms, they control the content that is driven to the users, and they control all of the data therein, can do more and must do more.

You asked about our interaction with them. We interact with these companies on a regular basis in terms of the investigations that we are conducting.

Mr. BILIRAKIS. How much cooperation are you getting?

Mr. DELENA. These social media companies, Congressman, need to do more. As I stated, they control all of that content, and there must be more transparency. There must be efforts for preservation of evidence.

There is applications that have disappearing stories. Twenty-four hours, you know, later, all of that information can be gone. I can tell you firsthand that the men and women of DEA who are—and our friends in law enforcement who are responding to these drug poisoning deaths, you know, the first thing they want to do is take steps to prevent another death from happening in that community.

And the way they do that is by identifying who that drug trafficker was that maybe sold those drugs to the decedent. If that information is gone, if there is no way that we can look at it, there is no steps that can be taken.

Mr. BILIRAKIS. Well, we must hold them accountable. In the spirit of being proactive and keeping pace to address new concerns on the horizon, I am also interested in addressing the drug xylazine, a tranquilizer drug with no approved medical use in humans. It is used for horses. It is used as a sedative and veterinary medicine, I understand.

Florida has led the way in addressing this by scheduling xylazine on the State level. It is time that we follow suit and do this federally since it is being discovered in fentanyl overdose deaths and has horrifying side effects on the human body and does not respond to naloxone.

Mr. Chester, what can be done to properly trace and track the presence of xylazine in our drug supply? How important is it to accurately pinpoint the drugs that are contributing to overdose deaths throughout the U.S.?

Mr. GUTHRIE. Thanks. Can we get that on the record so we can—can you give your answer on the record, do you mind?

I am sorry, your time is expired, and we are trying to get two panels through. So the gentleman yields back. The Chair now recognizes Ms. Kelly from Illinois for 5 minutes.

Ms. KELLY. Thank you so much, and I have one dilemma. Congratulations to you, Mr. Chair, and I want to thank Chairman Guthrie and Ranking Member Eshoo for holding a hearing on this very important topic.

We need to eliminate the racial and ethnic disparities that plague the overdose epidemic and the broader healthcare system, and I do believe we all agree on that.

Unfortunately, overdose deaths are beginning to rise even before the pandemic, and Black and Brown communities are experiencing the fastest increasing rates of overdose deaths involving synthetic opioids.

In 2020, drug overdose death rates increased by 44 percent for Black people, 21 percent for Hispanic people, and 39 percent for American Indian and Alaska Native people.

Moreover, access to opioid and substance use disorder treatment is lower in Black, Latino, and Asian communities.

We could go on forever in the remainder of this hearing, highlighting diseases and conditions for which people of color have higher incidences of illness and less access to healthcare.

Dr. Gandotra, what is SAMHSA doing to reduce disparities in substance use and mental health in the United States?

Dr. GANDOTRA. Thank you for that question, and certainly SAMHSA has recognized this issue as well. We require all new grant programs, recipients, to submit a data-driven disparity impact statement, outlining how they are going to address behavioral health disparities within their grants.

We also have several programs themselves to address closing equity gaps. In particular, we have the Tribal Opioid Response Program, which addresses the public health crisis caused by escalating opioid and stimulant misuse in Tribal communities.

We also have our Technology Transfer Centers, which disseminate information, specifically Technology Transfer Centers dedicated to American Indian and Alaska Native populations, and a separate one for Hispanic and Latino populations.

We also have three Centers of Excellence for African American populations, LGBTQI-plus, as well as older adults.

We also fund the Center of Excellence for historically black colleges and universities to help expand the workforce within behavioral health.

We have the minority fellowship program which provides stipends to increase the number of culturally competent, behavioral health professionals.

And finally, we fund the National Network to Eliminate Disparities in Behavioral Health Network, which really does exchange a lot of information between organizations and provide networking to advance best practices.

Ms. KELLY. Thank you. I just want to make sure that Congress is taking a holistic approach by investigating significantly in prevention treatment and recovery.

And also, as my colleague, Mr. Griffith, had brought forward, my district is urban, suburban, and rural, and it has become even more rural in the remapping. I have over 2,000 farms in my district, so I want to make sure that we are paying attention to the rural areas also.

How are you addressing the social determinants of health and their impact on human well-being?

Dr. GANDOTRA. Certainly, social determinants of health can not only impact treatment outcomes, but they also impact treatment engagement. SAMHSA understands that not all services are clinical in nature, and they need to be covered.

Through our Block Grant Program, there are set-asides for wraparound services such as case management. We have partnerships with other entities such as HUD to establish housing opportunities for those within—who are suffering from HIV or AIDS.

We have a number of other programs that address the social determinants of health as well.

Ms. KELLY. And may I ask what other agencies you collaborate with to address health inequities?

Dr. GANDOTRA. I would say within HHS, our operational divisions, we with coordinate with HRSA, the Bureau of Indian Health Services as well, as well as the Bureau of Prisons. We work with a number of Federal entities when it comes to establishing treatment and evidence-based care.

Ms. KELLY. Thank you so much. We must intentionally address the root causes and the inequities, or else we will never get out of this situation. Thank you.

Mr. GUTHRIE. Thank you. The gentlelady yields back.

And I should have pointed out to my colleagues on the other side earlier, Dr. Larry Bucshon will be vice chair of this committee, and we look forward to working together with him. So you will see him in the chair quite often. Just want to make that aware and that announcement.

But I will now recognize the vice chair of the committee, Dr. Bucshon, for 5 minutes for questions.

Mr. BUCSHON. Thank you, Mr. Chairman, and I apologize, I have another hearing at the same time, as many of us do, but I have read through your testimony.

Thank you, Chairman Guthrie, for holding the hearing and drawing attention to this very important point we so often take for granted, that all life is precious and valuable.

Each of these bills before us today serves as an important reminder of that fact. Two of them touch on the issue of illicit drug trafficking and use which affects each of our districts.

As the medical community has attempted to deal with increasing rates of illegal drug use and addiction, we have developed medication-assisted treatment.

And just so you know, I was a physician before I was in Congress.

While this can be an important tool, and it is an important tool in the right circumstances, I have long voiced concerns about its potential to cause harm without the proper guardrails.

Furthermore, buprenorphine, the primary medication being used in medication-assisted treatment for opioid use disorder, is itself an opioid and is extremely vulnerable for misuse and diversion.

People who have been on the committee know that I have long been opposed to the broad expansion of prescribing authority under the umbrella of expanding the availability of treatment.

In medicine, sometimes we are in these situations where medications are dangerous potentially, and even though we want more access, we still have to stick with science and make sure the proper individuals, who are properly trained, are the only ones that have the ability to prescribe these medications.

Unfortunately, I haven't been able to convince all my colleagues of my view on this issue. So we have dramatically expanded it, and I hope that we don't see problems.

Mr. Gandotra, you spoke to my colleague, Mr. Griffith, earlier about the potential for buprenorphine diversion and said that you were not aware of it being used as a street drug. Is that correct?

Dr. GANDOTRA. Most cases are of buprenorphine have been utilized for treatment, or for withdrawal mitigation as far as——

Mr. BUCSHON. Well, just, I mean, as you probably know, there is multiple peer-reviewed articles and even some NIH and DOJ intelligence research suggesting that it is a significant risk, that buprenorphine, being a diverted drug.

So even though it sounds like you think that that is a small issue—we can agree to disagree—what steps is SAMHSA taking to combat the possible diversion of buprenorphine?

Dr. GANDOTRA. Thank you very much for that question. Certainly we know that education on substance use disorder is important as practitioners diagnose and treat these conditions.

We are working with professional societies to ensure that there is appropriate and summative information provided to all members so that ongoing education and training becomes the standard. That is irrespective of the ex-waiver itself.

And certainly as far as diversion goes, I could also turn to my DEA colleague for specific diversion actions.

Mr. BUCSHON. Yes, sure.

Mr. DELENA. Congressman, thank you for your question. You asked about buprenorphine and you asked about potential abuse——

Mr. BUCSHON. Yes, potential diversion, and I mean, for many years it has been considered one of the highly vulnerable drugs to being diverted because it is an opioid itself, and as we increase access, and as I have previously stated, probably have people that aren't properly trained prescribing it. So what are you going to do when we start to see it on the street?

Mr. DELENA. I think the word you used, Congressman, guardrails, puts it best. While we want to make sure that people get access to the treatment that they need, it has to be done in a way that does not contribute to overprescribing, misprescribing, or diversion of that substance.

And we need to make sure that we educate and make aware our communities and our law enforcement partners as such.

Mr. BUCSHON. Yes, I would agree with that. And I mean, as probably anyone knows that works in this space—and that is not my area of expertise, but I was a physician—that ongoing counseling and therapy is extremely important. You know, showing up and getting medication-assisted treatment without proper counseling, follow-up, probably almost for the lifetime in many cases, doesn't give very good results.

I will save this question for your written response. Naloxone, it is going to come over the counter. This is for Mr. Gandotra. Will that change any, or affect any existing work or grant programs at SAMHSA, and how do you plan to deal with those changes? If you could submit that for the record, I would appreciate it.

Dr. GANDOTRA. Thank you.

Mr. BUCSHON. Thank you very much. I yield back.

Mr. GUTHRIE. Thank you. I appreciate the vice chair for yielding and now recognize Ms. Barragán from California for 5 minutes for questions.

Ms. BARRAGÁN. Thank you, Mr. Chairman.

Mr. DeLena, I am looking at your testimony, and under the Sinaloa Cartel, you mentioned drug trafficking activity in various regions in Mexico, particularly along the Pacific coast. Would that include trafficking through boats across waters, or is that not included in that?

Mr. DELENA. Thank you for the question, Congresswoman. Those cartels, the Jalisco Cartel and Sinaloa Cartel, will use any method possible to get drugs into the United States and into all of our communities.

Ms. BARRAGÁN. So do you work with the Coast Guard for operations on water?

Mr. DELENA. Thank you. We work with all our Federal partners. We do work with the Coast Guard, and we work with State and local law enforcement throughout the country.

Ms. BARRAGÁN. Thank you. I was stricken by your testimony. You, on several occasions, mentioned your top priority—your operational priority is to defeat these two Mexican cartels that are responsible for driving the drug poisoning epidemic in the United States.

You say it once there, and then you go on later to say they are using cars and trucks and other routes to transport these drugs from Mexico to the United States. And then you continue to say it on the crossing points, and you even end with saying, again, that the cartels are driving drug poisoning and threatening the safety of our health communities.

And I guess I was struck by the number of times you mentioned driving, just because there has been a lot of misinformation sometimes put out there.

My understanding has been since, I think, 2020 about 97 percent of fentanyl seizures have been ports of entry. You previously testified the majority have been at ports of entry. Does that 97 percent sound about accurate?

Mr. DELENA. Congresswoman, thank you again for the question.

I don't have the specifics related to the border and the points of entry. That is probably a better question for the Department of Homeland Security and the entities therein.

Ms. BARRAGÁN. OK. Well, thank you.

I think your testimony about the majority is important. It is also, I think, why Democrats have prioritized making sure there was more than $400 million in nonintrusive inspection systems at the southwest land border, because we know the majority of this is coming over through the ports of entry.

Democrats also funded additional staffing for CBP points of entry in the fiscal 2023 omnibus because it historically has been understaffed. These are the officers that are doing the interdicting drug attempts to enter our communities. And so we are going to continue to work on that as one of the tools. I think in your testimony you mentioned there has to be an entire—a lot of tools that are necessary for that.

So I just want to thank you for the efforts that you are doing, and we certainly want to be helpful in making sure that Congress is funding efforts to help in your fight, in the DEA's fight.

Dr. Gandotra, I would like to now shift a little bit. In Los Angeles County and across the country, we are seeing the humanitarian

crisis of people experiencing homelessness, and they are dying from fentanyl overdoses.

Between 2017 and 2019, people experiencing homelessness in L.A. County were more than 36 times more likely to die of a drug overdose compared to the general population. Drug overdose deaths involving fentanyl tripled between 2018 and 2020, and drug overdoses remains the primary cause of death for people experiencing homelessness in L.A. County.

I believe we need a drug policy aimed at reducing harm caused by fentanyl, and it must include a holistic public health approach.

So my question to you is: You know, the last time this committee came together, it was on a bipartisan basis to pass the Restoring Help for Mental Health and Well-Being Act, which reauthorized billions of dollars in programs to address mental health and substance abuse.

Can you discuss how the Substance Abuse and Mental Health Services Administration can use these programs to address social factors, like homelessness, that worsen fentanyl-related substance overdoses among the more than 500,000 people experiencing homelessness in our country?

Dr. GANDOTRA. Thank you for the question.

Certainly, when we try to address substance use disorder and mental illness, we have to address people where they are. Through our block grant funding, the Substance Abuse and Mental Health Services Administration does provide billions of dollars to each State, where they can identify the interventions that are best suited for their communities. This may involve wraparound services, prevention efforts, harm-reduction efforts, as well as things specifically such as naloxone administration.

As far as homelessness goes, we also expanded our educational resources. We recently released our evidence-based resource guide, "Expanding Access to and Use of Behavioral Health Services for People Experiencing Homelessness." This guide has strategies for engagement, retention, as well as involvement of recovery efforts. We also highlight key strategies to ensure success and measure that success in terms of recovery support for both the unsheltered and sheltered homeless.

Ms. BARRAGÁN. Thank you.

My time has expired. I yield back.

Mr. GUTHRIE. Thank you.

The gentlelady yields back.

The Chair recognizes Dr. Joyce from Pennsylvania for 5 minutes.

Mr. JOYCE. Thank you for yielding, Mr. Chairman.

And I further would like to thank our full committee Chairwoman McMorris Rodgers for holding this hearing today and for your continued focus on stopping the scourge of the illicit fentanyl substances and the tragic impact that they have on our Nation, specifically in my community in Pennsylvania.

Last month, we were able to hear powerful testimony here from two of my constituents, Ray and Deb Cullen, who tragically lost their son to fentanyl poisoning just months ago. Their loss and those who have felt this across the Nation over the past year underscores how critical it is that we act to permanently schedule fentanyl-related substances classwide.

It is shocking to hear that in 2022 alone the DEA seized almost 379 million deadly doses of fentanyl, which is more than enough to kill every single man, woman, and child in the United States. And this is just what was seized.

Lack of operational control over our southern border has allowed the cartels, the drug traffickers, to flood our streets with these deadly substances, literally placing every community in America at risk.

Associate Administrator DeLena, the CDC estimates that illicit fentanyl or fentanyl-related substances are responsible for most overdose deaths in our country. I firmly believe that we must empower law enforcement with every tool that is necessary to stop those who traffic these deadly substances into our communities.

For this reason, I am troubled by the Biden administration's insistence that we should exempt certain fentanyl-related substances scheduled by class from all quantity-based mandatory minimums.

Associate Administrator DeLena, with this approach of less-harsh sentencing guidelines for fentanyl-related substances under the Biden plan, if a drug trafficker would bring, let's say, this amount of a fentanyl-related substance into the United States and, in contrast, had this amount of cocaine, the mandatory minimum sentences would be greater for this in cocaine than the more deadly fentanyl-related substances, which potentially could kill everyone in my district.

Wouldn't this incentivize the drug traffickers to bring fentanyl-related substances, more of them in, causing more tragedy, more deaths in the United States?

Mr. DELENA. Congressman, thank you for the question.

It is the top legislative priority of DEA for the permanent classwide scheduling of fentanyl-related substances.

DEA is a law enforcement agency. We conduct investigations and make arrests. When it comes to the sentencing and everything that goes along with it, we defer that to the prosecutors that we work with and the judges.

Mr. JOYCE. So the Biden administration does not recommend decreased or absent mandatory minimum sentences for fentanyl-related substances?

Mr. DELENA. Congressman, again, thank you. I would have to defer to those prosecutors and the judges that make those decisions, is the best answer to that.

As an investigative law enforcement agency, our goal is to target those cartels and the drug-trafficking organizations that are doing the most harm and to make those arrests. Then we move that forward for prosecution, and those decisions are made by prosecutors and judges.

Mr. JOYCE. Would you agree with me that mandatory minimum sentences for fentanyl-related substances should be equal to other narcotics that could be introduced into our country?

Mr. DELENA. Thank you, Congressman, for the question.

I would have to defer to the people that make those decisions. As a law enforcement agency, we are laser focused on defeating the two cartels and reducing harm in all of our communities.

Mr. JOYCE. And you talk about that harm in our communities. I think every Member, both sides of the aisle, has witnessed those

harms and has heard those stories in our communities, in our families, in our neighborhoods.

I think protecting our southern border is utmost important. And I think those mandatory minimum sentences should not allow the exemption of fentanyl-related substances.

I think we have to agree that the impact of fentanyl-related substances and the ability to carry the similar mandatory sentencing has to stop the cartels from looking at it as a business decision, which would carry a great amount of harm throughout the United States.

I thank you for participating.

And I yield the remainder of my time.

Mr. GUTHRIE. The gentleman yields back.

The Chair now recognizes Ms. Craig from Minnesota for 5 minutes for questions.

Ms. CRAIG. Thank you so much, Mr. Chairman.

And especially to our witnesses, thank you for being before us today to address this absolute crisis here across our country and in Minnesota's Second Congressional District that I represent.

You know, families across America are suffering unthinkable losses as a result of these drugs. I know firsthand that our Nation's public safety and healthcare professionals are on the front lines of this battle. In November of last year, I was on a ride-along with the Shakopee Police Department in my congressional district. Our first call of the night led us to the scene of a public drug overdose, where I watched Officer Soto and two of her colleagues literally bring a young man back to life from the bathroom floor of a family restaurant.

I know that is just another night in the line of work that they are in, but addiction, mental health, and other challenges have stretched them thin. We in Congress owe them both the utmost respect and the conviction to address and fight these issues, or we face the possibility of losing countless more lives to this opioid crisis.

We owe the parents, the grandparents, the friends, and family of all that were not saved the responsibility to address these issues in a comprehensive way and not use these tragedies as another political wedge issue.

Look, I know this is complex. Congress doesn't do complex very well. I have learned that in my first 4 years in Congress. And I am disappointed this morning that my Republican colleagues, some of them, have decided to use this hearing as a partisan pulpit rather than address this as a forum to talk about bipartisan solutions to this deadly epidemic.

Yes, we have to disrupt the flow of these drugs and their raw materials into our Nation. Yes, we have to ensure that Customs and Border Patrol have what they need in order to detect and seize these drugs at our border. Yes, we must permanently schedule these drugs as Class I.

And yes, we have to figure out what to do about social media companies across our Nation that are promoting on Snapchat and other platforms these drugs to our young people. And yes, we have to treat addiction across our Nation.

You know, we sit up here this morning and we ask you single questions in 5 minutes, and none of those individual questions encapsulates the enormity and complexity of these issues.

So I am just going to start with this, and I only have about 1 minute for each answer. But, first of all, the legal ports of entry, what else do you need to keep them from getting to our Nation in the first place? What do you need from Congress?

Mr. DeLena or Mr. Chester?

Mr. DELENA. Thank you, Congresswoman, for your question and for sharing that story of your ride-along and the heroic actions of the men and women in law enforcement that day. That is a scene that I have seen play out personally in all of the communities that I have served. I know that first responders are doing that same exact duty all day every day, and we are seeing it in communities throughout the entire United States.

What we need is the permanent classwide scheduling of fentanyl-related substances. That is a critical step for us as we move forward.

I would like to thank Congress for the enhancements that came to our budget last year. That is very important to us. DEA's operations that I mentioned, Operation Overdrive and One Pill Can Kill—One Pill Can Kill, not just an enforcement operation but an actual outreach and awareness program that is having such impact in all of our communities—and the counter-threat teams that I talked about.

We need the support of Congress to be able to continue to move forward. We want to stay ahead of these cartels when it comes to our infrastructure, our digital and data. We need that support to be able to stay ahead of those violent, ruthless drug cartels.

Ms. CRAIG. Thank you so much.

And just one more time, why do we need to treat this as a public health topic? Why do we need a public health solution?

Dr. GANDOTRA. Thank you for that question.

Certainly, it affects all aspects of public health—communities and schools, as well as employment, the GDP, as well as crisis services. We would like to address this on several fronts, as it affects all aspects of our lives.

Ms. CRAIG. Thank you so much.

And, with that, Mr. Chairman, unfortunately, my time has expired. I yield back.

Mr. BUCSHON [presiding]. The gentlelady yields back.

I now recognize the gentlelady from Tennessee, Mrs. Harshbarger.

Mrs. HARSHBARGER. Thank you, Mr. Chairman.

Thank you to the witnesses today.

Mr. Chester, some Members of Congress and a number of State attorney generals, both Democrat and Republican, support designating illicit fentanyl analogs and all precursor chemicals as weapons of mass destruction, whether through executive branch action or congressional legislation, either way.

This would increase interagency coordination to stop fentanyl and would increase resources for technical development and deployment of sensors to detect fentanyl and analytical, data-based decisionmaking.

What are your thoughts on the merits of such a policy?

Mr. CHESTER. Thank you very much for that question.

That issue and the related issue of a foreign terrorist designation are something that the administration has looked very, very closely at across the interagency, and we have examined it from top to bottom.

The fundamental question is, would doing so provide us any capabilities, authorities, or procedures that we don't already have and are not already applying to this problem? And the answer is "no."

All of the architecture, the structure, the capability, and the authorities that we need to be able to deal with this problem in a comprehensive way we have available and we are already applying to this particular problem.

Mrs. HARSHBARGER. OK.

I have another question for you, sir.

The High Intensity Drug Trafficking Areas, the HIDTA, program that was created back in 1988 is administered by ONDCP and provides assistance to law enforcement agencies at the Federal, State, local, and Tribal levels. They are operating in regions of the United States that have been deemed as critical drug-trafficking regions.

My district is east Tennessee, and we are part of the Appalachian HIDTA. And that plays an important role in pursuing the disruption and dismantlement of drug-trafficking organizations and drug threats in the Appalachian region. And we have been inundated, along with southwest Virginia and eastern Kentucky, with that.

Its activities include multiagency intelligence-sharing and enforcement initiatives involving investigation, interdiction, and prosecution, and also drug use prevention and treatment initiatives.

Over the past several years, Congress has steadily increased appropriations for this program, funding it at $280 million in fiscal year 2019 to a point most recently for fiscal year 2023 at $302 million.

My question is, do you believe it is sufficient funding for HIDTA? And explain your answer as to why or why not.

Mr. CHESTER. First off, I agree with your characterization of the HIDTA program. And, particularly, the Appalachia HIDTA and Vic Brown do an enormous job in that part of the country. And we appreciate very much the Congress' continued support for the HIDTA program, and we appreciate the funding that we have received.

What I can tell you is that every single penny that the Congress provides the HIDTA program is put in the right place to do the right work that they need to do to protect our communities and protect our country. And we thank you for that.

Mrs. HARSHBARGER. Well, do you think it is sufficient?

Mr. CHESTER. Yes, ma'am. We appreciate all of the funding that we have gotten. Thank you.

Mrs. HARSHBARGER. OK. Very good.

Mr. DeLena, the DEA—I am very familiar with the DEA and a bunch of other three- and four-letter agencies in my profession, as a matter of fact.

My question to you is, can you provide us an update on the status of DEA's two proposed rules addressing controlled-substance

prescribing via telemedicine? And when will they be released to the public for review and comment?

Mr. DELENA. Thank you, Congresswoman, for your question.

DEA takes telehealth very seriously, and it is something that we are moving forward towards. My understanding is that we are very close to making that. Anything beyond that, I could take it back and try to get back to you with a more accurate update.

Mrs. HARSHBARGER. OK. So it is not open for public comment yet, but you are close.

Does that mean you have put rules on the books to where we can look at some of the—I mean, I can't give you information if I don't know what you have talked about.

Mr. DELENA. Thank you. I don't have that exact answer, but I will get it back to you.

What I can say is, you know, we want to ensure that Americans have access to telehealth, and it has to be done in a way that is safe and, you know, has guardrails that prevent from overprescribing and misprescribing and diversion.

Mrs. HARSHBARGER. Yes. Absolutely.

With such a short timeframe before the end of COVID, what is DEA's plan to ensure patients don't lose access to those controlled substances that they need? And I guess that would include buprenorphine as medication for opioid use disorder.

And, you know, I look at that in different ways. I have seen it misused. There are people who take those strips, you know, heat them up, use them as injectables. There is a lot of diversion that goes on with that. But you can't just stop somebody. But you don't try to drag forward a drug either. You know, there is a lot that goes into that.

I just wondered what your thoughts are on that.

Mr. DELENA. Thank you, Congresswoman.

We are committed—DEA is committed to continued access to medications for opioid use disorders. When the COVID–19 public health emergency has ended, we will address that when it happens, and we will take steps to make sure that everybody that is seeking medication has access to it.

Mrs. HARSHBARGER. OK. All right. Thank you, sir.

And, with that, I yield back.

Mr. BUCSHON. The gentlelady yields back.

I now recognize Ms. Blunt Rochester from Delaware for her 5 minutes.

Ms. BLUNT ROCHESTER. Thank you, Mr. Chairman, for the recognition, and congratulations.

I also want to thank the Biden administration officials testifying today for their tireless efforts to disrupt the global illicit drug-trafficking enterprise as well as your efforts to address the public health and national security challenges that this crisis presents.

Fentanyl remains the deadliest drug threat facing the people of Delaware and America. In 2021, Delaware had the fourth-highest rate of drug overdose deaths in the country, and over 80 percent of these deaths involved fentanyl.

That is why addressing the opioid crisis, now driven by fentanyl, is one of my top priorities in Congress. I am pleased my colleagues on the other side of the aisle have also prioritized addressing the

fentanyl crisis, because, at over 100,000 overdose deaths per year, this crisis is sparing no one.

Unfortunately, the legislation we are considering today misses the mark. The approach we are considering today focuses almost exclusively on law enforcement solutions, and, as I have said many times before in this committee, we cannot incarcerate ourselves out of this public health problem.

I have been working on legislation with Congresswoman Kuster called the STOP Fentanyl Act to comprehensively address both supply-side and demand-side drivers of the fentanyl crisis. I want to run through a few important provisions of this legislation.

Our bill will help States improve their fentanyl surveillance and forensic laboratories so that States can distinguish between fentanyl, fentanyl analogs, and fentanyl-related substances.

It will improve access to all forms of medication-assisted treatment, including methadone, which, along with psycho-social therapies and community-based recovery supports, is the gold standard for treating those with opioid use disorder.

It will extend the reach of harm-reduction programs so that they can help keep more people alive long enough to seek treatment.

And it will support law enforcement agencies in detecting and handling fentanyl.

And my first question: Dr. Gandotra—make sure I say that correctly. Is that correct?

Dr. GANDOTRA. Thank you. That is correct.

Ms. BLUNT ROCHESTER. Can you describe SAMHSA's approach to expanding harm-reduction strategies and evidence-based treatment? And explain why focusing on those suffering from substance use disorder is important, why it is important, focusing there.

Dr. GANDOTRA. Thank you, Congresswoman, for this question.

This is part of SAMHSA's mission, to not only address substance use disorder but reduce the harms that are associated with its use. Harm reduction is an important pathway to ensure that patients who may not be ready to engage in full treatment are at least able to mitigate the harms associated with use.

Harm-reduction principles such as overdose mitigation with naloxone has been shown to be very beneficial, not just in training providers but also making them sensitive to asking the right questions. In addition to that, if we don't identify patients, we are not actually able to get them into treatment.

Of course, medications for opioid use disorder are the gold standard for preventing overdose mortality. So certainly we expand that with our substance use block grants as well as our State opioid response grants, as well, which dedicates billions of dollars to the States.

Ms. BLUNT ROCHESTER. Thank you.

Our legislation focuses heavily on public health surveillance and data collection, because data is a powerful tool that can help us target resources to those most in need.

For example, through robust data collection on overdoses in Delaware, public health officials identified that 23 percent of overdose deaths in recent years occurred among those working in the construction industry.

Through this information grew a partnership between public health officials and the State's construction industry to directly distribute Narcan into the hands of workers at risk, train supervisors on overdoses, and train workers on the stigma associated with addiction.

Mr. Chester, can you share how Biden administration agencies currently track fatal and nonfatal overdoses? And do you have suggestions on how the many different data sources can be integrated in a way that is more helpful to policymakers?

Mr. CHESTER. Thank you, Congresswoman. I will be as quick as I can.

The tracking of fatal overdoses is done by the Centers for Disease Control and Prevention through the National Center for Health Statistics. What we were lacking was nonfatal overdose data, which is a prime indicator for the eventuality of a fatal overdose.

Just recently, within the last 2 months, ONDCP has launched a dashboard that works with other agencies to track nonfatal overdose data, which is incredibly important. And we work across the interagency in order to track that.

The most important thing that we can do—and I think you brought this up in your statement—is to use that data and bring it together to figure out those areas that have the greatest need, where we can surge resources and make the greatest effect. And that is principally how we use that data.

Ms. BLUNT ROCHESTER. Thank you so much.

I am over time. I will be reaching out to you with a question about data and DEA.

Thank you, Mr. Chairman, and I yield back.

Mr. BUCSHON. The gentlelady yields back.

I now recognize the gentleman from Georgia, Mr. Carter, for his 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here.

I think that we would all agree—members of the committee, witnesses, everyone in America—this is an epidemic. This is something that has got to be addressed. We all know what is going on here.

And there are a number of reasons, none that are more important than the fact that we have to secure our southern border. I mean, we all know that this is where the vast majority, if not all, of the fentanyl is coming across, and it is causing problems. A lot of people look at the border situation, the crisis that exists down there as being just illegal immigrants coming across, but we know that it is much more than that.

And we know that it is infesting all of our communities. In my district, we—and I represent south Georgia. I represent the entire coast of Georgia, but I have a lot of rural areas in south Georgia. We had an incident just last week where we had a number of people who overdosed in a small community, a small rural community in south Georgia, and overdosed on fentanyl. And if it weren't for the heroics of the public safety personnel in administering Narcan and naloxone, they would have perished.

And we know what is happening here, and I won't take up my valuable time with repeating all the numbers. You know, 7 bil-

lion—enough fentanyl in this country to kill 7 billion people, almost 21 times our population. Unbelievable.

You know, I want to share to you a quick story that happened to me. And, you know, I am a pharmacist, and it happened to me. I was at a townhall meeting this past August, and I made a comment about fentanyl addiction, and a mother rightfully corrected me. She said, "No, sir. You are wrong." She said, "It is not fentanyl addiction. It is fentanyl poisoning." She said, "My son took one pill, and he is dead."

She was right, and I was wrong. It is fentanyl poisoning. And we have to do something about it, and we have to address it. The number-one killer, according to the CDC. It is the leading cause of death in the U.S. for adults age 18 to 45.

So, enough of that. Mr. Chester, I will start with you and ask you: In a White House press release dated September the 2nd of 2021, DEA Administrator Anne Milgram stated, "The permanent scheduling of all fentanyl-related substances is critical to the safety and health of our communities. Class-wide scheduling provides a vital tool to combat overdose deaths in the United States."

Is support for permanent scheduling the official position of the Biden administration?

Mr. CHESTER. Yes, Congressman, it is. We support the scheduling of fentanyl-related substances as a class. We do.

Mr. CARTER. I want to remind members of this committee and everyone here that we are considering the HALT Fentanyl Act, and that would permanently schedule fentanyl-related substances and keep them out of our communities, hopefully.

You know, I dealt with this when I was in the Georgia State legislature and a member of the pharmacy caucus there. We dealt with this every year when trying to identify the analogs and trying to—and every time we would identify them one year, they would come up with different ones the next year. It was just a vicious cycle.

This is something that has to be done. And I hope that we will have the administration's support with this, and I hope we will have everyone on this committee's support.

Mr. DeLena, I want to ask you—and I can't help but bring up this report that was in The Washington Post recently about some of the problems that we have had with the DEA agents down in Mexico. In fact, we had a 6-month time when we were without personnel down there that we should have had.

And I just need—I need reassurance from you that the personnel problems that we have had down in Mexico, particularly with the DEA agents, have been straightened out.

And I think you know what I am talking about. I am talking about, specifically, the DEA's Mexico office was in turmoil for more than 6 months, with the Director recalled to Washington while investigators probed his conduct.

Mr. DELENA. Congressman, thank you for your question.

While I can't comment directly on a personnel matter, what I can tell you is that DEA's top operational priority is defeating these Mexican cartels. And the——

Mr. CARTER. That is not what I asked you. Come on, now.

Mr. DELENA. The administration——

Mr. CARTER. You need to give me confidence that you all got this straightened out. This is too important. Two hundred people are dying every day.

Mr. DELENA. Thank you, Congressman.

The Administrator in summer of 2021 ordered a review of all of our foreign operations to make sure that we have the right people and that we are most effective in all of the places where we are situated——

Mr. CARTER. This article also indicates that the Mexican Government is not working with us on this. Can you shine any light on that with us?

Mr. DELENA. Congressman, thank you.

The Mexican Government needs to do more. We are there in Mexico laser focused on the cartels and the fentanyl and methamphetamine that they are producing, but we know that they need to do more when it comes to collaboration. And——

Mr. CARTER. I trust that you all are getting your staff worked out, straightened out, your situation straightened out. Two hundred people every day. We don't have time. We don't have time for this. We have to do something about this right now.

Thank you, Mr. Chairman, and I will yield back.

Mr. BUCSHON. The gentleman yields back.

I now recognize the gentlelady from Washington, Ms. Schrier, for her 5 minutes.

Ms. SCHRIER. Thank you, Dr. Vice Chair.

And thank you to these excellent witnesses for being here today. I have learned a lot from this conversation.

In my State of Washington, like every other State, fentanyl has had profound and devastating impacts. Just months ago, in my hometown of Sammamish, a Seattle suburb, two parents of a toddler were buying, using, and dealing fentanyl. They left pills on their nightstand. Their toddler found them, and the toddler died from the overdose.

On the other side of my district, in Chelan County, a rural county in the eastern part of my district, the coroner recently reported that deaths from fentanyl overdose rose from 6 in 2021 to 20 in 2022.

And, in recent years, local high schoolers have died from fentanyl overdoses because they did not know that a pill that a friend gave them or that they got elsewhere or online was laced with fentanyl.

And I know that every one of us—and we have heard them today—every one of us has stories just like this from our own districts.

Mr. DeLena, you noted in your testimony that the Drug Enforcement Agency investigated more than 129 cases directly linking the sale of fake pills containing fentanyl to social media sites, and then alluded to Snapchat just earlier with links that disappear. And this is where teens are getting these pills.

So, as a pediatrician, I need to ask, can you talk a little bit more about what the DEA is doing on this issue to make sure we don't keep losing our kids? Because they are all on social media.

Mr. DELENA. Congresswoman, thank you for the question.

And your references to the tragedies that occurred in your district—at DEA, we have over 4,800 photos of those that have been

lost to fentanyl poisoning in our lobby. The youngest is 17 months, and the oldest is 70 years. So, you know, this drug does not distinguish.

We are laser focused on the cartels that are pushing this drug into our country, and we know that those drug cartels and their entire drug-trafficking organizations are using social media platforms to try to reach hundreds of millions of potentially new customers. Because that is truly where Americans are spending time, is on those social media sites, particularly young people, which is something that, you know, is gravely concerning to all of us.

We need to continue with programs like One Pill Can Kill, where not only are we conducting enforcement and seizing these pills—50 million pills DEA seized last year—but we are educating and getting the word out there. We——

Ms. SCHRIER. In addition to educating parents and students, what is your interaction with social media sites on this? Do you get cooperation? And what do you need from Congress to get those tools?

Mr. DELENA. Thank you, Congresswoman.

We do interact with the social media companies. We do so on a regular basis, specific to each investigation that we are conducting. But we know that these social media companies can and must do more.

They control all of the algorithms. They know how content is being pushed to all of their hundreds of millions of users. They control all of the data. And unless we can get a look inside there, as DEA or, as you said, for Congress to be able to do something, we can't make those type of recommendations.

So there needs to be more transparency. If they want to fix this problem, they can fix this problem.

Ms. SCHRIER. Thank you. This is an area that I look forward to working with my colleagues on both sides of the aisle to figure out for a variety of reasons.

I have another question for you. As you may know, Washington State has many ports. And I have supported legislation to build up law enforcement capacity to detect synthetic drugs.

And I appreciate that your testimony also focuses on the southern border. Can you tell me a little bit about what DEA is doing to monitor at our seaports?

Mr. DELENA. Thank you, Congresswoman.

First of all, DEA is focused on wherever the threat takes us and wherever these investigations shall lead. We do work in all of our communities not only with our other Federal partners but with our State and local partners as well. I have personally been involved, in my tenure, particularly in my time in Florida, with investigations that lead us, you know, to the sea. And we work hand-in-hand with those that are conducting those investigations.

And each of it is threat based. If we know that there is a threat, you know, in your specific area coming in through the seaport, we are going to be focused on that.

Ms. SCHRIER. Thank you.

I don't have time to get an answer to this, but, Dr. Gandotra, I would love it if you could, afterwards, submit perhaps a list of places that parents can consult so that they can have conversations

with their children about how to not fall prey to fentanyl poisoning online.

Thank you. I yield back.

Mr. GUTHRIE [presiding]. Thank you.

The gentlelady yields back.

The Chair recognizes Dr. Miller-Meeks for 5 minutes for the purpose of asking questions.

Mrs. MILLER-MEEKS. Thank you very much. And I thank the Chair and all the witnesses that are here for this extraordinarily important topic.

And just as an introduction to you, I am a physician, as is Dr. Schrier. I am the former director of the Iowa Department of Public Health, under which behavioral health, substance use disorder was a part. And I also was a State senator and, as a State senator, passed no preauthorizations for medicated-assisted treatment, or MAT, for substance use disorder in one session; also schools as a site of service for behavioral health, which I think was very forward thinking at the time.

And so my question, Dr. Gandotra: SAMHSA's 2022 report titled "National Guidelines for Child and Youth Behavioral Health Crisis Care" outlines best practices for implementing mobile crisis response teams. And we have set these up in Iowa, when we have set up our child and mental health—or like I would prefer to call it, brain health—systems. These mobile crisis teams are typically made up of mental health professionals, nurses, and peer support providers.

The report recommends that these teams respond to crises without law enforcement accompaniment unless special circumstances warrant their inclusion.

And let me also say that in SAMHSA's September 2021 "Ready to Respond," also on mental health, on page 20, it also notes shifts away from traditional law enforcement responses in many cases.

So my question: Is it SAMHSA's position that mobile crisis teams should respond to calls in lieu of law enforcement?

Dr. GANDOTRA. Thank you for that question.

Certainly, we understand that, when it comes to crisis management, providers who are going to deliver the service have to maintain their safety but also approach this from a trauma-informed perspective, understanding that sometimes individuals who have experienced past trauma may be more vulnerable and more sensitive to the application of law enforcement entities. Certainly, that has to be balanced with public safety as well as the information that is given.

And that is really the key, is having the most information, most up-to-date information, so that the approach can be tailored and individualized for those purposes, would be my first and ideal situation. Certainly——

Mrs. MILLER-MEEKS. So, just to make sure I am understanding, you are saying it is not in lieu of law enforcement.

Dr. GANDOTRA. I am saying it should fit, from the information, from the clinical perspective, what is best required for the safety of the patient as well as for the community provider that is delivering that service, certainly.

Mrs. MILLER-MEEKS. So, as in an episode we saw—and this was not a child, but—in subways in New York City where someone was pushing somebody else off a train track but they are in a mental health crisis, how do you respond to that then? Because you may not have that information when a 911 call is made to know clinically what is the best approach. So, again, is it in lieu of law enforcement?

And, then, what are the criteria for determining special circumstances that warrant the involvement of law enforcement? That perhaps will better answer this question.

Dr. GANDOTRA. So the strategy that should be employed would be an evidence-based strategy that would still incorporate trauma-informed approaches but still maintain safety for the individual delivering the care as well as the individual needing the care. We would try to encompass all aspects of the needs of the provider as well as for the patient.

Mrs. MILLER-MEEKS. Well, I can certainly see that, perhaps, if someone is calling a crisis line before there is a crisis. But when there is an actual incident, as you may see in public, it could be very difficult to do that.

So thank you so much for the answer, and perhaps you could elucidate that further in writing.

And I yield back my time.

Mr. GUTHRIE. The gentlelady yields back.

The Chair now recognizes Mr. Crenshaw from Texas for 5 minutes for asking questions.

Mr. CRENSHAW. Thank you, Mr. Chairman.

Thank you all for being here.

I would like to direct most of my questions towards you, Mr. DeLena. I do have an interest in battling what seems to be a war with the cartels south of our border.

One of my first questions to you is, you know, you laid out three strategies the DEA is currently engaged in, but do you really have enough resources? And do you need more engagement from other entities, such as the intelligence community and perhaps the Department of Defense? What else do you need that would help battle this problem?

Mr. DELENA. Thank you for the question and for your commitment to this issue, Congressman.

DEA is equipped right now with the resources that have been allocated to us to focus on these two cartels. Any additional resources is something, obviously, that, you know, we would be open to and to discuss, but it would have to be sort of specific to, you know, maybe what you are talking about.

Mr. CRENSHAW. Well, yes, you have certainly been allocated the resources, and that is what you are working with. I understand that to be the case. But the question is not that. It is, is it enough? Are you making an impact against these cartels?

And if not—clearly not, because they are able to wage a war against the Mexican Government at will in the state of Sinaloa just recently, a couple weeks ago. So, obviously, we are not doing enough. What more is needed?

Mr. DELENA. Congressman, thank you.

I think, you know, with the successes that we talked about, that DEA seized over 50 million pills last year and 10,000 pounds just of fentanyl and, you know, an exorbitant amount of methamphetamine as well, you know, our focus right now is to defeat those two cartels and——

Mr. CRENSHAW. OK. OK. What about authorities?

So I have a bill that I am reintroducing today called Declaring War on the Cartels Act. And what this does is deliver the same authorities that you would have to go after ISIS without necessarily labeling them as a terrorist organization.

Would that be helpful? Because that would allow you to go after their financing. It would allow the U.S. Government to sanction officials in Mexico that operate with the cartels. Would that be helpful?

Mr. DELENA. Congressman, thank you.

I can't comment on pending litigation like that. We would work the interagency process as those things came in.

Mr. CRENSHAW. Sure. I imagine it would be helpful if you had more authority. That is not a trick question. Yes.

All right. What is your cooperation like with the Mexican Government? Is it good? Is it bad? Has it been better? Does it mirror at all the longstanding cooperation we have had with, say, the Government of Colombia during Plan Colombia and the successes we have had there?

Mr. DELENA. Thank you, Congressman.

This is obviously a fluid and rapidly evolving situation. We see these cartels in their switch from plant-based drugs to synthetic-based drugs. This thing continues to evolve every single day.

We know that the Mexican Government needs to do more. They need to take steps in their own country, and they need to assist us additionally than how they are already doing that right now.

Mr. CRENSHAW. OK. So, no, they are not doing enough. They don't cooperate with you to the extent that you would like.

Do you trust them? If you give them intelligence—like, for instance, I am assuming that you know where some of these clandestine labs are that they are making fentanyl that is killings tens of thousand of Americans a year. I am assuming you know that. You currently do not have the authority to go raid that facility in Mexico. The Mexican Government does. If you tell them about it, will they go take care of it?

Mr. DELENA. Congressman, thank you.

I don't want to get into specifics of investigations, and that is essentially——

Mr. CRENSHAW. I am not asking you to get into specifics. I am asking you in generalities. You know where a bad guy is. You tell the Mexican Government to go get them. Will they do it? Do you even trust them with that information, or do you think they will tip them off?

Mr. DELENA. Thank you, Congressman.

The Mexican Government needs to do more. They need to seize those drug labs. They need to disrupt those drug labs. They need to assist with extradition on the investigations that we build.

Mr. CRENSHAW. All right. You are being very diplomatic, and that is fine.

Earlier, you mentioned specifically the Jalisco Cartel and the Sinaloa Cartel. It is worth also naming the leaders of those cartels and how dangerous these two particular people are to tens of thousands of Americans. The leader of the Jalisco Cartel is Nemesio Oseguera Cervantes. They know him as El Mencho. The leader of the Sinaloa Cartel is Ismael Zambada García, known as El Mayo.

Everyone should know who these two guys are, because they are killing tens of thousands of Americans. We all know who Osama bin Laden is. We started a war just to go after him. And we should start a war with these cartels, because they are at war with us. And I would encourage all of my colleagues, across the aisle, all Republicans, all Democrats, to join with us on this issue.

I have currently introduced an Authorized Use of Military Force to go after the cartels specifically with every aspect of our government's power. I think this needs to be a whole-of-government approach. And I think we need to be unified, as Democrats and Republicans, in dealing with this problem.

Thank you.

Mr. GUTHRIE. Thank you.

The gentleman yields back.

The Chair now recognizes Mrs. Trahan from Massachusetts for 5 minutes to ask questions.

Mrs. TRAHAN. Thank you, Chairman Guthrie—and I am sorry the elevator closed on us earlier—Ranking Member Eshoo.

Thank you to the administration witnesses for being here today.

Based on today's hearing, it is clear that passing policy solutions to address the fentanyl crisis is top of mind for Democrats and Republicans alike. And I hope this will be one of many hearings this subcommittee holds to build on the bipartisan addiction prevention and treatment policies like the MAT Act that we passed at the end of last Congress.

The Biden administration's proposal to permanently schedule FRS within Schedule I includes an important off-ramp to reschedule an FRS found to have medicinal value, as well as research provisions which have been adopted by my Republican colleagues in their HALT Fentanyl bill.

It is important because fentanyl itself has an approved medical use, and it is possible there are unknown pharmacological effects and therapeutic potential for the entire class of substances if studied and regulated properly. For example, studying FRS may be key to discovering the next generation of naloxone, commonly known as Narcan, which will help to save lines.

Our recent trends in overdose deaths show the emergence of fentanyl adulterated with a powerful animal sedative called xylazine, which has been talked a lot about today, more commonly known as "tranq dope."

According to the Lowell Sun, the paper in my district, first responders have already seen this deadly drug make its way into Lowell, the gateway city where I grew up and I represent. In fact, the Lowell Police Department has sent out alerts to residents to inform them of the dangers of this drug. The city worries that Narcan does not counteract xylazine like it does with fentanyl. And the FDA issued a similar alert back in November.

So, Dr. Gandotra, can you please shed light on how naloxone was discovered and how research into FRS may lead into similar opioid antagonists?

Dr. GANDOTRA. Thank you, Congresswoman, for the question.

Certainly, we know naloxone is an important tool for reversing opioid overdose. It was discovered in the 1960s by a researcher who was trying to alleviate symptoms of constipation from chronic opioid use, and it is derived from oxymorphone.

I will also state that it is this property as an opioid antagonist that makes it incredibly useful as a mono product for reversing overdoses but also as a combination product with buprenorphine for Suboxone for opioid treatment and has quite a different risk profile and diversion profile, making that a wonderful, evidence-based practice for treating opioid use disorder.

Mrs. TRAHAN. Thank you, Doctor. It seems that we do agree that reforming the research landscape is key to finding new therapeutic treatments and those lifesaving antidotes.

I am going to attempt to switch gears a bit, because I would like to focus on access to treatment for opioid disorder.

Since March 2020, the DEA, under authorities associated with the public health emergency, has allowed registered clinicians to prescribe some controlled medications after a telehealth examination for patients suffering from mental health issues.

The expansion of telehealth services has been vital to patients across the country who rely on controlled-medication prescriptions to support their mental health care and aid in their recovery. And there is broad support across the medical community for maintaining access to controlled-medication prescribing through telehealth to ensure patient access to treatments even if they can't make it into the doctor's office.

I was pleased to see that a very recent study published in GEMMA Network found that rules permitting doctors to prescribe buprenorphine via telehealth to treat OUD did not increase overdose deaths involving the drug.

Congress has directed the DEA to establish a special registration for providers to prescribe controlled medications through telehealth. Congresswoman Kuster and I have urged DEA to release this special registration and maintain access to OUD treatment via telehealth.

With the public health emergency ending on May 11th of this year, it is unlikely that the special registration process will be in place, and patients may lose access to a critical pathway of treatment.

So, Mr. DeLena, what is the timeline for this special registration proposed rulemaking? And to avoid a gap in access to treatment and care, does DEA intend to extend that waiver allowing clinicians to prescribe controlled medications through telehealth until the special registration process is in place?

Mr. DELENA. Congresswoman, thank you for the question.

DEA strongly believes that Americans should have access to telehealth, but it has to be done so in the appropriate way to avoid overprescribing and misprescribing.

I can't speak to the specific dates and what you are asking for, but I can certainly take that back and try to get you some of that information.

Mrs. TRAHAN. Terrific. Thank you so much.

I have run out of time. I yield back.

Mr. GUTHRIE. Thank you.

The gentlelady yields back. And that does conclude our first witness panel.

And I will just say to all three of you: A couple of things we might have had a difference of opinion on, but I know we are going to have to all work together. And I respect all of you, and we look forward to going forward, because this is a crisis.

There are other bills on the agenda as well, but certainly the fentanyl crisis is first and foremost in everyone's mind. So hopefully we can find opportunities to move this legislation forward in a way that we all can support in the end but also be effective. So we have to have both moving forward.

So thank you very much. Thanks for your patience. Thanks for being here, and thanks for your answers. And there was a couple of "ran out of time, you are going to have to answer on paper." I know we have a record of that, and we look forward to your timely responses for that.

So the first panel is dismissed, and we will set up for the second panel.

[Recess.]

Mr. GUTHRIE. Well, thank you. The subcommittee will come back to order.

We appreciate all of our witnesses being here today.

This is the beginning of our second panel. And I will introduce our witnesses, and then we will begin our witness testimony.

First we have Ms. Kandi Pickard, the president and CEO of the National Down Syndrome Society.

Then we will hear from Frederick—I-sah-si, is that correct, because we all want to know how to say your names correctly—Isasi, the executive director of Families USA.

And then from Molly Cain, a parent advocate who has been directly impacted by the fentanyl crisis.

And then Dr. Stephen Loyd, the chief medical officer of Cedar Recovery.

And, finally, we will hear from Dr. Timothy Westlake, an emergency room physician and former chairman of the Wisconsin Medical Examining Board as well as former member of the Badger State's Controlled Substance Board.

So we thank you all for being here and thank you for your testimony. It is all important to know. Some of you bring in personal stories.

And some of you haven't testified here before, so I am just going to explain. You will see the lights in front of you. You have 5 minutes to do your opening statement. After 4 minutes, you will see a yellow light to kind of let you know when moving forward.

But I know you have some stories to tell, so we are not going to gavel you down too hard. We want to hear your stories. And so, just relax. And if you are not—people that haven't testified before, sometimes that can be daunting, but we are glad to have you here.

And we will begin with Ms. Pickard. You have 5 minutes—you are recognized for 5 minutes for your opening statement.

STATEMENTS OF KANDI PICKARD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL DOWN SYNDROME SOCIETY; FREDERICK ISASI, EXECUTIVE DIRECTOR, FAMILIES USA; MOLLY A. CAIN, PARENT ADVOCATE; STEPHEN LOYD, M.D., CHIEF MEDICAL OFFICER, CEDAR RECOVERY; AND TIMOTHY W. WESTLAKE, M.D., EMERGENCY MEDICINE PHYSICIAN

STATEMENT OF KANDI PICKARD

Ms. PICKARD. Thank you.

Chairwoman Rodgers, Chair Guthrie, Ranking Member Eshoo, and members of the committee, thank you for inviting me here today to testify on quality-adjusted life year measures, or QALYs, in combating discrimination against people with disabilities.

My name is Kandi Pickard, and I proudly serve as the president and CEO of the National Down Syndrome Society. I am also the proud parent of four children, including my 10-year-old son, Mason, who has Down syndrome.

As the leading human rights organization for all individuals with Down syndrome, NDSS stands in strong support of a nationwide ban of the use of QALYs and similar measures in coverage determinations under Federal healthcare programs, like the one proposed in the Protecting Health Care for All Patients Act of 2023.

As you know, QALYs place numerical value on the quality of one's life before and after healthcare treatments and interventions, and these calculations are then used by Federal health programs to determine the cost-effectiveness of treatments and services and, thus, coverage for patients.

Since a substantial number of individuals with disabilities receive their healthcare through Medicaid, this flawed and discriminatory metric directly impacts access to necessary healthcare treatments when they are not deemed cost-effective enough to administer to individuals with disabilities.

At NDSS, we are very concerned about the use of QALYs and other value assessments in all instances. And I would like to share two examples of how these discriminatory practices are affecting the Down syndrome community.

People with Down syndrome are uniquely situated in the Alzheimer's landscape because of their extra copy of chromosome 21, which carries the amyloid precursor protein gene that is strongly associated with Alzheimer's disease.

As a result, individuals with Down syndrome have a higher than 90 percent lifetime risk for developing Alzheimer's disease, with the onset of symptoms coming earlier and progressing faster than the general population. In fact, Alzheimer's disease is the number-one cause of death for individuals with Down syndrome.

CMS recently cited several studies that relied on QALYs in their national coverage decision for Aduhelm, a first-of-its-kind Alzheimer's treatment.

Access to treatments for this life-altering disease is paramount for our community, yet value assessments such as QALYs and

other similar one-size-fits-all approaches are heavily relied upon in coverage decisions. Medicaid coverage decisions cannot be made based on flawed assessments that devalue the lives of people with disabilities, especially when those lives are uniquely at risk, as is the case for our loved ones with Down syndrome.

Discriminatory metrics and value assessments are also experienced by individuals with disabilities in the organ transplant system. A 2019 report from the National Council on Disability, an independent Federal agency, found that discrimination against people with disabilities persists in the organ transplant system, rooted in biased attitudes about the value of the life of an individual with a disability.

NDSS is proud to champion the bipartisan Charlotte Woodward Organ Transplant Discrimination Prevention Act, named after NDSS staff member Charlotte Woodward, who is here with us today, which prohibits discrimination based solely on disability in the organ transplant system.

While advocating for the passage of this bill, we remain vigilant in our responses to other forms of value assessments, such as QALYs, that persist in many aspects of our healthcare system and threaten to access nondiscriminatory healthcare for people with Down syndrome and other disabilities.

Today, alongside a diverse and nonpartisan group of stakeholders, including the National Council on Disability, the Consortium for Constituents with Disabilities, and 100 other disability advocacy groups, I urge you to ban the use of QALYs in Federal programs.

A person's value is more than what can be determined by a metric. My son Mason is no less valuable than my other three children who don't have a disability just because he has Down syndrome. I see the value in how hard he works at school, the love of his siblings, and the joy he brings our friends and family.

It is outright discrimination to deny individuals with disabilities access to treatment and the care they deserve and they need because a calculation determines their value.

Congress deals with many challenging and controversial issues. This should not be one of them. No party condones discrimination against people with disabilities, and both Democrats and Republicans are on the record against the use of QALYs.

I implore you to support this legislation and take the important step of protecting people like my son from healthcare discrimination.

Thank you all for inviting me here to speak today. I look forward to working with the committee on commonsense health reforms that value patients and people with disabilities.

[The prepared statement of Ms. Pickard follows:]

Testimony before the

United States House of Representatives Energy and Commerce Committee,

Subcommittee on Health

Hearing Titled: *Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities*

Kandi Pickard

President & CEO

National Down Syndrome Society

Chairwoman Rodgers, Chair Guthrie, Ranking Member Eshoo, and Members of the Committee:

Thank you for inviting me to testify on Quality Adjusted Life Year (QALY) measures and combatting discrimination against people with disabilities. My name is Kandi Pickard and I proudly serve as the President and CEO of the National Down Syndrome Society (NDSS). NDSS is the leading human rights organization for all individuals with Down syndrome. We envision a world in which all people with Down syndrome have the opportunity to enhance their quality of life, realize their life aspirations, and become valued members of welcoming communities.

In my role at NDSS, I work closely with individuals with Down syndrome, their families, and members of the greater disability community. I have the privilege of seeing the Down syndrome community through many stages of life – from prenatal and birth diagnoses, many of which are delivered to new and expectant parents in a troubling manner, to adulthood and aging and the dignity that comes from living a full and meaningful life. I get the opportunity to see people with Down syndrome and other disabilities experience and accomplish life's greatest joys: attending school, getting their first paycheck, finding love, and more. I am also tasked with supporting our community through some of the most arduous circumstances: segregated workplaces and barriers to competitive integrated employment, heightened lifetime risk of developing Alzheimer's disease, and potentially the most life-threatening – being denied coverage or access to quality health care solely because they have a disability.

These experiences become even more real for me when I think of my ten-year-old son, Mason, who has Down syndrome. As a leader in the disability community, I advocate tirelessly against discrimination. As a mother, I fear that, one day, Mason's life will be devalued by an equation, and he will be denied needed health care because he has Down syndrome.

NDSS stands in strong support of a nationwide ban on the use of quality-adjusted life years (QALYs) and similar measures in coverage and payment determinations under federal health care programs, like the one proposed in the Protecting Health Care for All Patients Act of 2023. This bill is critical to preventing discrimination against individuals with disabilities and chronic conditions by prohibiting QALYs and similar metrics that fail to account for people who do not fit arbitrarily determined standards of health.

QALYs seek to measure the value of health outcomes by placing a numerical value on the quality of one's life before and after health care treatments and interventions. These indicators are often determined by individuals who do not understand the day-to-day life of a person with a disability and may consider them to be in a less valuable state of health than someone without a disability. Thus, people with disabilities are frequently assigned a lower QALY, opening the door for further discrimination.

These measurements are regularly used by federal programs, such as Medicaid, to determine the cost-effectiveness of treatments and services, and thus coverage for patients. Since a substantial number of individuals with disabilities receive their health care through Medicaid, this flawed and discriminatory metric directly impacts access to necessary, and at times critical, health care treatments when they are not deemed "cost-effective" enough to administer to individuals with disabilities.

NDSS is particularly concerned about the use of QALYs in response to Alzheimer's disease. People with Down syndrome are uniquely situated in the Alzheimer's landscape because they have an extra copy of chromosome 21. The 21st chromosome carries the amyloid precursor protein (APP) gene, which is strongly associated with the formation of amyloid peptides and plaques, a hallmark of Alzheimer's disease. As a result, individuals with Down syndrome have

an elevated lifetime risk – higher than 90 percent – for developing Alzheimer's disease, with the onset of symptoms coming earlier and progressing faster than in the general population.[1] In fact, Alzheimer's disease is the number one cause of death for individuals with Down syndrome.[2]

Access to and coverage of treatments for this life-altering disease is paramount for our community. Yet, in the Centers for Medicare & Medicaid Services (CMS) most recent National Coverage Decision (NCD) for Alzheimer's treatments, a report from the Institute for Clinical and Economic Review (ICER) was used to inform coverage decisions that ultimately excluded the Down syndrome community from access and coverage of these drugs.[3] In ICER's report, QALYs and similar one-size-fits-all approaches were used to determine the cost-effectiveness of such treatments. The lack of transparency around how people with disabilities were considered in these value assessments, and the lack of transparency from CMS on how this study affected their coverage decision, only reinforces the need for a QALY ban. Medicaid coverage decisions cannot be made based on flawed assessments that devalue the lives of people with disabilities. Especially when those lives are uniquely at risk.

Discriminatory metrics and value assessments are also experienced by individuals with disabilities in the organ transplant system, which is distinctly challenged by the fact that demand always far outweighs supply. Put simply, there are never enough organ donations to ensure that all patients who need organs can receive them. This in turn raises questions about which patients should receive organs and in what order. A 2019 report from the National Council on Disability (NCD), an independent federal agency advising Congress and the executive branch on disability

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[1] *McCarron, M., et al. "A Prospective 20-Year Longitudinal Follow-up of Dementia in Persons with down Syndrome." Journal of Intellectual Disability Research, vol. 61, no. 9, 2017, pp. 843–852., https://doi.org/10.1111/jir.12390.*

[2] *Hithersay, Rosalyn, et al. "Association of Dementia with Mortality among Adults with down Syndrome Older than 35 Years." JAMA Neurology, vol. 76, no. 2, 2019, p. 152., https://doi.org/10.1001/jamaneurol.2018.3616.*

[3] Synnott PG;Whittington MD;Lin GA;Rind DM;Pearson SD; "The Effectiveness and Value of Aducanumab for Alzheimer's Disease." *Journal of Managed Care & Specialty Pharmacy*, U.S. National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/34714106/.

policy issues, found that discrimination against people with disabilities persists in the organ transplant system rooted in biased attitudes about the value of the life of an individual with a disability.[4]

NDSS is proud to champion the bipartisan Charlotte Woodward Organ Transplant Discrimination Prevention Act, named after self-advocate and NDSS staff member Charlotte Woodward, which prohibits discrimination based solely on disability in the organ transplant system. While advocating for the passage of this bill, we remain vigilant in our response to other forms of value assessments, such as QALYs, that persist in many aspects of our healthcare system and threaten access to non-discriminatory health care for people with Down syndrome and other disabilities.

For decades, QALY prohibitions have been supported by a diverse group of stakeholders and a bipartisan group of lawmakers. In 1992, soon after the passage of the Americans with Disabilities Act, the Secretary of HHS publicly stated the discriminatory implications of QALYs.[5] In 2010, QALYs were barred from use in Medicare decisions related to coverage, reimbursement, and incentive programs.[6] In 2019, NCD released a report titled "Quality-Adjusted Life Years and the Devaluation of Life with Disability" as a part of their series on bioethics and disability.[7] In its report, NCD found sufficient evidence of the discriminatory effects of QALYs. Furthermore, as a part of their 2022 Health Equity Framework for People with Disabilities, NCD recommends that Congress "mandate a blanket prohibition on the use of Quality Adjusted Life Years by any federal agency, or recipients of federal financial assistance

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[4] "National Council on Disability First Report of Bioethics Series Examines Organ Transplant Discrimination, Calls on HHS OCR, DOJ to Issue Life-Saving Guidance." NCD.gov, 25 Sept. 2019, https://ncd.gov/newsroom/2019/NCD-bioethics-series-organ-transplant.
[5] "Oregon Health Plan Is Unfair to the Disabled; Doesn't Single out Poor." *The New York Times*, The New York Times, 1 Sept. 1992, https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-doesn-t-single-out-poor-664092.html.
[6] 111th Congress of the United States of America. (2010). H.R. 3590 The Patient Protection and Affordable Care Act. *Section 1182*. Washington, DC.
[7] National Council on Disability. Quality-adjusted life years and the devaluation of life with disability. (2019) at https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

from the Department of Health and Human Services, both directly and through third-party assessments."[8]

Patient and disability communities stand united in our advocacy to end the devaluation of the lives of people with disabilities through the use of QALYs and to remove barriers to accessing affordable and appropriate treatments and health care. As members of the Consortium for Constituents with Disabilities (CCD), NDSS presents a united voice with other organizations representing people with disabilities in affirming that a ban on QALYs is long overdue.

Every person is valuable. When I look at my son Mason, I see his value. I see value in his gummy smile when his favorite song is played. I see value in how hard he works at school to learn and keep up with his peers. I see value in the immense love his brothers and sister have for him. I see value in the joy he brings to the lives of our family and friends. Mason is no less valuable than my three children who do not have disabilities just because he has Down syndrome, and you would only need to meet him to know that for yourself.

It is outright discrimination to deny individuals with disabilities access to the treatment and care they deserve and need because a calculation determines their life is not worth the cost. Congress has the opportunity to take an important step toward ending this injustice with the passage of the Protecting Health Care for All Patients Act of 2023. I urge all members of this subcommittee to work in a bipartisan manner to pass this critical legislation. NDSS looks forward to working with the committee on common-sense health reforms that value patients and people with disabilities.

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[8] "National Council on Disability." *Health Equity Framework*, https://beta.ncd.gov/report/health-equity-framework/.

Mr. GUTHRIE. Thank you for your testimony. Let us welcome Charlotte. Charlotte Woods, did you say? What was her last name?

Ms. PICKARD. Charlotte Woodward.

Mr. GUTHRIE. Woodward, stand up, and welcome to our committee. Yes, thank you. Thank you very much. Appreciate you being here.

So now, Mr. Isasi, you are recognized for 5 minutes for an opening statement.

STATEMENT OF FREDERICK ISASI

Mr. ISASI. Thank you very much, Chairman Guthrie, Ranking Member Eshoo, members of the subcommittee. Thank you for the opportunity to testify today.

I also want to say thank you to Ms. Pickard for the beautiful testimony you just gave.

For more than 40 years, Families USA has been working to achieve our mission of a Nation where the best health and healthcare are equally accessible and affordable to all. We are very proud to have always been, and will always be, a very strong partner with the disability community in support of their healthcare needs.

I know the topic of this hearing is personally very important to many of us, especially full committee Chair McMorris Rodgers.

No matter what our ideology, we are all much more alike than we are different. Everyone struggles with how to care for a loved one, and so many live with the financial stress of high-cost medical bills and the unaffordablity of our healthcare system.

We at Families USA believe that every person in the United States should have high-quality, affordable healthcare that prevents illness, allows them to see a doctor, and helps to keep their family healthy.

Yet almost half of all Americans report having to forego medical care due to unaffordable costs, and almost the same number live under the stress and burden of healthcare debt.

For people with disabilities, the situation is considerably worse. Disabled people are 2½ more times likely to delay or to skip or delay healthcare because of cost, and they are significantly more likely to have unmet medical, dental, and prescription drug needs.

It is because of our dedication to the needs of all families, including people with disabilities, that I urge the subcommittee to oppose the antivalue legislation that is under consideration.

First, the proposed legislation's prohibition on the use of quality adjusted years, or such similar measures, is a solution in search of a problem. The Inflation Reduction Act drug negotiation provisions already have very specific guardrails against discrimination from many groups, including people with disabilities.

Quoting directly from the text of the drug price negotiation law, it explicitly and unambiguously bars measures that treat "extending the life of an elderly, disabled, or terminally ill individual as of lower value."

Moreover, similar guardrails exist in other elements of Federal law, like the Affordable Care Act. In fact, Families USA, working with our disabled partners, supported inclusion of these very guardrails in the drug price negotiation law.

So given the explicit Federal protections that already exist, what is the real effect of the legislation being considered by the subcommittee today?

This legislation is a giant loophole to allow the greed of drug companies to continue and would let other elements of our corporate healthcare sector to continue to price gouge unchecked, hurting millions of families, employers, taxpayers, and healthcare costs will continue to soar.

The proposed legislation uses very broad language that drug company lawyers will argue bans any attempt to develop an understanding of whether a drug is worth the astronomical price being charged across pretty much all Federal programs.

We know that terrible pricing abuses and waste are rampant in our healthcare system, totaling almost a trillion dollars a year. That is right, almost $1 trillion in healthcare spending each year is flat-out waste, hurting both the economic security of families and the U.S. taxpayer.

But we also know that many American families are being hurt because of low-quality care. Over a quarter of a million people die each year not from their illness but from the medical system itself.

Let me say that again. A quarter of a million souls in our Nation die each year because our healthcare sector is killing them through low value, poor care, all while we continue to spend 2 or even 3 times more on healthcare than other Nations.

It is time for this to end, period. It is time for our Nation to hold our corporate healthcare sector responsible for providing high-quality care that is affordable.

If Federal policymakers want to live up to our collective ideals of supporting people with disabilities, we should refocus our efforts, end the Medicare disability waiting period, extend Medicaid program in every State, fully fund and staff Medicaid home and community-based services, and train a healthcare workforce that will provide high-quality care to people with disabilities with dignity and without discrimination.

I urge members of the subcommittee to oppose this ill-conceived legislation that is simply playing into the hands of drug companies' greed. Thank you very much.

[The prepared statement of Mr. Isasi follows:]

Testimony of Frederick Isasi, JD, MPH
Executive Director
Families USA

Before the House Energy and Commerce Health Subcommittee

Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities

February 1, 2023

Families USA
1225 New York Avenue, NW
Suite 800
Washington, DC 20005

Chairman Guthrie, Ranking Member Eshoo, members of the Committee, thank you for the opportunity to testify today at this legislative hearing focused on *the Protecting Health Care for All Patients Act*. It is an honor to be with you this morning. My name is Frederick Isasi, and I am the executive director of Families USA, a leading national, non-partisan voice for health care consumers. For more than 40 years, Families USA has been working to achieve our vision of a nation where the best health and health care are equally accessible and affordable to all. We are very proud to have always been a strong partner with, and supporter of, the disability community and their health care needs.

Every person in the United States should have high-quality, affordable health care that prevents illness, allows them to see a doctor when needed, and helps to keep their families healthy. Yet, almost half of all Americans have reported having to forgo medical care due to the cost, a third have indicated that the high cost of medical care is interfering with their ability to secure basic needs like food and housing,[1] and over 40 percent of American adults – 100 million people – face medical debt.[2] For people with disabilities these statistics are considerably worse: disabled people are 2.5 times more likely to skip or delay health care because of cost,[3] and they are significantly more likely to have unmet medical, dental, and prescription drug needs.[4] Despite spending two or even three times more on health care than other industrialized countries, the United States has some of the worst health outcomes including some of the lowest life expectancy and highest infant mortality rates.[5,6] For people with disabilities, these trends are even worse. People living with disabilities in the United States have a significantly lower life expectancy than those without disabilities.[7] Adults with disabilities are also four times more likely to report their health to be fair or poor than people with no disabilities (40.3

percent vs. 9.9 percent).[8] In nursing homes alone, more than 181,000 disabled people died from COVID in the first two years of the pandemic.[9] Having an intellectual disability was and is the strongest predictor for COVID-19 infection, and the second strongest predictor for COVID-19 death.[10]

I appreciate being part of this legislative hearing because for too long, people with disabilities have been largely left out of the public conversation about improved health care. They face ongoing disparities that are exacerbated by those in the medical community who perceive disabled people's quality of life as diminished and are less likely to treat them with proactive care.[11] Disabled people are often left out of decisions about their own health on both an individual and systemic basis, and they face very real threats of bias toward deprioritizing their needs in periods of scarce resource allocation.[12] The time is now to prioritize their health and well-being, and to ensure our healthcare system works for *everyone*.

In recent years this Committee, under the leadership of now-Ranking Member Pallone and Ranking Member Eshoo, prioritized investments in Medicaid, one of the most important sources of health coverage for people with disabilities. The committee approved legislation to expand Medicaid access in states that have refused to do so and pushed for billions of dollars in additional funding for Medicaid Home and Community Based Services (HCBS).[13] This is a good foundation to build on. I sincerely hope this work will continue under the leadership of Chairwoman McMorris Rodgers – a passionate champion for the health and financial security of disabled people – and Chairman Guthrie. For example, this Congress could work in a bipartisan way to ensure that no Medicaid beneficiary is forced to accept services from institutional or segregated settings. Congress should also better support health and quality of life by making

HCBS a mandatory Medicaid service, ending the two-year Medicare disability waiting period, developing a sustainable federal long-term care program for all in our nation, and by robustly funding the direct care workforce needed to sustain these services.

Given these critical priorities, **I believe the Committee's focus on *The Protecting Health Care for All Patients Act* is misplaced** and urge the committee to oppose this legislation for several reasons. I am concerned that the proposed legislation's prohibition on the use of Quality-Adjusted Life Years (QALY) *"or such similar measures"* in federal programs, is a solution in search of a problem. Specifically, I am concerned that the legislation is being proposed at this time to undermine the recently passed Inflation Reduction Act (IRA) and key provisions that allow the federal government to negotiate fair drug prices, and note that **the IRA already includes explicit disability (and other) safeguards.**[14]

These new IRA drug pricing negotiation authorities are critical to safeguarding the American people, including disabled people, from unaffordable or low-quality drugs. Furthermore, a blanket federal prohibition of the use of "adjusted life years or a similar measurement" would likely call into question non-discriminatory measures of health care value and exacerbate the terrible waste in other aspects of the U.S. health care system – estimated at an astounding $760 - $935 billion.[15] Ultimately, *the Protecting Health Care for All Patients Act*, could play a significant role in worsening the health care affordability and quality crisis faced by millions upon millions of our nation's families, including people with disabilities.

Just by examining the pricing abuses in the prescription drug industry, we know that price gouging is rampant; and the industry continues to dramatically overcharge for medications, including some that are low value.[16] In 2021 alone, drug makers cost the U.S. healthcare system

an additional $805 million due to unjustified price increases.[17] It is critical to note that disabled people are particularly at risk for this price gouging, given their health needs, their reliance on Medicare and Medicaid, and their likelihood to have fewer financial resources.[18] The Medicare program is still being egregiously overcharged for prescription drugs, including for those that offer little therapeutic value to justify their pricing.[19] For example, Trulicity, the brand name drug of dulaglutide – a medication prescribed for type 2 diabetes – has a monthly list price ranging from $886 to nearly $11,000, a price that most Americans cannot afford.[20] Its drug maker, Ely Lilly, made headlines for falsely advertising the benefits of the drug for all diabetic populations despite it only being approved to treat people type 2 diabetes.[21]

As a nation, we need the capacity to assess the overall effectiveness and value of a drug like Trulicity to ensure the American people receive safe, effective, and affordable drugs. We can't continue to be at the mercy of the predatory marketing and pricing practices of the pharmaceutical industry that are simply designed to push profit at the expense of people's lives.

Moreover, had stronger federal guardrails to assess value been in place at the onset of the opioid epidemic (the subject of other legislation being considered during today's hearing) to actually scrutinize the underlying safety, efficacy and affordability of OxyContin, it is very likely that millions of lives - and billions of dollars - could have been saved. Instead, those guardrails did not exist and a very dangerous and highly addictive drug was unleashed into our society.

As federal lawmakers, you have an obligation to ensure that we carefully steward our national health care resources and taxpayer dollars. Central in that effort is assessing the value of the goods and services being provided to the American people through federally funded

programs. I appreciate and share concerns about any measure of the value of prescription drugs or other health care goods and services that weights a year of life differently for a person based on their disability status. To provide high value health care and ensure improved health for all, including people with disabilities, we must ensure that any measure being used in health care decision-making is able to accurately capture the multifaceted lives of people living with disabilities, and does not inadvertently undervalue their lives or experience.

For that reason, Families USA supported Congress's guardrails on value assessments under the Affordable Care Act (ACA) and mostly recently under the IRA. Specifically, the IRA bars any discriminatory practices in setting a drug price for Medicare negotiation and lays out nine factors that the Secretary of Health and Human Services must use in developing negotiated prices, many of which can and should be themselves composed of multiple factors, and **explicitly bars any measure of comparative effectiveness that "treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill**."[22]

This important protection would have to be met when considering how to incorporate any measure of clinical value or quality of life impact. For example, the Institute for Clinical and Economic Review has developed the Equal Value of Life Years Gained (evLYG) measure, which incorporates such safeguards, by:

> "evenly measur[ing] any gains in length of life, regardless of the treatment's ability to improve patients' quality of life. In other words, if a treatment adds a year of life to a vulnerable patient population – whether treating individuals with cancer, multiple sclerosis, diabetes, epilepsy, or a severe lifelong disability – that

treatment will receive the same evLYG as a different treatment that adds a year of life for healthier members of the community."[23]

For these reasons, I believe that the committee should oppose enactment of *the Protecting Health Care for All Patients Act*. If federal policymakers want to live up to our collective ideals in supporting the civil rights, financial independence, and overall health of people with disabilities, we should refocus our efforts on the investments necessary to support the end of the Medicare disability waiting period, the extension of the Medicaid program in every state, fully funding Medicaid home and community-based services, and the other reforms described above. At the same time, it is critical that federal policy makers are able to engage in the informed analyses necessary to ensure a thoughtful approach to measuring health care value. The health and financial security of our nation, and every single person living in it, depends on it.

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[1] Americans' Views on Healthcare Costs, Coverage and Policy (Chicago: NORC at the University of Chicago and West Health Institute, March 2018) https://www.norc.org/NewsEventsPublications/PressReleases/Pages/survey-finds-large-number-of-people-skipping-necessary-medical-care-because-cost.aspx

[2] Levey, N., *100 Million People in American Are Saddled With Health Care Debt*. Kaiser Health News. June 16, 2022. https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/

[3] Centers for Disease Control and Prevention. "QuickStats: Delayed or forgone medical care because of cost concerns among adults aged 18–64 years, by disability and health insurance coverage status–National Health Interview Survey, United States, 2009." *MMWR Morb Mortal Wkly Rep* 59.44 (2010): 1456.

[4] Mahmoudi, E., & Meade, M. A. (2015). Disparities in access to health care among adults with physical disabilities: Analysis of a representative national sample for a ten-year period. Disability and Health Journal, 8(2), 182–190. https://doi.org/10.1016/j.dhjo.2014.08.007

[5] OECD (2023), Life expectancy at birth (indicator). doi: 10.1787/27e0fc9d-en (Accessed on 27 January 2023). *See also*, Peterson-KFF Health System Tracker: Health Consumption Expenditures Per Capita. https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries-2/#Health%20consumption%20expenditures%20per%20capita,%20U.S.%20dollars,%20PPP%20adjusted,%202020%20or%20nearest%20year (accessed 27 January 2023).

[6] Rabah Kamal, Julie Hudman, and Daniel McDermott, "What Do We Know About Infant Mortality in the U.S. and Comparable Countries?" Peterson-KFF Health System Tracker, October 18, 2019, https://www.healthsystemtracker.org/
chart-collection/infant-mortality-u-s-compare-countries.

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DISABILITY

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OVERVIEW

Advancing Health Equity And Reducing Health Disparities For People With Disabilities In The United States

ABSTRACT Definitions of *disability* have evolved over time. Consistent with the biopsychosocial model used by the World Health Organization, we conceptualize disability as an interaction between a person's functional impairments or chronic health conditions and the physical and social environment. Having a disability is not synonymous with poor health, and maintaining and improving health is equally important for both people with and people without disabilities. In this article we review estimates of disability prevalence in the US and present evidence of differences in prevalence by race, ethnicity, and sexual orientation; health disparities by disability status and type of disability; and health disparities for people whose disability intersects with other forms of marginalization. We suggest policy changes to advance equity, reduce disparities, and enhance the health and well-being of all Americans with disabilities.

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Despite significant health disparities experienced by people with disabilities, their needs are poorly addressed and understood in health policy, research, and practice. Estimates of prevalence vary depending on the definition of *disability* and the survey methods, but the consensus is that rates of disability are increasing with the aging of the US population, rising rates of chronic conditions among the nonelderly population, and more recently the COVID-19 pandemic. More than three decades after the passage of the Americans with Disabilities Act (ADA), disabled Americans still face barriers to health care, lower quality of care, and disparate health outcomes, in addition to inequitable access to transportation, education, housing, employment, and other social determinants of health. Existing health, economic, and social policies further exacerbate these disparities.

In this overview article we discuss disability definitions and prevalence, and we identify subgroups with a higher prevalence of disability. We present evidence of health disparities by disability status and type, as well as health disparities among people whose disability intersects with other forms of marginalization, and we provide policy recommendations to advance health equity for all disabled Americans.

Defining *Disability*

Disability can be defined in many ways, depending on context. The definition chosen affects benefits eligibility, civil rights protections, prevalence estimates, social stigma, and personal identity.[1-4] One report identified sixty-seven federal statutory definitions of *disability* alone.[5]

Although there is no single way to define *disability*, there are prevailing concepts. Historically, the medical model has been dominant.[6,7] It

defines *disability* as an impairment or problem existing within the body or mind that can be identified by objective scientific or expert observations and ameliorated with the guidance or treatment of experts to help the person adapt and conform to the "normal" environment.[3,7]

The social model challenges the medical model's definition identifying disabled people as defective and disabled lives as inherently inferior to nondisabled lives.[6,8] From a social-model perspective, disability occurs when a person with an impairment interacts with physical or social environments that do not take the full range of human body variation into consideration and are unaccommodating or hostile as a result. In the social model, disability is a social construct, and disabled people are an oppressed minority group with unique histories and perspectives.[4,-11]

Critics identify limitations in both the medical and social models.[2,6,12] They argue that disability is both a social and an embodied phenomenon. There have been models that draw on aspects of both models, such as the interactive or biopsychosocial model used by the World Health Organization.[13]

For the purposes of this article, we adopt this third approach and conceptualize disability as an interaction between a person's functional impairments or chronic health conditions and the physical and social environment. Although some people's disabilities are the result of health problems, disability and health are distinct concepts. Having a disability is not synonymous with poor health, and maintaining and improving health are equally important for people with and without disabilities.

Challenges In Estimating Disability Prevalence

Administrative records, such as those collected during health care visits, are inadequate in identifying people with disabilities, as they do not capture the full conceptual definition of *disability*. Therefore, researchers use surveys to estimate the size and characteristics of the disability population. Surveys differ in how they identify disabled respondents, and none does so perfectly—a limitation that hinders understanding of health needs and experiences of people with disabilities, as well as their health outcomes.

During the first several decades that the National Health Interview Survey (NHIS) was conducted, it used questions about health- or impairment-related limitations in the performance of age-appropriate life activities, such as attending school, working, or taking care of personal and household needs, to identify people with disabilities.[14] Gradually, the NHIS moved away from this approach and, in 2019, adopted two measures of functional limitations developed by the Washington Group on Disability Statistics: the Short Set on Functioning (WG-SS), which asks about difficulty performing physical or cognitive tasks,[14] and the Enhanced Short Set, which includes the Short Set along with additional questions to measure communication and mental health, as well as difficulties with cognitive tasks and a range of physical tasks broader than those measured by the Short Set. Either measure can be used to define a disability population, according to researcher preference.

In the early 2000s the Census Bureau introduced the annual American Community Survey (ACS). The ACS includes six questions, known as the ACS-6, about functional limitations to identify respondents with disabilities.[15] This approach has been criticized because the questions fail to identify substantial portions of certain disability groups, such as people with mental health or intellectual disabilities.[16,17] Nevertheless, the ACS disability questions have been adopted as a standard for federal health surveys,[18] as mandated by Section 4302 of the Affordable Care Act (ACA). The Centers for Disease Control and Prevention (CDC) also adopted the ACS-6 in 2016 in its Behavioral Risk Factor Surveillance System (BRFSS).

As shown in exhibit 1, there is large variation in estimates of the disabled population from these surveys. For example, the proportion of working-age adults estimated as disabled varies from 6.3 percent (2019 NHIS using the Short Set measure) to 23.3 percent (2019 BRFSS). Even when the disability questions are the same, as is the case with the ACS-6 and the BRFSS, the population estimate can vary considerably because of survey context, mode of administration, and potential sampling bias, particularly with telephone-based surveys.

Regardless of survey or measure set, adults ages sixty-five and older have substantially higher disability rates than do working-age adults. Despite the greater prevalence in the sixty-five and older age cohort, however, a majority of the disabled population is younger than age sixty-five, as assessed by the measures shown in exhibit 1.

Differences In Prevalence By Race, Ethnicity, And Sexual Orientation

Among racial and ethnic groups, disability prevalence is highest among American Indian/Alaska Native populations and lowest among Asian populations (exhibit 2). Black populations have a slightly higher prevalence of disability than White populations, and the difference increases

EXHIBIT 1

Estimates of disability prevalence in the US from selected federal surveys, 2018–19

	Surveys				
	NHIS, 2018	**NHIS, 2019**	**NHIS, 2019**	**ACS, 2019**	**BRFSS, 2019**
Type of disability measure used	Activity limitation[a]	Functional limitation[b]	Functional limitation[c]	Functional limitation[d]	Functional limitation[d]
No. of survey items on disability[e]	11	27	33	6	6
Estimate of the total disability population					
No. (1,000s)	45,992	29,535	38,897	43,281	—[f]
% of US population	14.2	9.3	12.3	13.2	—[f]
By age group (years)					
Younger than age 18					
No. (1,000s)	6,869	6,875	6,875	3,191	—[f]
% of US population	9.4	10.5	10.5	4.4	—[f]
Ages 18–64					
No. (1,000s)	21,948	12,477	20,178	21,177	43,884
% of US population	11.1	6.3	10.2	10.5	23.3
Ages 65+					
No. (1,000s)	17,175	10,183	11,844	18,913	22,133
% of US population	33.5	19.1	22.2	35	42.6

SOURCE Authors' tabulations of data from the National Health Interview Survey (NHIS), 2018–19; American Community Survey (ACS), 2019 (six questions on disability, or ACS-6); and Behavioral Risk Factor Surveillance System (BRFSS), 2019. **NOTES** The NHIS and BRFSS exclude people living in institutions, such as long-term care facilities. The ACS includes both people living in institutions and people living in community settings. [a]A limitation in the performance of age-appropriate life activities, such as attending school, working, or meeting personal and household needs. [b]Defined according to the Washington Group Short Set on Functioning (WG-SS), developed by the Washington Group on Disability Statistics to measure difficulties in physical and cognitive tasks. [c]Defined according to the WG-SS Enhanced, developed by the Washington Group on Disability Statistics; includes the WG-SS along with additional questions to measure communication and mental health, as well as difficulties with cognitive tasks and a range of physical tasks broader than those measured by the WG-SS. For respondents younger than age 18, no additional questions were included. [d]Defined as difficulties with physical and cognitive tasks. [e]Number of distinct survey questions on disability used for adults, children, or both. [f]The BRFSS collects data from people ages 18 and older only.

with age adjustment. Unadjusted disability prevalence among Latino/a populations and Native Hawaiian/Pacific Islander populations is significantly lower than among White populations, but these differences disappear in the age-adjusted data.

Bisexual, transgender, and gender-nonconforming people also have a higher prevalence of disability than heterosexual cisgender people.[19] Analysis of survey data from one state found that age-adjusted disability rates were significantly greater among gay, lesbian, and bisexual people than among heterosexual people.[20,21] Data from a recent national survey on disability found higher rates of mental and psychiatric disabilities and intellectual and developmental disabilities among LGBTQI+ respondents, as well as greater prevalence of multiple disabilities, compared with heterosexual cisgender respondents.[22]

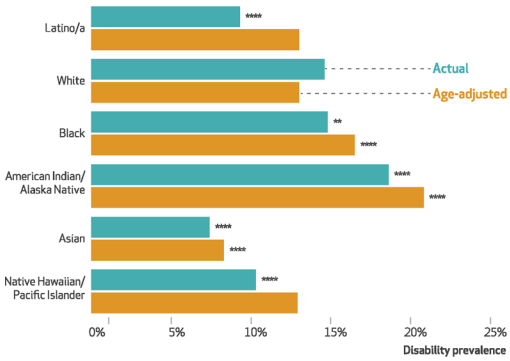
Health Disparities By Disability Status And Type Of Disability

The phrase "health disparity" refers to adverse health differences affecting marginalized groups, arising from systemic factors that lead to social disadvantage.[23] Health disparities are an equity issue and reflect both gaps in the quality of care received and broader patterns of injustice within society.[24] Work on health disparities has largely focused on racial and ethnic minorities, but people with disabilities are increasingly recognized as a health disparity population.[25] For example, through the *Healthy People 2030* initiative, the Department of Health and Human Services has designated people with disabilities as a health disparity population.[26] A challenge in identifying health disparities affecting disabled people is that some disabling conditions do inevitably lead to poorer health, regardless of individual circumstances, whereas in other instances, poorer health may be attributable to economic and social inequities such as barriers to health care access, thereby being accurately described as health disparities.[1] Disentangling cause and effect in attributing and addressing these differences is an ongoing challenge.[27]

People with disabilities are more likely to report poor health and experience higher rates of chronic health conditions than nondisabled people. Data published in 2012 and 2015 indicate

EXHIBIT 2

Disability prevalence in the US, by race and ethnicity, actual and age-adjusted, 2019



SOURCE Authors' tabulations of data from the American Community Survey, 2019. **NOTES** Age-adjusted rates were calculated by applying the disability prevalence for each racial and ethnic group in 5-year age categories to the age distribution of the total population. All race categories shown are non-Latino/a. The *p* values refer to differences in disability prevalence (actual and age-adjusted) between the White population and other racial and ethnic populations. $^{**}p < 0.05$ $^{****}p < 0.001$

that disabled adults were more likely to experience chronic conditions such as cardiac disease, diabetes, higher weight, and asthma and to lack emotional support.[28,29] They were also more likely to experience both injuries and intimate partner and interpersonal violence, according to studies published in 2015 and 2016.[30,31]

Disabled women are more likely than their nondisabled peers to have chronic health conditions and to describe their general health as fair or poor.[21] Women with disabilities have lower rates of breast and cervical cancer screening compared with nondisabled women, and disabled women with circulatory or respiratory conditions have higher rates of breast cancer mortality than women without disabilities.[32]

Limited research identifies differences in health status and outcomes based on type of disability.[33] One study published in 2013 found that people with multiple disabilities had worse health outcomes and that people with hearing disabilities fared better on most outcomes than people with vision, physical, or cognitive disabilities.[34] Another study published in 2019 found that adults with intellectual disabilities or autism were more likely to report comorbidities, including poor mental health, than adults with other disabilities.[35]

Disability-related health disparities have come into sharp focus during the COVID-19 pandemic. As of January 2022 an estimated 200,000 nursing home residents had died of the disease, constituting roughly one-quarter of all COVID-19 deaths in the US.[36] People with intellectual and developmental disabilities were also disproportionately affected, having higher case-fatality rates than the general population, especially for those in residential settings.[37,38] Recent statements from the CDC that postvaccination mortality is largely confined to people with multiple comorbidities[39] imply that the disability population is also experiencing disproportionate mortality.

Health Disparities And Intersectionality Among People With Disabilities

Health disparities among people with disabilities are affected by other forms of marginalization. The self-reported health status of disabled people has been found to vary across racial and ethnic groups.[40] Black and Latino/a adults with intellectual and developmental disabilities were more likely to report fair or poor physical and mental health compared with their White peers in a study published in 2016.[41] Adults with mobility limitations who are members of racial or ethnic minority groups were more likely to report that their health was worse than a year ago and more likely to experience depression and to have diabetes, hypertension, or vision impairment than White people with mobility impairments in a study published in 2008.[42]

Gender identity and sexual orientation also are factors in health disparities among people with disabilities. LGBTQI+ people with disabilities are more likely to report diminished health-related quality of life, including poor physical and mental health, than their non-LGBTQI+ peers with disabilities.[22] Variations in the rates of poor health and chronic health conditions among disabled people with additional marginalized identities suggest that these disparities are associated with systemic issues related to multiple forms of oppression.[21]

Policy Changes To Advance Health Equity And Reduce Disparities

In this section we recommend policy changes to advance equity and reduce disparities for all people with disabilities in the US.

EXPANDING ACCESS TO HEALTH COVERAGE Access to health insurance coverage is key to reducing health disparities that can be attributed to cost and access to health care. Although public programs such as Medicaid serve a subset of disabled people, many other people with disabil-

Disability-related health disparities have come into sharp focus during the COVID-19 pandemic.

ities have long faced barriers to health coverage, including lack of affordability and preexisting condition exclusions. Through increased regulation of private coverage, subsidized premiums, and expansion of Medicaid eligibility, the ACA enabled many disabled people to overcome these barriers. Uninsurance declined significantly among disabled people after the ACA's provisions went into effect.[43] In addition, the proportion of disabled people who delayed or did not get care because of cost fell significantly. Even so, barriers to care remain.[43,44] A single-payer system would provide a promising solution by eliminating financial barriers to care across the board. Medicaid expansion in the states that have thus far not expanded their Medicaid programs could also go a long way toward removing financial barriers for at least a subset of low-income people with disabilities. However, lack of political consensus and concerns about cost currently limit progress toward both of these potential solutions.[45]

EXTENDING MEDICAID BUY-IN PROGRAMS A new approach to Medicaid buy-in programs could offer a viable alternative to these options. Depending on the state, disabled people whose work income renders them ineligible for Medicaid can participate in a "buy-in" program that involves paying premiums to enroll in Medicaid. Forty-five states offer such programs, which differ from broader Medicaid buy-in programs that may be used to expand Medicaid eligibility authorized under the ACA that do not necessarily include a disability requirement.[46] However, most of the narrower, disability-focused buy-in programs have very low income and asset limits that would exclude all but low-wage or part-time workers. As a result, many people with disabilities remain in poverty so that they can obtain health coverage for services not covered by private insurance, such as personal assistance services.[47] A small number of states, such as Massachusetts and Arkansas, offer Medicaid buy-in programs with no income or asset limits; these programs advance equity and reduce disparities by empowering disabled people to participate fully in the workforce without fear of losing essential services or becoming impoverished.[47] Congress should enact legislation that provides states with enhanced federal reimbursement as an incentive to offer Medicaid buy-in programs to people with disabilities without income and asset limits. Premiums, additional tax revenues, and reduced participation in other government programs resulting from increased employment could help offset the cost of these programs.[47]

EXPANDING ACCESS TO HOME AND COMMUNITY-BASED SERVICES Although Medicaid has long paid for institutional services, the program first paid for home and community-based services in the 1980s. In its 1999 landmark decision in *Olmstead v. L. C.*, the United States Supreme Court interpreted the integration mandate contained in the ADA to mean that states must take an even-handed approach to providing care in community settings and institutions instead of limiting services to institutional care.[48] By making enhanced federal reimbursement available to states that increase access to home and community-based services and establishing a state plan option [Section 1915(i)] to enable states to provide these services to people whose disabilities are not severe enough to warrant institutional care, the ACA reduced the "institutional bias" that had long been a major feature of Medicaid long-term services and supports programs.[49,50] There is evidence that a gradual rebalancing of community versus institutional services can lead to reduced costs[51] and that unmet need for home and community-based services leads to negative health and community living outcomes.[49]

Despite this progress, access to home and community-based services varies substantially from state to state,[50–52] and access to community-based long-term services and supports remains elusive for people ineligible for Medicaid but not wealthy enough to pay the high costs. A Medicare home and community-based services benefit would help address that gap, as would a universal public long-term services and supports insurance program, but concerns about financing have historically been barriers to adoption of these measures.[53]

EXPANDING THE SCOPE OF COVERED SERVICES Definitions of *medical necessity* in public programs and private insurance, as well as the Medicare "homebound" requirement, lead to unmet health care needs and undermine the ADA's goal of community integration.[54,55] Medicare's definition of *medical necessity* emphasizes diagnosis and treatment, and the homebound requirement limits reimbursement for Medicare home health services to those needed to function solely at

home, thereby precluding coverage of services primarily needed for people with disabilities to participate in community life and putting them at risk for social isolation, which has been shown to have deleterious effects on well-being.[56] *Medical necessity* definitions used by state Medicaid agencies and private insurers vary, and they likewise generally have the effect of restricting access to services for people with disabilities. A few state Medicaid programs, however, have definitions that are consistent with the goal of community integration for people with disabilities; Delaware's definition, for example, refers to the aim of "attain[ing] or retain[ing] independence, self-care, dignity, self-determination, personal safety, and integration into all natural family, community, and facility environments and activities."[57] Adoption of this or similar language in other state Medicaid programs, as well as in Medicare and private insurance, would help advance the widespread social integration and well-being of people with disabilities.

PURSUING INTEGRATED CARE PROGRAMS Challenges to community integration for people with disabilities also may be addressed through innovative integrated care programs for Medicaid recipients being pioneered by many states such as Massachusetts; these programs often feature flexibility in coverage of services beyond the usual bounds of the Medicare and Medicaid programs through the use of strategies such as care coordination and person-centered planning.[58,59]

FOSTERING RESEARCH TO INFORM POLICY An important step in advancing policies to reduce disparities and achieve equity would be to designate people with disabilities as a health disparity population under the Minority Health and Health Disparities Research and Education Act of 2000.[60,61] This designation is long overdue and would foster research to provide the evidence base for policies to improve the health and well-being of all people with disabilities and reduce disparities.

Long-standing systemic factors undermine the full participation of many disabled people in US society.

Conclusion

Despite the hope that the ADA's nondiscrimination provisions would eliminate barriers to health care for disabled people, they continue to face deep and sustained inequities in health and health care access. Although these widespread inequities were undoubtedly exacerbated by the COVID-19 pandemic, long-standing systemic factors undermine the full participation of many disabled people in US society and widen disparities among marginalized groups within the disability population. It is critical to officially recognize people with disabilities as a Health Disparity Population under federal law and pursue evidence-based policy changes to realize the ADA's goal of enhancing full participation, independence, inclusion, and equality of opportunity for all Americans with disabilities. ■

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Mr. GUTHRIE. Thank you for your testimony. I appreciate that.

Ms. Cain, you are now recognized for 5 minutes for your opening statement.

STATEMENT OF MOLLY A. CAIN

Ms. CAIN. Thank you, Chairs Guthrie and Rodgers and Ranking Members Eshoo and Pallone and members of the committee for inviting me to come and speak out about fentanyl, how it has invaded our communities, devastated families, and how it has become a public health crisis.

My name is Molly Cain, and I lost my beloved 22-year-old son Carson to fentanyl poisoning on November 27th, 2020. Thank you for allowing me to share his story.

I would like to begin by painting a story of who Carson was. Carson had a beautiful soul. He loved deeply and was wise beyond his years, and his heart was true.

Carson persevered in the face of adversity. When Carson was 6, he was diagnosed with dyslexia; at 7, he was diagnosed with a familial tremor that progressively worsened, and at 10 years old, he watched his healthy father be ravaged by and ultimately succumb to brain cancer.

Carson and his brother took on more responsibility within our family without being prompted or asked. Carson graduated high school with both his high school diploma and his AA degree and went on to Gonzaga University to further his education.

During his college years, Carson was prescribed Xanax for anxiety. Carson was a genuine and empathetic person who wanted to better the world around him. He would lend a hand or an understanding ear to those in need and did not expect anything in return.

He was the shoulder of strength others leaned on, especially those friends who had lost a parent. Carson helped to guide them out of the dark abyss they now faced.

During his college years, Carson would plow snow in the early-morning hours without request or compensation, would stop at the parking lot of a local cancer center to clear the lot. When asked why he made the stop, he replied, "The patients going for treatment have enough challenges. They don't need one more to navigate." These actions embodied his compassionate and devoted spirit.

At 22, Carson was diagnosed with appendix cancer. After a battery of scans and procedures, it was determined the cancer had not spread, but a spot found on his lung needed to be monitored. The anxiety my son had became elevated, and suddenly COVID hit.

Carson, feeling immense pressure, went to counseling and was given Xanax again. He told me he felt counseling online was impersonal, and he was only offered appointments during his working hours. He stopped going.

On November 26, 2020, Carson came home for Thanksgiving. He was exhausted. He said he was not sleeping. He had been working long hours and wasn't able to get the rest he needed. He hugged me goodbye and thanked me for a wonderful dinner and told me he loved me.

The next day, after not hearing from him as I usually would, I called him with no answer. I went to his home, and I found my beautiful, loving son on his living room floor, deceased. I cannot put into words the guttural pain of finding Carson dead and knowing I couldn't save him.

We had to wait almost 3 months for the toxicology report to find out that fentanyl had killed him. During this waiting period, we had Carson's phone, and he began to receive Snapchats with pictures of drugs and emojis from an individual.

We dug into Carson's Cash App account and discovered a payment to the same individual the night he passed away. For months, the individual continued to Snapchat pictures of drugs and emojis.

The DEA did a sting. The individual served less than 24 hours in jail.

I was the one who brought the drug dealer's account to the attention of Snapchat. Snapchat claims they have filters in place to monitor for such illicit activity. Then why for 5 months did this individual continue to Snapchat such things if Snapchat's filters were operational?

In my opinion, Snapchat is the courier, and they provide the getaway for the traffickers of this poison.

In the months and now years that have ensued, I have grieved immeasurably. I knew what devastation was after losing my husband, but losing my child has left a gaping hole within my being.

The heartache and pain is gripping. My son bought something, thinking it would ease anxiety, a mistake that cost him his life. It was not his intent to die. These individuals who are dying are not overdosing. They are being poisoned.

In the 2 years since Carson's death, tens of thousands of people have lost their lives to this weapon of mass destruction. Many victims were unknowing.

We need to be educating our children and families alike about fentanyl and its lethal effects. It has been published that in Seattle the fentanyl crisis is so bad the medical examiner is running low on storage for the dead bodies.

I was told by a DEA agent that we will not see an end to fentanyl in my lifetime. I find these words exceptionally chilling. I never thought my son's photo would be hanging on the DEA's wall as one of the victims of fentanyl. Heartbreakingly, he is a statistic.

How many lives must be lost before we hold the players in this hellish nightmare accountable? We must do more to prevent fentanyl from coming into our country, so one more mother, one more family, will not have to be brought to their knees in sorrow. I plead with you to take action.

Thank you for allowing me the opportunity to speak.

[The prepared statement of Ms. Cain follows:]

Testimony of Molly A. Cain

Thank you, Madame Chair and members of the committee, for inviting me to come and speak out about fentanyl; how it has invaded our communities, devastated families, and how it has become a public health crisis. My name is Molly Cain and I lost my beloved 23-year-old son, Carson, to fentanyl poisoning on November 27th, 2020. Thank you for allowing me to share his story.

I'd like to begin by painting a picture of who Carson was. Carson had a beautiful soul. He loved deeply, was wise beyond his years, and his heart was true. Carson persevered in the face of adversity. When Carson was six, he was diagnosed with dyslexia. At seven, he was diagnosed with a familial tremor that progressively worsened. At ten years old he watched his healthy father be ravaged by, and ultimately succumb to brain cancer. Carson and his brother took on more responsibility within our family without being prompted or asked.
Carson graduated high school with **both** his high school diploma and his AA degree, and went on to Gonzaga University to further his education. During his college years he was prescribed Xanax for anxiety.

Carson was a genuine and empathetic person who wanted to better the world around him. He'd lend a hand, or an understanding ear, to those in need and did not expect anything in return. He was the shoulder of strength others leaned on,

especially those friends who'd lost a parent. Carson helped to guide them out of the dark abyss they now faced.

During his college years, Carson would plow snow in the early morning hours and, without request or compensation, would stop at the parking lot of a cancer center to clear the lot. When asked why he made that stop, Carson replied, "The patients going for treatment have enough challenges. They don't need one more to navigate." These actions embodied his compassionate and devoted spirit.

At twenty- two, Carson was diagnosed with appendix cancer. After a battery of scans and procedures, it was determined the cancer had not spread but a spot found on his lung needed to be monitored. The anxiety my son had, became elevated and suddenly Covid hit. Carson, feeling immense pressure went to counseling and was given Xanax again. He told me he felt counseling online was impersonal and he was only offered appointments during his working hours. He stopped going.

On November 26th, 2020, Carson came home for Thanksgiving. He was exhausted. He said he was not sleeping. He had been working long hours and wasn't able to get the rest he needed. He hugged me goodbye and thanked me for a wonderful dinner and said he loved me. The next day, after not hearing from him as I usually would, I called him, with no answer. I went to his home and found my beautiful loving son, on his living room floor, deceased. I can't put into words the guttural

pain of finding Carson dead, and knowing I couldn't save him.

We had to wait almost three months for the toxicology report to find out that fentanyl killed him. During this waiting period we had Carson's phone and he began to receive Snapchat's with pictures of drugs and emoji's from an individual. We dug into Carson's Cash app account and discovered a payment to the same individual the night he passed away. For months, the individual continued to Snapchat pictures of drugs and emojis. The DEA did a sting. The individual served less that 24 hours in jail. I was the one who brought the drug dealer's account to the attention of Snapchat. Snapchat claims they have filters in place that monitor, for such illicit activity. Then why for five months did this individual continue to Snapchat such things, if Snapchat's filters were operational? In my opinion, Snapchat is the courier and provides the getaway for the traffickers of this poison.

In the months, and now years, that have ensued, I have grieved immeasurably. I knew what devastation was after losing my husband, but losing my child has left a gaping hole within my being. The heartache and pain, is gripping. My son bought something thinking it would ease anxiety. A mistake that cost him his life. It was not his intent to die. These individuals who are dying are not overdosing. They are being poisoned.

In the two years since Carson's death, tens of thousands of people have lost their lives to this weapon of mass destruction. Many victims were unknowing.

We need to be educating our children and families alike about fentanyl and its lethal effects. It has been published, that in Seattle, the fentanyl crisis is so bad that the Medical Examiner is running low on storage for the dead bodies. I was told by a DEA agent that we will not see an end to fentanyl in our lifetime. I find these words exceptionally chilling. I never thought my son's photo would be hanging on the DEA's wall as one of the victims of fentanyl. Heartbreakingly, he is a statistic. How many lives must be lost before we start holding the players in this hellish nightmare accountable? We must do more from preventing fentanyl from getting into our country so one more mother, one more family, will not have to be brought to their knees in sorrow. I plead with you to take action.

Thank you for allowing me this opportunity to speak.

Molly Cain

Summary of Molly A. Cain's testimony

- **Who was Carson Cain**
- **How did Carson die**
- **How did Snapchat play a role**
- **Public Health Crisis**
- **Accountability for those involved in the manufacturing and trafficking of fentanyl**

Mr. GUTHRIE. Thank you for your very moving testimony. Thank you.

Dr. Loyd, you are recognized for 5 minutes for an opening statement.

STATEMENT OF STEPHEN LOYD, M.D.

Dr. LOYD. I am so sorry, Ms. Cain.

Good afternoon, Chairman Guthrie, Chairwoman Rodgers, Ranking Members Eshoo and Pallone, and members of the committee. I am Stephen Loyd. I am an addiction medicine physician, and I am in recovery from opioid and benzodiazepine addiction myself.

Through my work as a physician in Tennessee, I see at least 5,000 patients a year in opioid treatment and recovery, and I serve as the chief medical officer at Cedar Recovery, which is an outpatient addiction medicine practice in middle and east Tennessee.

Also, I am the medical director for an opioid treatment program in Cocke County, Tennessee, which serves an inmate population, as well as the medical director at Renewal House, a Nashville organization, which serves marginalized women with underlying substance use disorder.

Thank you for the opportunity to appear here today as you consider these important bills and continue to discuss how to best address the fentanyl crisis in the United States.

This is something I deal with every day, and I hear stories like this every day in my work in Tennessee, Kentucky, and Virginia, in both the patients I treat but also in my role as Tennessee's opioid czar that has been tasked with figuring out how to best abate the crisis in our State.

This includes working with our citizens in jails and prisons as we consider best how to serve their needs along the needs of other Tennesseans who have been impacted by the opioid crisis.

Under the Americans with Disabilities Act, those with substance use disorder are considered to have a disability. This protects individuals who are in recovery or who have used drugs in the past, a category that would apply to many individuals who are incarcerated in the United States.

Under the ADA, as interpreted by the U.S. Department of Justice, people in recovery but who would be limited in a major life activity, including activities like communicating, caring for oneself, and thinking, in absence of treatment of recovery services are protected.

This extends to inmates within the correctional system who are prescribed medications for opioid use disorder. In my own experience, both as someone who has been previously addicted to opioids and benzodiazepines and was given a second chance, as well as an addiction treatment doctor, a pathway to recovery is essential for all individuals, including those who may be incarcerated on drug-related charges.

I have seen that many, not all, of the individuals who are incarcerated on drug-related crimes are dealing drugs as a means to get their own drugs in the midst of their own substance use disorder.

In those cases, minimum sentencing won't work. If you want these individuals to stop dealing drugs and reenter society, you

must safely stop their use. This includes not only medication if needed, but other things like safe housing and education.

For the past few years, I have been fortunate enough to work with Judge Duane Slone who runs a drug recovery court in Tennessee's Fourth Judicial District, which covers four rural counties. This includes a TN ROCS docket, a program that serves offenders who have an urgent need for treatment but do not qualify for drug recovery court.

Judge Slone and myself agree that addressing the social determinants of health are key to helping offenders with persistent substance abuse problems break the cycle of their addiction. This includes access to medical care, as well as food, steady income, housing, access to transportation and education opportunities.

While I believe that violent drug offenders should be appropriately punished under the law, I would argue that those who were merely engaging in a system that are actively addicted to the drugs they sell should be afforded the same opportunity that I was given two decades ago.

I appreciate the opportunity to appear before this committee, and I look forward to answering any questions you might have.

[The prepared statement of Dr. Loyd follows:]

Stephen Loyd, MD
Testimony – House Subcommittee on Health, Wednesday, February 1, 2023
"Restoring a Healthy Nation: Addressing the Fentanyl Crisis, Protecting Criminal Lifelines, and Ending Discrimination Among Those with Disabilities"

Key Points

- Under the American with Disabilities Act, those with substance use disorder are considered to have a disability; this protects individuals who are in recovery or have used drugs in the past. This extends to inmates within the prison system who are prescribed medications for opioid use disorder.
- A pathway to recovery is essential for all individuals, including those who may be in prison on drug-related charges. Many of the individuals who are incarcerated on drug-related crimes are dealing as a means to get their own drugs in the midst of substance use disorder.
- I agree that addressing some of the key social determinants of health are key to helping non-violent offenders with persistent substance abuse problems break the cycle of their addiction. This includes access to medical care, as well as food, steady income, housing, and access to transportation and education opportunities.
- While I believe that violent drug dealers should be appropriately punished under the law, I would argue that those who are merely engaging in a system because they are actively addicted to the drugs they sell should be afforded an appropriate opportunity for recovery.

Planned Oral Testimony

Good morning, Chairman Rogers, Ranking Member Pallone, and members of the Committee. I am Stephen Loyd, and I am an addiction medicine doctor and recovering opioid addict, and through my work as a physician in Tennessee, I see at least 5000 patients a year in opioid treatment and recovery. I currently serve as the Chief Medical Officer for Cedar Recovery, which is an outpatient addiction medicine practice in Middle and East Tennessee. I also am the medical director for an opioid treatment program in Cocke County, Tennessee, which serves an inmate population, as well as the medical director for Renewal House, a Nashville organization which serves marginalized women with an underlying substance abuse disorder.

Thank you for the opportunity to appear before you today as you consider these important bills on criminal justice reform and continue to discuss how to best address the Fentanyl crisis in the United States. This is something that I deal with every day in Tennessee, in both the patients I treat, but in also my role as Tennessee's opioid czar that has been tasked with figuring out how to best abate the crisis in our state. This includes working with those citizens in jails and prisons as we consider how to best serve their needs, alongside the needs of other Tennesseans who may be impacted by the opioid crisis.

Under the American with Disabilities Act, those with substance use disorder are considered to have a disability; this protects individuals who are in recovery or have used drugs in the past – a category that would apply to any individual who is incarcerated in the United States. Under the ADA, and as interpreted by the U.S. Department of Justice, people that are in recovery, but who would be limited in a major life activity – including activities like communicating, caring for

oneself, and thinking – in the absence of treatment or recovery services are protected.[1] This extends to inmates within the prison system who are prescribed medications for opioid use disorder.[2]

In my own experience, both as someone who was previously addicted to opioids and was given a second chance, as well as an addiction treatment doctor in Tennessee, a pathway to recovery is essential for all individuals, including those who may be in prison on drug-related charges. I have seen that, many – not all – of the individuals who are incarcerated on drug-related crimes are dealing as a means to get their own drugs in the midst of substance use disorder. In those cases, minimum sentencing will not work; if you want these individuals to stop dealing drugs and reenter society, you must safely stop their use. This includes not only medication, if needed, but also other things like safe housing and education.

For the past few years, I have been fortunate enough to work with Judge Duane Slone, who runs a Drug Recovery Court in Tennessee's Fourth District, which covers four rural counties.[3] This includes the TN ROCS docket, a program that serves drug offenders who have an urgent need for treatment but who are not considered high risk enough to qualify for Drug Recovery Court.[4] Judge Slone, who has become a close friend, and I agree that addressing some of the key social

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[1] U.S. Department of Justice Civil Rights Division, *The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery* (April 5, 2022), available at https://archive.ada.gov/opioid_guidance.pdf.
[2] *Id.*
[3] Tennessee State Courts, *O. Duane Slone*, available at https://www.tncourts.gov/courts/circuit-criminal-chancery-courts/judges/o-duane-slone.
[4] Tennessee State Courts, *Recovery Oriented Compliance Strategy Latest Tool in Opioid Fight* (October 1, 2018), available at https://www.tncourts.gov/news/2018/10/01/recovery-oriented-compliance-strategy-latest-tool-opioid-fight.

determinants of health are key to helping non-violent offenders with persistent substance abuse problems break the cycle of their addiction. This includes access to medical care, as well as food, steady income, housing, and access to transportation and education opportunities.

While I believe that violent drug dealers should be appropriately punished under the law, I would argue that those who are merely engaging in a system because they are actively addicted to the drugs they sell should be afforded the same opportunity for recovery that I was given two decades ago.

I appreciate the opportunity to appear before this Committee, and I look forward to answering any questions you may have.

Mr. GUTHRIE. Thank you for your testimony, Dr. Loyd, and the Chair now recognizes Dr. Westlake for 5 minutes for your opening statement.

STATEMENT OF TIMOTHY W. WESTLAKE, M.D.

Dr. WESTLAKE. Great. Thank you, Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the subcommittee.

Fentanyl-related substances, or FRSs, are highly active opioids almost identical to fentanyl except for a tiny difference in their chemical structure, created by tweaking the chemical scaffold of fentanyl during synthesis in Chinese and cartel labs. The result of this chemical tweak is a new potent opioid with the same deadly effect as fentanyl and which, before FRS class scheduling was put in place, would have been legal until causing numerous deaths, raising them on the radar to be scheduled reactively by DEA.

As an emergency physician telling parents, unimaginably at times, even friends, that their kids will never come home is the worst part of my job.

It was shortly after one such conversation with my good friend Lauri Badura that the idea for fentanyl class scheduling reform came to mind. Lauri's son Archie was an altar server with my daughters.

It started with prescription opioids, then snorting heroin, and, unknowingly, fentanyl. I resuscitated Archie on his second-to-last overdose. At that time I pulled out a body bag, laid it down next to him, and warned him that that is where he would end if he didn't accept help.

He stayed clean for 6 months until illicit fentanyl ended his life. One of the last things my friend Lauri saw of her son Archie was him being zipped up into a body bag.

Motivated to act by hundreds of such deaths, FRS scheduling legislation, which is proactive and not reactive, as had previously been the case, came together quickly and was enacted with unanimous vote in the Wisconsin State legislature in 2017.

Almost immediately, DEA adopted it as national policy, but only temporarily. Before that, scheduling new fentanyls was like a lethal game of Whac-a-mole. We literally had to wait for people to die before we could take action.

So why isn't the Wisconsin law permanent Federal law yet? Some who of oppose FRS scheduling point to the recent spike in deaths from illicit fentanyl as the proof that it doesn't work. In reality, they are confabulating and misconstruing the facts.

FRS scheduling does not address illicit fentanyl. Tt was never designed to do so. Rather, it removes the incentives for transnational criminal organizations to create new fentanyl-related substances, thus stopping them from ever existing in the first place.

It is truly the ultimate form of overdose prevention and harm reduction. At its core, it is not a law enforcement tool designed to put criminals in jail. In fact, in the years since FRS class scheduling has been in place, there have been a total of eight Federal prosecutions—I will repeat that: eight Federal prosecutions—in the entire United States under the FRS scheduling language, half of whom had already known ties to drug cartels.

As well, there has never been a prosecution for a nonbioactive fentanyl-related substance because there are no nonbioactive fentanyl-related substances. All FRSs encountered in research to date have been found to have potent opioid activity.

Concerns raised about the potential negative impacts of FRS scheduling on research are purely theoretical and have already been addressed by discussions with stakeholders.

These proposed research accommodations that have been signed off on are supported by the very agencies and organizations representing academic scientific research in the U.S., including the National Institutes of Drug Abuse, the National Institutes of Health, the Department of Health and Human Services, and the FDA.

These agreed-upon accommodations would significantly loosen research restrictions into studying all Schedule I substances, not just FRSs, and would open up wide, promising areas of research into substance abuse.

Any dampening or restriction of research is purely theoretical. Fentanyl and its derivatives have been extensively researched since its discovery in 1960. And since then, not one fentanyl-based reversal agent or medication-assisted treatment agent has ever been found.

It has been said that FRS class scheduling would impede research into life-saving opioid reversal agents, and that Narcan isn't a strong enough antidote. Take it from me, someone who sadly uses Narcan to resuscitate fentanyl poisonings far too often, Narcan works almost miraculously if given in time.

Our kids are dying because they have ingested a lethal dose of toxic opioids, not because Narcan isn't potent enough.

In conclusion, for 5 years now, FRS scheduling has been Federal policy, albeit temporary. I can't be more pleased about that and the big impact my small idea has had.

According to NFLIS, the National Forensic Laboratory Information System, in a matter of a few short years, the creation and distribution of new FRSs from China has ground to a halt, as have the associated deaths.

In the devastating battle we are in against the scourge of fentanyl, the elimination of related substances that had previously escaped our scheduling and made their way to devastate communities across the Nation is surely one bright spot.

Fentanyls are so toxic and lethal that they can be classified and actually have been used as chemical weapons. The lethal dose is 2 milligrams, which is equivalent to 5 grains of sand. This means that one teaspoon can kill 2,000 people.

That is the amount in this packet of sugar.

Thank you for—I think I ran out of time. Thank you for the testimony.

[The prepared statement of Dr. Westlake follows:]

143

STATEMENT

OF

TIMOTHY W. WESTLAKE, M.D., FFSMB, FACEP

FORMER WISCONSIN MEDICAL EXAMINING BOARD CHAIRMAN

FORMER WISCONSIN CONTROLLED SUBSTANCES BOARD MEMBER

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

U.S. HOUSE OF REPRESENTATIVES

RESTORING A HEALTHY NATION: ADDRESSING THE FENTANYL CRISIS, PROTECTING CRITICAL LIFELINES, AND ENDING DISCRIMINATION AGAINST THOSE WITH DISABILITIES

FEBRUARY 1, 2023

RELEASE UPON DELIVERY

Dear Members,

Thank you for the opportunity to testify at this hearing and contribute to the discussion on this topic.

THE ISSUE

What Congress Can Do

As Congress grapples with how best to address opioid overdose deaths, it should start by making permanent a proven strategy to eliminate the creation and supply of all new deadly fentanyl related substances (FRSs), by passing the HALT Fentanyl Act. After FRS Class Scheduling was enacted in Wisconsin in 2017, the U.S. Drug Enforcement Administration enacted temporary FRS class scheduling federally in 2018, authorization of which has been extended multiple times since (including 6 times by the current administration, the most recent being a 2-year extension passed in the omnibus). In short, these efforts have resulted in shutting down the creation and flow and very existence of new fentanyl related substances into the U.S. It's why Congress must act to finally make permanent this temporary policy. **The fact is, no one can die from ingesting something never created or be incarcerated for trafficking something that does not exist.**

Background on Fentanyl Class Scheduling Legislation

By design, FRS class scheduling is preventative, not punitive. As the primary architect of current FRS class scheduling policy, my goal was to stop the creation and spread of deadly new fentanyl related substances from transnational drug trafficking organizations. It was not to incarcerate people with substance use disorder.

I am a full-time emergency physician and recent part-time medical regulator in Wisconsin. I provide medical direction for a statewide peer-to-peer recovery program that provides naloxone training and 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. I have testified three times before Congress in hearings focused on opioid reforms.

As well, I have been on the front lines in the opioid battle for more than 30 years. One of the most devastating aspects of my job is to inform parents and other family members their loved one is never coming home due to an opioid overdose. Inspiration for the fentanyl class scheduling reform arose out of the tragedy of my friend Lauri Badura, whose son Archie died of an overdose. Archie was an altar server with my daughters. He got hooked on prescription medicine and then IV opioids. I was able to resuscitate Archie on his second to last overdose. On that occasion, I showed him a body bag and warned he would end up in it if he didn't accept help. He attended rehab and stayed clean for six months. Sadly, fentanyl caught up with him once more. The last memory my friend Lauri has of her son Archie is his lifeless body being zipped up into a body bag.

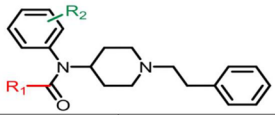
At the time I originated FRS class scheduling legislation over six years ago, doctors and other health care professionals -- in Wisconsin alone -- were battling more than nine nearly identical fentanyl variants.

While each was responsible for dozens or more overdose deaths in our state and across the U.S., they 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 literally had to wait for the body count to pile up before we could find and schedule new fentanyl variants individually.

I knew something had to change, thus 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. Knowing these entities could simply add or delete one minor chemical group and stay ahead of U.S. scheduling, my calculus was simple: stop the drugs at their source. If we could get it done in Wisconsin, we could then scale it nationally and impact global production, especially in China and elsewhere where these lethal fentanyl variants have largely been manufactured.

Working with the DEA, FRS class scheduling language was created. In part, the Stopping Overdoses of Fentanyl Analogues (SOFA) Act, or Wisconsin Act 60, which passed unanimously in the state legislature, memorialized Archie Badura. Then State Senate Leader, now Wisconsin Congressman Scott Fitzgerald (R-WI), shepherded the bill through the process. It was signed into law on November 9, 2017. Within its first week on the books, the DEA published its intent to use emergency scheduling powers to temporarily schedule FRSs 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.

Table 1. Examples of recent structural modifications to fentanyl observed on the illicit market.



Substance	R_1	R_2
fentanyl[14]	$-CH_2CH_3$	H
acetyl fentanyl	$-CH_3$	H
butyryl fentanyl	$-CH_2CH_2CH_3$	H
furanyl fentanyl	-furan-2-yl	H
4-fluoroisobutyryl fentanyl	$-CH(CH_3)_2$	*para*-F
acryl fentanyl	$-CH=CH_2$	H
ortho-fluorofentanyl	$-CH_2CH_3$	*ortho*-F
tetrahydrofuranyl fentanyl	-tetrahydrofuran-2-yl	H
methoxyacetyl fentanyl	$-CH_2OCH_3$	H
cyclopropyl fentanyl	-cyclopropyl	H
valeryl fentanyl	$-CH_2CH_2CH_2CH_3$	H
isobutyryl fentanyl	$-CH(CH_3)_2$	H
para-chloroisobutyryl fentanyl	$-CH(CH_3)_2$	*para*-Cl
para-methoxybutyryl fentanyl	$-CH_2CH_2CH_3$	*para*-OCH_3
cyclopentyl fentanyl	-cyclopentyl	H
ocfentanil	$-CH_2OCH_3$	*ortho*-F
para-fluorobutyryl fentanyl	$-CH_2CH_2CH_3$	*para*-F

To date, DEA has found 36 new 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. The NFLIS (National Forensic Lab Information System) data show 7,058 encounters for FRSs in 2016-2017, and a decrease in 2018-19 to 758 encounters [a 90% decrease], and of these, the vast majority were for previously 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 essentially ceased.

CONCERNS RAISED AND CONSIDERED

Increased Incarceration?

The goal of fentanyl class scheduling is singularly focused: to remove the incentive for and therefore halt development of deadly fentanyl poisons at their origin, namely, in drug labs overseas. Those opposed to fentanyl class scheduling initially suggested there would be a large increase in societal costs due to increased incarceration of people suffering from substance use disorder, but that has not proven to be the case. According to a 2021 GAO report, in the three years since FRS class scheduling was placed into regulation, there have been exactly eight prosecutions in the U.S. using the temporary scheduling language and half of these defendants had known ties to transnational criminal organizations/ drug cartels.

Opposition also mischaracterizes FRS scheduling as a partisan matter at the federal level given the years in which the policy has taken hold. I beg to differ. I have talked with federal and state policymakers across the political spectrum who care deeply about this issue and are determined to do what they can to help fix it. Plain and simple, by halting the creation and existence of new fentanyl variants, there has been significantly less availability and supply, causing a reduction in harm, overdose deaths and incarceration.

This underscores the primary strategy of overdose prevention and harm reduction. When considering societal effects, we must also consider the impact on mortality rates. In Florida alone, in 2016 and 2017, there were over 2500 deaths from FRSs. Since 2018, FRS related deaths in the US have been almost nonexistent. As such, those who have opposed this policy because of concerns related to incarceration, now suggest it is unnecessary because of the low number of prosecutions. Their pivot proves the policy is working. We have already witnessed the positive societal impacts 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 U.S. Not only are people with opioid use disorder not being incarcerated as a result of FRS scheduling, they are alive today, in part, because of this policy.

Other false claims used by opponents of FRS class scheduling include that deaths and incarcerations due to fentanyl and FRSs have sharply increased in recent years. As mentioned previously, deaths and incarcerations from new FRSs have ground to a halt. Increases are due to illicit fentanyl which FRS scheduling is not designed to stop. Rather, it is to prevent overdoses at the hands of new FRSs by removing the incentive for their creation and distribution at foreign points of origin. **FRS class scheduling is the ultimate form of harm reduction and overdose prevention: you can't die from ingesting something never created, nor can you be incarcerated for selling something that doesn't exist**.

Effect on General Research

Concern about not wanting to impede general research was thoughtfully considered, and great care was given to ensure the language would be specific and narrowly crafted. We looked at more than structural similarity when arriving at the definition of fentanyl related substances. Structure-Activity Relationship (SAR) considers the relationship between changes in chemical structure relative to changes in pharmacological activity; it 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. The detailed scheduling language includes specific modifications to only those portions of the fentanyl molecule with documented high likelihood of bioactivity. The language is the equivalent of a surgical scalpel, not a hand grenade.

Concerns raised about the potential negative impact of FRS scheduling on research are **purely theoretical** and have already been addressed by discussions with stakeholders. These proposed research accommodations have been signed off on and are supported by the agencies and organizations representing academic scientific research in the US - including the National Institute of Drug Abuse, the National Institutes of Health, HHS and the FDA. Why would they all support FRS class scheduling if it would harm research? The agreed upon accommodations would significantly loosen research restrictions into studying all schedule 1 substances (not just FRSs) and open up wide areas of substance abuse research.

- Those who oppose FRS scheduling point to increased numbers of illicit fentanyl deaths as reason for why FRS scheduling is not working. Some have said that "Temporary scheduling is a failed experiment that hasn't curbed the devastation of the opioid crisis." At best, this is disingenuous and a misunderstanding of the issue. In fact, the opposite is true. FRS scheduling has accomplished the one and only thing it is designed to do: stop the creation and very existence of new FRSs and therefore shut down all new FRS related deaths.

- Tragically, overdose deaths from illicit fentanyl have skyrocketed, but deaths from illicit fentanyl are a separate issue from FRSs and FRS scheduling, and one that could never be impacted by FRS class scheduling. Arguing that FRS class scheduling has not worked because illicit fentanyl deaths have risen is a complete confabulation and misrepresentation of the facts on the effects of FRS scheduling. The correct question should be whether deaths and trafficking arrests from new FRSs have slowed down or stopped as a result of FRS scheduling - which they incontrovertibly have.

- Opponents of permanent FRS scheduling have said that "Temporary scheduling has preemptively criminalized potentially life-saving antidotes to fentanyl overdoses and impeded the medical, research and scientific community's ability to develop solutions we need to effectively tackle this crisis", and that "One FRS has been shown to have similar properties to naloxone." But this is a misrepresentation and is based on one FRS (Mirfentanil) that was studied in the early 1990s that had antagonistic properties at low levels, but agonist effects at high levels and has never passed beyond phase 2 studies. Again, a purely theoretical argument about a theoretically negative effect on research when weighed against the actual death of thousands of Americans from FRSs when they were left to be reactively scheduled individually. The fact is, academic scientific research would actually be significantly advanced if research

accommodations similar to the ONDCP proposal in the HALT Fentanyl Act were to be enacted allowing easier access to research on all controlled substances.

Others have argued that FRS scheduling would impede research into new opioid versions of fentanyl. Obviously, the last thing we need is a better or more powerful opioid.

Similarly, some suggest research into new lifesaving treatments such as a FRS reversal agent or medication assisted treatment would be impeded.

- The scientific basis for this argument seems to be based on one line in testimony by Dr. Throckmorton, Deputy Director of the Center for Drug Evaluation and Research at the FDA, at a December 2021 Energy and Commerce Committee hearing, "The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances": "Among the individual FRS for which pharmacological activity has been studied, FDA has identified examples of substances lacking in mu-opioid agonist activity, the presumed pharmacology that would lead to opioid-related harms."

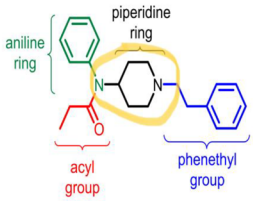
- While it is true there is a single FRS that is a predominant kappa receptor stimulator at low levels (which are thought to have lower abuse potential and theoretically beneficial antagonistic properties) as cited by Dr. Throckmorton, however at high levels it does stimulate mu receptors.

- However, when reviewing research into FRSs, every substance studied and classifiable under the FRS class scheduling language has been found to have opioid receptor bioactivity. Almost all are dozens to hundreds and even thousands of times more potent than heroin and morphine. More complete information is forthcoming from federal chemists at DEA conducting FRS research. It is my understanding this research will show that as of August, 2022 the DEA has encountered 36 FRSs and completed preliminary pharmacological investigations on 27 of them, with additional testing ongoing. It was found that all FRSs studied to date bind and activate at least one opioid receptor with varying affinities and efficacies. In short all FRSs are bioactive.

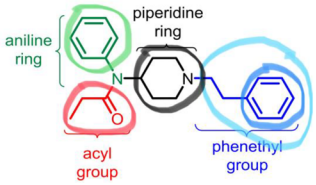
- To date, and over the past 60 years of exhaustive structure-activity relationship studies on fentanyls, research has failed to highlight any activity leading to the development of a fentanyl based antagonist/ reversal agent or medication assisted treatment.

- In contrast, prior to FRS class scheduling, legal FRSs pouring across our borders took the lives of countless Americans.

Fentanyls fall into the 4-anilinopiperidine 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 without any of the specified modifications would not be included in the 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. FRS Class Scheduling Language: must include 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 precursors 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 FRS 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 on fentanyls 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. 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 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 not being researched as a possible therapeutic prior or since the DEA emergency control in 2018.

Sufficient Oversight & Collaboration Across Agencies

In the normal sequence of scheduling, 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 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.

Proactively, and also in response to research concerns raised by the Department of Health and Human Services (HHS) and other stakeholders, DEA has already addressed and significantly simplified the research requirements for FRSs including, 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. 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 oversees [in China mostly] and not by American scientists and researchers.

Theoretical Research Concerns

It is interesting to note that the main groups opposing FRS scheduling for reason of theoretical negative effects on research are in fact mainly criminal justice reform based activist organizations. These same organizations initially opposed FRS scheduling due to concerns of theoretical effects of mass incarceration preferentially affecting of people of color. This did not happen. A report by the GAO in 2021 said there were eight prosecutions for drug trafficking in the U.S. in the 3 years FRS scheduling had been temporarily enacted, four of which were known cartel traffickers. As designed, "**No one can die from ingesting something never created or be incarcerated for trafficking something that does not exist."**

Lethality and Potency, as Deadly as Chemical Weapons

The most accurate way to view fentanyl-related substances is as weapons of mass destruction, not 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 1980s and as an extension of the war on drugs, but this perspective fails to account for the chemical weapon-like level of lethality that exists with fentanyl and FRSs.

The following table is a representation of the precise level of lethality [how much is required to kill an average human] of common narcotics and chemical weapons agents. It is almost incomprehensible how small a dose of fentanyl will kill someone: **2mg or approximately the equivalent of 4 grains of sand**.

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 (approx. equal to 4 grains of sand)**	**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	

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 . When Congress failed to act, in December 2019 a second unanimous letter from NAAG was sent urging Congress to adopt FRS class scheduling showcasing the strong bipartisan support for this policy. https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/Letter-to-Congress-SOFA-Act-8.23-1.pdf , https://1li23g1as25g1r8so11ozniw-wpengine.netdna-ssl.com/wp-content/uploads/2020/10/NAAG-Support-for-FIGHT-Act-Letter.pdf.

Signors of both letters included HHS Secretary Xavier Becerra in his capacity as California Attorney General. It speaks to the importance of this matter as a critical national public safety measure and which has no political affiliation.

Targeted control of specific fentanyl-related substances as a class and not as discrete chemicals is not a minor change to the U.S. 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 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. That is 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 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 percent in just one year: 965 in 2016 to 1,588 in 2017. 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 the former

Governor of New York called for fentanyl class scheduling language in NY and why other states and nations including Canada 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-Bioactive 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 substance classifiable under the FRS class scheduling language (all 27) has been found to have potent opioid bioactivity - dozens or more times more potent than 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 backyard; there is no bathtub lab manufacturing occurring; and, 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 decide not to test their product lest they put new FRSs in their distribution networks that were duds [non-psychoactive]. How long would they be able to sell them if they didn't have potent opioid bioactivity?

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 this fentanyl related substance class scheduling language that is then manufactured and internationally trafficked would be bioactive. If the bioactivity were similar to fentanyl, it would be at the level of chemical weapons lethality: one teaspoon deadly enough to kill 2,000 people.

Those opposed to enacting permanent fentanyl class scheduling suggest a drug trafficker could be incarcerated for distributing a FRS that was actually beneficial or an antagonist like naloxone. This is simply not the case. As 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, if Congress were to enact the rapid de-scheduling pathway proposed by President Biden in his ONDCP FRS scheduling recommendations (also in the HALT Fentanyl Act), rescheduling could be done rapidly in the highly unlikely circumstance of a substance being trafficked turns out to be non-psychoactive.

Sentencing Guidelines
Under current federal 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. I would venture to guess that most, if not all, physicians [and Americans too for that matter] would agree: if you could have only one class of drug with associated mandatory minimums, it would be fentanyl and FRSs.

There is information being disseminated that there have been prosecutions for FRSs that are not bioactive. This is not correct. As mentioned previously, every FRS researched to date under the FRS language has been found to have opioid effect bioactivity far more potent than heroin and morphine. The most recent new FRS studied was found to be four to eight 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 respectively]. In fact, it would not have qualified under the fentanyl class scheduling language as a FRS. 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 List 1 precursor benzyl fentanyl have occurred under FRS scheduling. 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]. **There have been Zero prosecutions for FRSs that are not bioactive.**

In addition, n several occasions, substances that do not fall under the FRS class scheduling language have been misclassified as such by those arguing against FRS Class Scheduling: benzyl fentanyl, remifentanil, Imodium and AT202 adding to the confusion on the issue of impact on research. In fact, all are not classifiable as schedule 1 under the FRS scheduling language.

International Coordination (with China Especially)

In trade negotiations with the Chinese government, the U.S. included targeted FRS class scheduling among its priorities. As a result, China permanently enacted similar scheduling language in May 2019. The United Nations includes it in its toolkit of model opioid legislation for member nations. Several other countries [including Canada] and many American states have adopted similar scheduling language. In this case of harm reduction to benefit American citizens, even China sees the value in permanent FRS class scheduling. It is not inconceivable -- and many would say likely -- that if the U.S. doesn't permanently enact FRS class scheduling, China may not continue its prohibitions on fentanyls, and the incentives for the creation and distribution of new FRSs would re-open, or that some of the thousands of chemical companies in India would start on the FRS creation pathway that would re-open if FRS scheduling were to sunset.

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 FRS loophole at home and overseas and saving countless lives in the process. If Congress allows the FRS-class scheduling to expire, it's only a matter of time before other countries like China and India could restart fentanyl-related substance creation and unleash the devastating consequences.

My roles as an emergency physician, parent of young adult daughters and a medical regulator, drove me to design a legislative solution to prevent the development of new FRSs by illicit overseas chemists, but at the same time not incarcerate people with substance use disorder or impede critical research. The FRS class scheduling language that has been embraced by the Biden Administration/ONDCP and HALT Fentanyl Act threads that needle.

Congress has in its power to permanently enact this important FRS class scheduling legislation 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 the creation of new FRSs 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 and pass the HALT Fentanyl Act.**

Thank you for the opportunity to contribute to the discussion and thank you for your leadership on this critical public health issue.

Timothy W Westlake, MD, FFSMB, FACEP
Wisconsin Medical Examining Board, Immediate-Past Chairman
Wisconsin Controlled Substance Board, Former Member

Mr. GUTHRIE. Thank you. And after—I will give you a couple seconds since that was interrupted. But you are completed? All right. Thank you. So the gentleman yields back.

That concludes testimony. This will begin the question-and-answer portion of the hearing, and I will begin the questioning and recognize myself for 5 minutes for such.

Thank you, Ms. Pickard, for being here. You know, if I would have come into this meeting—so you have already learned something today—from you, I would have thought the number one killer was probably heart disease or something such as that, but it is Alzheimer's. And I just didn't know that at all.

So that gives us—and I was talking with the Democrat leader, and we said, well, that was a statistic we just didn't know. So thanks for coming, and sharing testimony is important when you come here and testify, put it on the record.

I am going to kind of focus on the fentanyl side of it, but, Ms. Cain, thank you for coming. You are absolutely right, it is not necessarily people that are addicted or have addiction issues. There are people that may have prescription Xanax or Adderall.

I have heard that for some reason they get one, they don't have their prescription filled, somebody, a friend, has one, and they use it, thinking they are using it medicinally and it is laced with fentanyl.

And I tell everybody anywhere I go, if it doesn't come from a prescription bottle from a pharmacy, don't take it. But you just don't know that, and that is something that—you being here is important, and you being here continues—your child continues to live on that way, and we appreciate you being here for that.

I just want to talk more with Dr. Westlake, though, on the bill before us, and, you know, the administration's position is, we should schedule illicit fentanyl, fentanyl-related substances, but not make them subject to the mandatory minimums. And they said because, as they appear, there may be some medicinal purposes, they may be as harmless as water, as we heard before, and that just doesn't ring true to me.

One, I don't think there is anything going to be more harmless. Why would a cartel go to the effort to sell something as harmless as water? So it doesn't ring true.

But if there is medicinal purposes, if it is trafficking illegally, like I said before, you know, other diverted narcotics that are prescription narcotics you can have that are diverted, are of medical merit, but if they are being diverted and trafficked illegally, they would still be subject to the same punishment.

And so, what is your view of—I know you are kind of the founder of this idea—so what is your view of the administration's position? I mean, what effect would it have, if they say, "OK, we are going schedule them, we are not going to make them subject to the mandatory minimums like other drugs are"?

Dr. WESTLAKE. Yes, great question. I think the whole—what you really have to remember about FRS scheduling is that it is not about locking people up. It is not a criminal justice bill. What it is about doing is purely preventing. So it prevents the existence and creation of these new fentanyl-related substances——

Mr. GUTHRIE. Would you say it is not about locking people up, but if the risk of getting locked up is not there, then it changes people's behavior?

Dr. WESTLAKE. Absolutely. I mean, the effect is a preventative effect, but the law enforcement aspect is the key component to keeping it in place. And the reason that—that it is important to understand that the research behind structured activity relationships.

So there is 60 years of research into fentanyl-related substances and fentanyl, and so there is a wide dearth of research—if you take a look at my written statement, it goes into detail about that—a wide—a mountain of literature of little tiny modifications that you can do to the fentanyl molecule to make it bioactive.

And that is why the structural language that we used was targeted specifically for those modifications only. It is not this—you know, the opposition would say it is this broad-based thing, and, you know, like you said, it could be water or something.

And of the 27 substances studied of the 36 that were found by DEA, all of them have been highly, highly active, bioactive opioids. One of them is 7,000 more potent than morphine, almost as potent as carfentanil is.

Mr. GUTHRIE. So if we were to schedule fentanyl without subject to mandatory minimums—I am not saying—that is another debate whether we have a debate on, overall, the program. But if we were to schedule fentanyl and not subject it to the same penalties of other similar situation, then it would be a negative?

Dr. WESTLAKE. Yes. Because then it would take—what it would do, because right now, the cartels are producing illicit fentanyl because there is no reason to move to fentanyl-related substances because they are scheduled, you know, as a class. If that was removed, then there would be a lot of incentive to go back to making——

Mr. GUTHRIE. Which can be more potent or probably more likely to be more potent and less harmless?

Dr. WESTLAKE. Exactly.

Mr. GUTHRIE. So, Dr. Loyd, in your practice, what do you see as the number one thing that Congress needs to be doing? We are going to look at—I know it is not before—better look at the SUPPORT Act as we move forward.

I only have about a half a minute left, but what do you think—because we need to do the enforcement side, but we also need to the recovery side.

Dr. LOYD. Thank you, Chairman. The recovery side is extremely important. The number one thing is something we all have control over, and that is stigma, how we look at people with substance use disorder and allow them to step out and ask for treatment.

But when that happens, the treatment has to be there, and it has to be evidence based, meeting people where they are.

I heard the definition of "harm reduction" in the last panel, and I would argue that harm reduction is keeping people alive. I haven't figured out how to treat dead people, and so we got to keep them alive and then set up a system of recovery that allows them to succeed like the one I stepped into.

Mr. GUTHRIE. Thank you. Well, my time is expired, so I will yield back the time and recognize the ranking Democrat leader of the subcommittee, Ms. Eshoo from California.

Ms. ESHOO. Thank you, Mr. Chairman, and thank you to each one of the witnesses. Thank you for your patience in waiting to reach the witness table. To the two mothers at the witness table, thank you. I can't—I don't think that there can be a greater sorrow than burying one's own child.

And, you know, our work here is—what you come and share with us is a source of inspiration to us, because this is really what all of the work is about. So thank you to each one of you.

I want to say something about fentanyl. I know that it is going to be ongoing because we have legislation that is being proposed. You know what, I am struck by—and I am for the legislation, I think it should be scheduled, but I think that we are, in a way, deluding ourselves, because when I look at what has taken place over the last 5 years with fentanyl being scheduled, Schedule I, deaths have not been reduced in the country. They have gone up.

I don't think it is a result of their being Schedule I that it has gone up. I just don't think scheduling—I think scheduling is a whole other issue when it comes to law enforcement, what tools they have, et cetera, et cetera.

And I also think there is a 10-billion-pound gorilla in the middle of the room, and that is that sadly, tragically, the United States of America is the most extraordinary market for drugs. We have an insatiable appetite for drugs in our country.

And then look at all the things that we are dealing with—the grief, the sorrow, the wrecking of families, of human life, dealing with addiction, and all the things that we need to do to help people. So I just wanted to place those words on the table.

On QALYs, for those that are tuned in and don't know, have never heard this word before, it stands for quality adjusted life years. And they may still not understand it, but that is what it stands for. And these are measures to determine the value of drugs or treatments.

I think that QALY measures are discriminatory, period. They are discriminatory because they don't give equal weight to the lives of people with chronic disease or disabilities, as they do to the lives of healthy people.

And as my beautiful mother used to say, God never created any junk. Each one is precious. Each one is precious.

Now, maybe some legislators know this, others may not. It is why the Affordable Care Act banned their use in Medicare. That is very important. So this has not been lost on at least some of us.

I welcome the legislation, but there is something in this that refers to the legislation we are considering, where it refers to similar measures. I don't know what "similar measures" are.

Now, Mr. Isasi, I think that is what you were referencing in your testimony.

Mr. ISASI. Yes.

Ms. ESHOO. Is that term anywhere in the law today?

Mr. ISASI. So that term is in aspects of the law, but very importantly, as you are pointing out, the legislation that is proposed is

about one thing: It is about price. It is about similar measures being applied to price, and it applies——

Ms. ESHOO. Well, that is what QALYs are, aren't they?

Mr. ISASI. Right. So it is not just about——

Ms. ESHOO. I mean, the end result is discriminatory?

Mr. ISASI. That is right. But the problem here is, you know, as we know, in—so this is all about one thing. The pharmaceutical companies are trying to create a legal loophole so that we cannot actually negotiate fair prices with them.

And in this case, they are trying to drive a huge hole through the drug negotiation law by saying any measures to try to measure value, any measures that are based on any assessments, would be barred from being used to set a price. So it is just a gaping hole.

We are 100 percent with the disability community that they cannot be discriminatory. As I pointed out in my testimony, the law already says those prices cannot be set using metrics that are discriminatory against people with disabilities, against the elderly, against people who are terminally ill.

So the law has the protections already in place. This is about giving lawyers for the pharmaceutical companies a giant loophole to fight against fair prices for American families.

Ms. ESHOO. Well, I think that all of us, including the disabilities community, would rise up against what you just described.

We are going to have to get this straight now, Mr. Chairman, because I think that there is full support on the issue of QALYs. We know it is discriminatory, but—and we need to get that done, but we are going to have to address this other language. Thank you, and I yield back.

Mr. GUTHRIE. Thank you. I thank the gentlelady for yielding back. And the Chair now recognizes the chairman of the full committee, Mrs. McMorris Rodgers, for 5 minutes to ask questions.

Mrs. RODGERS. Thank you, Mr. Chairman, and I think I will just start with a little follow-up to Mr. Isasi, because I saw in your testimony that you say, quote, "IRA already includes explicit disability (and other) safeguards." So why shouldn't we apply similar prohibitions and protections to all Federal health payers? Why would that be a problem?

Mr. ISASI. So, in this case, the proposed negotiation goes much, much further. It doesn't just ban discrimination, it bans in setting a price. And it is really important to say that.

This is only about one thing in the legislation. It is about the price that is being set in drug negotiation, and it is saying clearly that any measure—and the language is so broad and so vague that a lawyer for the pharmaceutical industry will drive a truck through it and say you are trying to assess value——

Mrs. RODGERS. OK. Thank you. We are going to work on this.

Mr. ISASI. You bet.

Mrs. RODGERS. And I do want to work with the ranking member to figure out how we can get this language where we need it to be, to make it clear.

Mr. ISASI. And we are one——

Mrs. RODGERS. OK. Thank you. I am sorry.

Mr. ISASI. Sure.

Mrs. RODGERS. OK. Ms. Cain, I understand you gave pretty compelling testimony, and we have had the chance to sit down before, and I greatly appreciate you making the trip to be here. Carson should be here. Carson should be here today.

And, you know, we have been, especially on our side of the aisle, the Republicans have been sounding the alarm on fentanyl and the need for Congress to act. Just last week, we held a roundtable that was more focused on fentanyl and what is going on on social media platforms that are making it so available and platforms that are not taking their responsibility to moderate illegal activity on their platforms seriously enough.

I just wanted to ask, from your perspective, how can lawmakers make the most impact, to spread awareness, and curb the buying and selling of illicit fentanyl? What do you think that we can do that would be most effective?

Ms. CAIN. I think that we need to begin by educating—educating. Education is a huge thing. I think that I can only speak to Carson's case. The individual who sold him the pill served no time for my son's death because of these social media companies and Snapchat especially.

Once that chat is open, the evidence is gone. And because they said that—I believe they said that they hold them for 90 days in their server. It was already gone by the time we got the toxicology report.

In my opinion, which I am sure many will disagree with, I do think that we need to hold these people accountable. We need to have tougher laws. In this day and age, when we know that it is a poison, they are being poisoned, and, again, not all of these individuals are—many of them are taking it unknowingly. And we shouldn't be holding them accountable. I think we need to be, as Dr. Loyd said, we need to be looking at this through a different lens.

Mrs. RODGERS. Yes. Thank you, thank you for speaking out, thank you for being here. I will go back and listen to your testimony. I am sorry I had to step out.

Ms. CAIN. Thank you very much.

Mrs. RODGERS. Ms. Pickard, I appreciate you being here also, and as you know, our son Cole was born with that extra 21st chromosome that people know as Down syndrome. And I remember when he was born and just the doctors telling us, you know, what to expect. And in so many of the cases, they got it wrong. They got it wrong.

He is a freshman in high school now, a 15-year-old, has big dreams. He wants to go to college. He wants to play football. You know, he is going to be in a band, he plays the drums. He is going to do it all.

And, you know, he just reminds me every day as to the potential of every life. So, you know, I have heard some statements today about the QALY bill, and I am not sure that it is fair or conveys the full truth about QALYs.

For example, it has been asserted that banning QALYs is not necessary in Medicaid, for example, because States are already required to cover all drugs. However, we know that States have limited drugs for muscular dystrophy to those who can walk rather

than those who can't, because it is not necessarily seen as worth the cost of paying for it.

So my question is, what would you like to say about QALYs in 6 seconds?

Ms. PICKARD. Myself?

Mrs. RODGERS. Yes.

Ms. PICKARD. Thank you, thank you. So it sounds like Cole is just like every other 15-year-old young man. And I have to say, in the healthcare system, I can tell you that children and adults with Down syndrome regularly face deficiencies in care, including access.

Doctors who specialize in care for patients in our community are scarce. There are only 16 adult clinics that specifically serve individuals with Down syndrome in the country, leaving patients in States such as Kentucky or New Jersey without access to specialized care.

And in the moment of greatest need, discriminatory policies can even restrict individuals with Down syndrome from receiving those life-saving organ transplants.

Banning QALYs is a step in the right direction, but so much more needs to be done, and I look forward to working with the committee to address these important issues. Thank you for being here.

Mrs. RODGERS. I yield back.

Mr. GUTHRIE. The gentlelady yields back.

We are trying to—are we going to have time for one more, we think? Are we going to have time for one more?

Mr. CÁRDENAS. I am willing to risk it.

Mr. GUTHRIE. Mr. Cárdenas of California is recognized for 5 minutes.

Mr. CÁRDENAS. Thank you so much, Mr. Chairman, and thank you for all your testimony and your important information that you are sharing with us as policymakers for our country. Thank you, Molly and Dr. Loyd. You inspired me to call my son.

I want to apologize to my staff who wrote my questions, but I created my own after talking to my son.

I am one of the lucky ones. My son is in AA. He goes every day. Thank God.

So I asked him, what should I say? What should we talk about? What's the answers, et cetera? He doesn't have them all, but he did give me some advice.

He says, you know, one of the things that I was taught when I go to this group, there is a boulevard in my district called Sepulveda. Two people end up in jail because they were buying drugs on Sepulveda. One has a drug problem. He wakes up in jail, "Never going to do that again." Maybe he stops taking drugs.

The person who has an addiction, they wake up in jail and go, "Where am I, what is going on, I am never going to buy drugs on Sepulveda Boulevard." They are going to do it again.

So my first question to you, Dr. Loyd, is this: On a per-person basis, based on your testimony, what you provided for us, do you think that punitive incarceration answers is more or less expensive, in all aspects, than prevention, intervention, and support like you have been describing to us?

Dr. LOYD. Thank you, Congressman Cárdenas, and I am glad about your son. It is the best news. I am here to bring hope today. My son is in this audience today, watching me sit before my Congress and my country. It is because I got quality help.

I am talking about people with addiction. I am not talking about cartels. I am talking about those suffering from the disease of addiction. Incarceration won't help them. It won't cure them, because they will do exactly what your son said they will do, and I would have done it too, and I am a practicing physician, and I was a practicing physician when I was addicted.

Our money is much more better spent on prevention, education, and treatment. Carson didn't know he was getting fentanyl. He didn't know it. It shouldn't be a death sentence.

And so I think we have to understand as a body and as human beings that the disease of addiction is not a moral failure. It is a chronic, treatable disease of the brain, and it is driven by cravings.

And when you have somebody sitting in there—me, today, I would look at it and go, "I am not going to do that again, period." But in the throes of addiction, the response that your son gave to his friend is exactly right, and it is exactly what will happen. And the case I always made: If that worked, nobody would go back to jail a second time.

Mr. CÁRDENAS. Yes. Doctor, you are blessed and fortunate you are still with us.

Dr. LOYD. Yes.

Mr. CÁRDENAS. Molly, your son isn't. You are not one of the lucky ones. If we make good policy here, we are going to create more lucky ones, right, if we do it right.

But if we do it wrong, people are going to continue to die in the United States of America in a way that no one should ever leave us.

Is there any other advice you would like to give us, Molly?

Ms. CAIN. As I said, we—I can't speak to—I know that Carson's last year was a perfect storm. I can't speak to—I know that he was prescribed Xanax, and I know that he wasn't sleeping.

I have heard from people on social media criticizing the parents and the people who have used, and that is so detrimental to the healing. We need to be addressing this problem.

It is not a problem that just affects—fentanyl is indiscriminate. It affects all walks of life, every party.

I am not a lawmaker. I came to share my son's story. I am asking of you to please make some sort of change so another mother can look across the dinner table, can celebrate her child's birthday with them.

The only thing I can think of is, we have to educate and we have to educate young. I think about the Mothers Against Drunk Driving and how that started. And maybe this is something that we need to do.

Mr. CÁRDENAS. Thank you so much. My time having expired, I yield back.

Ms. CAIN. Thank you.

Mr. BUCSHON [presiding]. The gentleman yields back.

I recognize the gentleman for Texas, Dr. Burgess, for his 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman, and I want to thank our witnesses for being here today.

Ms. Cain, I will just tell you, we have worked on this problem of opiate dependence and addiction up here for a long time, but until our chairwoman, Mrs. McMorris Rodgers, did a roundtable last week, I had no idea about the Snapchat focus.

And clearly that has—when I talked to the previous panel, really concerned about fentanyl, because a lot of the work we have done has been more geared toward, oh, a dentist who prescribed too many Percodan after a wisdom tooth extraction and someone took it inappropriately.

Fentanyl is a different disease. It is so much more deadly than anything that could be contained in a diverted prescription.

And then Snapchat has added yet another dimension to this and, quite honestly, one that I had not appreciated, as I say, until we had done the roundtable up here.

So, as painful as it is, I appreciate you coming and sharing your story, because we have to focus on these delivery modules that weren't even in existence when I started on this committee many, many years ago.

I am up against a vote. I just want to ask, Ms. Pickard, briefly—thank you for your work that you have done for National Down Syndrome. We heard from our ranking member, Mr. Pallone, and I think we have seen in written testimony that this QALY legislation is a solution in search of a problem. Would you agree with that characterization?

Ms. PICKARD. I believe—thank you for the question. I believe that more research is needed. I think there is more research needed to really further develop and test those alternative methods and frameworks for determining the value of healthcare treatments.

And we must ensure that individuals with disabilities, their voices, are included in this conversation.

Mr. BURGESS. Well, I wanted to ask unanimous consent to include two articles in the record. One is by three authors, one of whom is well known to this committee, Ezekiel Emanuel, and this is from The Lancet, "Principles for allocation of scarce medical interventions."

And as frightened as I am about QALYs, he also talked about disability adjusted life years, and clearly that is a focus that I think will be exceedingly pernicious, and I do want us to focus on that.

And then the other is from early in the pandemic from an article that was published in ProPublica that was from the Arizona Daily Star, dealing with the problem of scarce or limited resources when we thought we needed more ventilators than we turned out to need, and who gets to go on the ventilator and those questions that came up.

ProPublica—I can't believe I am saying this—ProPublica actually did a very fair report on this, and, Mr. Chairman, I would just like to add these two articles for the record.

Mr. BUCSHON. Without objection.

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

Mr. BURGESS. And then I have got to go vote. Thank you very much. I will yield back.

Mr. BUCSHON. At this time, we are going to take a brief recess, probably for about 15 minutes, so Members can vote, and we will come back right after that. The subcommittee stands in recess.

[Recess.]

Mr. BUCSHON [presiding]. The subcommittee will come to order. We will restart with questioning, and I recognize the gentlewoman from Washington, Dr. Schrier, for her questions, 5 minutes.

Ms. SCHRIER. I should change this. I could take a new title.

Thank you, Mr. Chairman, and I especially want to thank you, Ms. Cain, for coming out from Washington State today to share your son Carson's tragic story, and from one mom to another mom, I can only imagine your heartbreak. And I think about this frequently, as I have a 14-year-old boy. And your account makes so clear why we need to crack down on social media companies, the avenue by which so many teens get access to these deadly drugs, poisons.

I am in the process of working on legislation to bring some of these issues to light and to make sure families have the tools to keep their children safe. And thank you for sharing your story, because it helps parents and the rest of this country and world understand how to keep others safe.

Fentanyl has had profound, devastating impacts in my State of Washington. And parents want to engage with their children. Sometimes they don't know how. Just this morning, I met with the Enumclaw Youth Empowered coalition from my district, and their focus is on reaching families early to prevent drug use, experimentation, anything that gets their kids even close.

Given the importance of educating kids and schools and prescribers and patients, I was wondering, Dr. Loyd, if you could highlight some of the ways that parents can find guidance on having these conversations.

Dr. LOYD. Thank you for the question, and it is very difficult. You know, today is a different world than I grew up in with social media and what Molly shared with us. But it is also the world of "take one pill and you die." And that is the message that is very, very hard.

So when I talk with parents, it is always about being open and not thinking that you know everything. I see parents make mistakes all the time—"Oh, I know what is going on inside my house and I know"—and the truth is, Congresswoman, we don't have near as much control as we think we do.

And so these opportunities to talk with our children and be open and honest, most of us have some kind of experience with things in our past that maybe we could have handled better, and we are not perfect, and our kids need to see that.

And so my son, I told you, is in this room, and so he was 9 when I got into recovery, and I started sharing my stuff with both him and my daughter at that time. So I think, for parents, it is important to realize that it is not the world that we grew up in, and now, not that anything is OK, but it is a one-time thing and you can literally die this afternoon.

And that is the part, if you don't know where it came from, you know, please don't take it, because it will look just like what comes out of somewhere.

And the other thing I see, Congresswoman, is this. Just because it comes out of a bottle that a doctor wrote a prescription for, it is not OK. And I think a lot of times that kids will look at that, and, well, "A doctor wrote this, this is OK"—I have seen it with numerous teenagers—and it is absolutely not. Those are the places I would start.

Ms. SCHRIER. I think those are great points, and I will tell you, even as a pediatrician, it is challenging to have these conversations, but just last night I had the conversation again with my 14-year-old because he can't—I am just speaking to parents out there—you can't have this conversation enough, and reminding teenagers, who are, by their very nature, impulsive and experimental and trust their friends sometimes more than their parents, that anything anybody hands you—whether they tell you it is an ibuprofen or somebody is trying to hand you an Adderall, telling you it can help you focus better—that that could be the pill that ends your life. And so thank you for bringing this to the forefront, and I will yield back my time.

Mr. BUCSHON. The gentlelady yields back. I now yield 5 minutes to the gentleman from Florida, Dr. Dunn.

Mr. DUNN. Thank you very much, Mr. Chair. So we have an important opportunity today to advance legislation that will protect all Americans, including the most vulnerable, the ones that Dr. Schrier mentioned, the children who are susceptible to accidental fentanyl exposure and experimentation with street drugs. So I am proud to support the bills before us today.

Importantly, the HALT Fentanyl Act will permanently place all fentanyl-related substances into Schedule I. This bill addresses a failure of the administration and represents an important step towards getting these deadly fentanyl analogs off our streets.

However, I believe that to wholly address the fentanyl crisis, we need to do some other things. We need to designate the entire class weapons of mass destruction.

That is not a frivolous proposal. It empowers the DHS to help us with this effort. It also makes international policing substantially easier.

We also have to better educate our youth again and again about the dangers of drug use. There is no street drug that is safe. There is no pusher who can be trusted. Everything could be laced with fentanyl.

We also have to work to address recidivism in our communities and, frankly, fix the broken families. An example of that, one of the counties in my district that was hardest hit by fentanyl poisonings has 40,000 citizens. Of those 40,000, 22,000 of them have spent time in the county jail. If we can address some of these root challenges that these communities face, we can decrease the demand for all street drugs.

Another important bill we are going to discuss today is the use of QALYs, quality adjusted life years, by government insurance programs.

I am a doctor. I think the entire concept of QALYs is contrary to the American values that set our free society apart from socialist healthcare systems that restrict care and choose for you and your family what life is worth.

It is disappointing to me that we have to legislate to prevent such tactics from driving our Federal healthcare policy. Our Nation supports some of the greatest biomedical research in the world. Regardless of one's ability or disability, all Americans should have the right to choose their care.

Ms. Pickard, can you give us some examples of how QALYs are used internationally—where they are used, how they limit access to care—and how are they used in the United States?

Ms. PICKARD. Thank you, Congressman. Many countries, including our friends in the U.K. and Canada, heavily rely on QALYs. They help determine who is worth treating and who is too expensive, thus determining which medicines or treatments are available to patients.

For example, from 2016 to 2019, the U.K. used QALYs to restrict access to the first-ever approved treatment for cystic fibrosis. Unfortunately, it is important to note that these metrics are not here, you know, used here in the United States as well.

As you asked about examples about the U.S., most recently CMS relied on a report from ICER, the Institute for Clinical and Economic Review, that used QALYs and similar one-size-fits-all metrics in its national coverage determination for Aduhelm, the first treatment approved for Alzheimer's disease.

The initial coverage determination excluded individuals with disabilities. This was particularly concerning, as individuals with Down syndrome have that heightened lifetime risk, higher than 90 percent, of developing Alzheimer's disease.

Access to treatments for this debilitating disease is paramount to our community, and we will continue to work with Members of Congress and this committee to ensure individuals with disabilities are not left out of this conversation.

Mr. DUNN. You know, I think my professors from med school would be rolling over in their graves if they heard us having this conversation. It defies belief.

Dr. Westlake, as a fellow physician, I agree with you regarding the importance of permanently scheduling the fentanyl-related substances into Schedule I. We all know this is a crisis. What the heck is the challenge here? We have been working on this for years. What is the head wind?

Dr. WESTLAKE. Yes, you and my wife have both the same question. I first testified at a hearing for House Judiciary 5 years ago on this topic and brought this up. I don't know. I don't know if it is politics, if, you know, there is advantage in trying to, you know, access criminal justice reform.

I think there is confusion between what this bill, you know, what the fentanyl-related scheduling does. You know, it is not going to stop all fentanyl deaths. It is going to stop fentanyl-related substance creation and fentanyl-related substance deaths, which it has.

So I really don't—it is very simple to me, but I think it gets cloudy when you involve what happens in Washington.

Mr. DUNN. I don't know, honestly, for the life of me, I have never come to one of these hearings and heard somebody say, "Fentanyl is pretty good stuff. We ought to have more of it or push it out on the streets." Nobody says that. In China, it is Schedule I.

Dr. WESTLAKE. Yes. The last thing we need is another fentanyl.

Mr. DUNN. This is crazy. Well, thank you. My time is elapsed, and I will yield back to the chairman.

Mr. BUCSHON. The gentleman yields back.

I now yield to the gentlelady from Tennessee, Mrs. Harshbarger.

Mrs. HARSHBARGER. Well, thank you, Mr. Chairman, and thank the witnesses. And, Ms. Cain, I am sorry about the loss of your son. I guarantee that there is not one person in this room who has not been touched by either the loss of a family member or friend to some type of drug overdose.

You know, I have been a pharmacist 36 years, so I have dealt with a lot of this. And, Mr. Loyd, I have dealt with a lot of impaired physicians, a lot of impaired pharmacists, you know, employed some to give them a chance to get their hours so they can practice again. So it is not anything that is new to me.

And I am telling you, I visited a lot of rehab clinics in the district, and I read that you have—you know, you are doing the incarcerated gentlemen at Cocke County in my district. And Judge Slone, I have met with Judge Slone, I have talked with him, and he walks the walk because, if I am not mistaken, he even adopted a child from a mom who was addicted to drugs.

So, you know, these are the kind of judges we need on the bench in these drug courts, and I have talked to numerous drug court judges and heard the stories. And he has offered to come let me sit in with them as they go through that process, and I said, "Absolutely, I will come. I want to hear that."

You know, when I visited some of those rehab clinics and talked to some of the physicians, you know, they have a multistep approach. It is not just giving them a drug to get off of a drug, because that is a problem. They can take those drugs—I have said this in the last session—they can heat those foils up. They can inject them. They can abuse that drug.

But what they do, they have the counselors, they have the group sessions, you know, and there's limiting factors. And one of the pharmacists left Walgreen's to do a pharmacy there at one of the rehab centers because he said these guys don't have a place to go.

A limiting factor is having a bed, having a home, and to get them back as contributing citizens to society, there's things that you have to address.

So I guess with all that said, and as an ER physician, you see this. They come to me, years ago, we would have to come up with modalities as a compounding pharmacist. We would have to help them with different drugs. They used to use clonidine to get them off the drugs.

There's so many things they do. Used to do things for patients with special needs or Down syndrome, you know, when you couldn't get specific products. We still do that. My son is a pharmacist now.

But I guess my question is, you know, sometimes insurance won't cover them. I know Blue Cross Blue Shield dropped a lot of the clinics, and they would not cover that, you know, the drugs that they needed to rehab them.

I guess my question is, what do you believe are the most important things Congress and/or the FDA or other Federal agencies can do this year to help us conquer this addiction?

I am saying close the borders for one thing, hold those people who are selling these narcotics accountable, make those laws to where—if it were up to me, I would probably label the cartel as a terrorist organization, but, you know, they probably don't want me to talk about that. But go ahead, anybody can answer that.

Dr. LOYD. Thank you, Representative Harshbarger. You are actually the Representative from my boyhood home district. I am from Jonesborough, Tennessee.

Mrs. HARSHBARGER. Jonesborough?

Dr. LOYD. Yes, ma'am.

Mrs. HARSHBARGER. For heaven's sake, who knew.

Dr. LOYD. So thank you, and I am very familiar with that area, it is my home, the foothills of the Appalachians. So the things that we can do as a society I have already talked about it, is decrease stigma.

As a legislative body, the areas that move the needle the most in our country, in my opinion, is the criminal justice system and emergency departments, because these are the places that our patients are showing up being overdosed.

And the system of care needs to be designed to, one, allow them to stay alive. And you are exactly right, medication will allow them to stay alive, but that is a pretty low bar.

If I stop one of my young pregnant women from, you know, using a needle and putting drugs in her body, that is a good thing. But if I am sending her back to the environment where she is getting abused at night, that is a pretty low bar.

So we have to have a system set up that allows us to reimburse for care, to help people with physical, sexual, and emotional abuse, which a lot of times are the underlying drivers of addiction.

And until we can do that and support things like safe housing, I don't know how all of us would be here today if we slept on the street last night. Probably not in very good shape.

And so our system needs to be designed as a comprehensive level of care to help people find what is right for them.

And a lot of times we judge people on medication, and we have to stop doing that. Sometimes it is the only thing keeping them alive.

And I really appreciate the plug for our drug court, and I invite everybody to come. It is good for your soul.

Mrs. HARSHBARGER. Yes, it is.

And, Ms. Cain, I just had a dear friend, she went up to wake her 17-year-old son up, and he was dead. It is the same thing, it only takes one pill. And people need to be aware of that. Two grains of sand is all it takes to kill you, and fentanyl is showing up in everything, and I have talked to a multitude of people about that.

So we have a problem, we need to fix it, and you can't fix it if you don't understand it. So I appreciate you being here. And with that, I yield back.

Mr. BUCSHON. The gentlelady yields back.

I now recognize the gentlelady from Iowa, Dr. Miller-Meeks, for 5 minutes.

Mrs. MILLER-MEEKS. Thank you very much, Mr. Chair, and again, I thank our witnesses for their patience throughout this and then throughout the brief recess as we voted.

I am a physician. I am the former director of the Iowa Department of Public Health, as I had mentioned earlier, and then also as a State senator. And it is a very timely topic.

As a State senator, I successfully passed—I can't speak, but passed in one session no preauthorization for Medicaid-assisted treatment through our programs, including Medicaid.

I was also able to get behavioral health treatment as a side of service at schools, so for those individuals who either don't have transportation or can't get to their providers, so that we make sure there is a continuum of care.

And, Dr. Westlake, as you referenced in your testimony, what can Congress do, and you mentioned the HALT Fentanyl Act. I am an original cosponsor of that, and I agree that there is a lot of misinformation about that.

And I am also interested, so we are kind of sisters, I am Iowa, you are Wisconsin, and Wisconsin has a program, but in Iowa we have the Billion Pledge Program which is another one of Iowa's leading opioid prevention initiatives.

Specifically, this program aims to remove 1 billion opioid bills from the medicine cabinets, using evidence-based protocols, peer-to-peer education, nurse support, and also preparation for surgery, because as we know, a lot of opioid addiction has started through postoperative care and pain management, pain relief.

As part of this, they have a tool kit that has an ice-heat pack, a nurse responsive, or someone that they can call in addition to their regular provider. It has a nutritional water supplement, which gets to the NPO, or nothing by mouth, for, you know, hours before surgery, which leads to increased pain afterward. And then a regimen of alternating ibuprofen and Tylenol.

So I think this program is a critical program that, you know, looking at their results and statistics, probably should be replicated. And I know that your experience is largely in the emergency room setting, but you were very instrumental in setting up Wisconsin's programs.

So I would like to ask if you have knowledge or information about what can be done regarding post-op monitoring to reduce the number of Americans that come away from a surgery with an opioid addiction and whether you have experience with enhanced recovery after surgery guided care.

Dr. WESTLAKE. Yes. Thank you for the question.

I think that education is key. You know, I led the prescription reform efforts in Wisconsin starting 8 or 9 years ago, 10 years ago, and educating the physicians about prescribing. But I think we also need to continue to educate the public.

And, you know, one of the things is—there is a study out of Michigan that, you know, 1 out of 16 kids that gets exposed to Vicodin for wisdom tooth extraction becomes addicted to it.

And so it is stopping the initial exposure. And I think as a society we have to understand that there are going to be things that are painful. I tell people when they have a broken wrist: It is going to hurt. You can take Tylenol, you can take ibuprofen, you do ice.

You know, take this tramadol or hydrocodone only if you have to, at night, and realize that if you take it there is a potential you could be addicted to it.

I think education is out there, though. I think we are moving forward significantly on that respect. I think prescription drugs are not nearly the problem they were 10 years ago.

Mrs. MILLER-MEEKS. Thank you for that.

We also have increased access to harm-reduction tools, and we have mentioned that. And I remember going through these as director of the Public Health Department. And as beneficial as they are, I just want to also mention that, in my meetings with both public health and with law enforcement, that we now also have, you know, individuals who are abusing those very same tools that we are using to save lives. So, when I am speaking with individuals in recovery and in law enforcement, mentioning the use of Narcan—overdosing on medication, knowing that there is Narcan available. So I think it is an extremely important tool, but we also have to be cautious and be mindful of that.

There have been significant efforts at the Federal and State levels to increase access to naloxone, but I want to ask you, Dr. Westlake, in the little time I have, what more can be done to ensure individuals, families, EMS, first responders, emergency departments have the tools they need to give individuals who have overdosed another chance at recovery?

Dr. WESTLAKE. Yes, I think that is key. I think, you know, making it over the counter would be ideal. There is no reason that you would need a prescription for it. There are no side effects to it, other than it stops opioids from, you know, affecting the nerve. And so there is really no downside to it.

I think that would be a huge step, and then it could just be—you know, it could be widespread much more easily.

Mrs. MILLER-MEEKS. Thank you.

And, Dr. Loyd, my time has expired, but if you had comments, please feel free to submit those in writing to us afterwards.

Thank you. I yield back.

Mr. BUCSHON. The gentlelady yields back.

I now recognize the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you, Doctor. I appreciate it very much.

Ms. Pickard, thank you for sharing your story with regard to Mason. Your words provide insights into the joy he brings to you and your family.

The topic of the quality-adjusted life year can get highly technical. Can you share with us the real-world implications for the use of QALYs in decisionmaking, particularly for people living with rare or chronic conditions, such as veterans?

Ms. PICKARD. Thank you for the question.

Mr. BILIRAKIS. My pleasure.

Ms. PICKARD. Well, I cannot speak directly to the rare patient disease community. I can imagine that they encounter very similar problems as the disability does in regards to the utilization of QALYs in all of our Federal healthcare programs, specifically access to those necessary and at times lifesaving treatments.

All lives have value, and no one should be discriminated against based on arbitrary, one-size-fits-all metrics.

Mr. BILIRAKIS. I agree.

Ms. Cain, I am sorry and saddened to hear about Carson's story, and I thank you for your bravery and your calls for action and need for accountability at every level, from Big Tech companies like Snapchat to the DEA itself.

We are losing this battle. And I agree with your testimony calling this a weapon of mass destruction. It is completely appalling that the drug dealer only served in jail for less than 1 day. Unbelievable.

Can you explain how we can better hold these bad actors and drug traffickers accountable and why both social media and the Federal agencies like the DEA need to coordinate better, please?

Ms. CAIN. That is a big question, and I don't know if I am qualified to answer that, to tell you the truth.

I am a teacher. I believe in education. I believe we need to be educating, even as young as kindergarten—I am a kindergarten teacher this year—"Don't touch a pill. Don't—touch nothing. Take nothing. Ask your parents."

We need to—as far as Snapchat, I think that they have been given a free pass, and there is no accountability on their part. And I think it is time we start holding them accountable.

I would encourage you to go visit the DEA and see the faces of fentanyl, because it is eye-opening. There are 4,800 pictures hanging in there. There is a family that lost three of their children. Three. There are children as young as 17 months. You walk around and you look at those faces, and it hits home. It hits home.

I would encourage you to go do that. They have a thousand more they haven't hung yet. They don't have the room to keep hanging them, and they are still coming in.

Mr. BILIRAKIS. It is affecting all our communities. And, you know, this committee has made it a priority——

Ms. CAIN. I thank you.

Mr. BILIRAKIS [continuing]. To go after fentanyl.

Ms. CAIN. Thank you so much.

Mr. BILIRAKIS. But, Dr. Westlake—thank you again. I know it is very difficult, but thanks for your testimony, ma'am.

But, Dr. Westlake, you say in your testimony that fentanyl-related substance scheduling is preventive, not punitive.

As we see other varieties of substances being laced and mixed in with fentanyl and other drugs like xylazine becoming more prevalent, can you explain how we can be more proactive—we need to be ahead of the game—more proactive and preventive to stay ahead of the latest drug-trafficking trends?

Dr. WESTLAKE. Yes, I think the first thing that can be done is to pass the HALT Fentanyl Act. I think that—I mean, just—the way I look at it, drug use and opioid poisonings are like a fire hydrant, and there are different nozzles on the fire hydrant. And you have got illicit fentanyl, which is this big, and you have got fentanyl-related substances, which is smaller. But right now it is closed off and it is closed. And to not permanently enact it is to let it reopen and to start that spewing again.

It is a huge problem, you know, fentanyl and illicit fentanyl deaths and poisonings. And Congress—you know, I think there is always a push to have a legislative solution to do everything, and I don't know that for a lot of things there is a legislative solution. I think this is a cultural solution to the drives for drugs.

But I think this is a legislative solution for FRSes, that you can stop that, and it doesn't impact, you know, other things. It is just going to stop the creation of these, and that is all it does.

Mr. BILIRAKIS. Thank you very much.

I yield back, Mr. Chairman.

Mr. BUCSHON. The gentleman yields back.

I now recognize the gentleman from Pennsylvania, Dr. Joyce, for 5 minutes.

Mr. JOYCE. Thank you for yielding, Mr. Chairman.

And thank you to our second panel for appearing here today, because you give us that critical insight into the bills that we are considering.

Dr. Westlake, thank you for turning around and coming back in to talk to us again.

And during the previous panel, we heard of numerous concerns regarding the permanent scheduling of fentanyl-related substances.

First, on the issues of mandatory minimum requirements for fentanyl-related substances, do you feel these requirements are necessary to deter the trafficking, to deter the cartels, to deter the business model, as they continue to bring these deadly poisons into our communities?

Dr. WESTLAKE. Yes, I think absolutely, without question.

I think that is what makes it prevention-based, is that it stops the incentive for creating them. If you remove mandatory minimums, just like you pointed out, you have something that has less—you know, there is less penalty with it, so that is where it is going to go, is they are going to start creating those fentanyl-related substances.

Because if it is easy—there is a lot of literature on researching fentanyl-related substances and how to make them, and it is as easy as using just a different reagent. So, if you want to make methyl fentanyl, all you do is you use methyl instead of an ethyl group. And so it is literally just one tweak in a cookbook that is well-delineated in the literature.

That is why the language for the structure is so surgically targeted, is because it just gets rid of those known pathways.

Mr. JOYCE. Dr. Westlake, do you feel that the cartels have those abilities to make those minor changes to the recipe, to cook the fentanyl-related products in just a different manner to allow them to come through and escape those sentencings?

Dr. WESTLAKE. Absolutely. If they can make fentanyl, they can make any fentanyl-related substance. All they have to do is look at—there is a Federal sentencing reform testimony that I put in my testimony that addresses that—Mike Van Linn of DEA, Ph.D. It is absolutely easy to find in the literature.

Mr. JOYCE. We have also heard substantial concerns raised over a classwide ban and how that could potentially criminalize harmless substances.

In this case, have there been any fentanyl-related substances that have been found to be harmless?

Dr. WESTLAKE. No, there have been zero. So there——

Mr. JOYCE. Have there been any fentanyl-related products that have been found to be not addictive?

Dr. WESTLAKE. No, there have been zero.

Mr. JOYCE. Have there been any fentanyl-related products that do not bind to the opioid receptors in the brain?

Dr. WESTLAKE. Zero. All of the substances studied by DEA, all 27 of them that have been studied, have bioactivity. Again, one of them is 7,000 times more potent than morphine.

Mr. JOYCE. Dr. Westlake, do you feel that all of these fentanyl-related products are poisons?

Dr. WESTLAKE. Absolutely.

Mr. JOYCE. I think that your ability to take your clinical experience as an emergency room physician, to bring that to Congress, to take your personal ability to recognize that, as you put it, all of these fentanyl-related products are deadly poisons—they are having that impact throughout our country, making every State a border State, something you have heard us frequently say but something that you as a physician recognize.

Would you relate personal experiences on what would make the fentanyl-related products more easily classified, more educated to those who potentially could see those?

Dr. WESTLAKE. So, again, I think the One Pill Can Kill idea, the education component of it, of just educating people that there is no—I have seen marijuana that people smoke that has fentanyl in it that they die from. I have seen all kinds—you know, fake Xanax pills.

I mean, I think just the education is key to the component of how dangerous the substances are.

Mr. JOYCE. Given the dangerous nature that we recognize,that just one pill can kill, if there could be only one Schedule I drug to have mandatory minimum sentences attached to it, what would that be?

Dr. WESTLAKE. Absolutely, without a doubt, fentanyl and fentanyl-related substances. I mean, it is literally—you know, it is literally a chemical-weapons-grade poison.

You know, it is hard to die overdosing on cocaine. It can happen, but it does. It is hard to die from heroin, actually, compared to fentanyl. Fentanyl, I mean, literally 2,000—I don't have my packet of sugar—2,000 deaths from 1 teaspoon? I mean, that is insane.

Mr. JOYCE. Thank you for your concise presentation.

I thank all of the members of the panel for being here today.

And I yield the remainder of my time.

Mr. BUCSHON. The gentleman yields.

I will now yield 5 minutes to myself for questions.

Dr. Loyd, Cedar Recovery specializes in outpatient care. I think it is important that we get people care in the least restrictive setting and that we get them the care early that they need. This is for substance abuse, of course.

However, we need access to all levels of care, including residential care and inpatient care, in my opinion. Do you agree that we should have all settings available to patients?

Dr. LOYD. Thank you for the question, Vice Chairman Bucshon.

And, yes, I do. I agreed with what you said earlier, and I am glad we are getting to talk right now, because I do agree with that. We need to help people find the level of treatment that is right for them, not the level of treatment that is right for the person who is providing the treatment. And I see that all the time.

And there is a difference between access to care and access to quality care. The patients that we focus on in the outpatient setting are Medicaid and Medicare as well as State opioid response patients who don't have resources otherwise.

So all levels of care need to be accessible, but we also need to look at what may hinder somebody from getting the necessary level of care. And the example I will give you is the single mom with two children. The level of care that she may need is inpatient care. And that is fine and dandy until they tell her she can't bring her kids with her, and she is the sole provider for her family.

And so we have to be willing to be flexible and give patients the level of care that will keep them alive, first, and then help them find the path to recovery that is right for them.

Mr. BUCSHON. So you must think—there are some Federal barriers probably, particularly in the Medicare program, like the IMD exclusion, that maybe we should change or revisit?

Dr. LOYD. Vice Chair, there are a lot of hindrances to people trying to get care for substance use disorder, and that would be one I would like to look at.

Mr. BUCSHON. Yes, I mean, I think we have talked about that quite a bit. And I think, personally, we need to just revisit some of the things we are doing and make sure we are not limiting access to care in all settings.

Dr. LOYD. Yes, sir.

Mr. BUCSHON. Well, Dr. Westlake, I want to ask you again about naloxone. And you say you are in favor of it going over the counter.

Dr. WESTLAKE. I am.

Mr. BUCSHON. Before we do that—and I am not saying I am against it. But I was a practicing physician before, a cardiovascular and thoracic surgeon. So I had a lot of patients in the ICU that, you know, as you know, sometimes patients aren't waking up. And you are saying, "Well, maybe they are narcotized, so let's try some Narcan and see if it works." And it does frequently.

You know, chronic ICU patients sometimes are given pain medication even when they are not awake, just with the assumption that, you know, they are in pain. And that happens.

But then, of course, you know naloxone in that setting and in other settings is not without some risk. I mean, there are cardiovascular—potential hypertension, tachycardia, cardiovascular ramifications. And sometimes people do awake suddenly and can be combative and have other issues.

So, once we go to over the counter, what type of public education do you think we should put in place maybe a little bit before we take that step? Or do you think we—what do you think we should do?

Dr. WESTLAKE. I see it as—I mean, I think the people that are going to be using it are not going to be the ones that are at cardio-

vascular risk. I think you saw pretty skewed patients in the ICU that present to the ICU with advanced cardiovascular——

Mr. BUCSHON. I did. That is correct.

Dr. WESTLAKE. So what I am seeing in the E.D. is younger people, you know, mostly under the age of 40, and if they had access to it. Someone may have had it at home. Because when it is given, it works.

And so——

Mr. BUCSHON. Absolutely.

Dr. WESTLAKE [continuing]. Definitely education is needed with it. But I think—and it is the same thing, I think, with buprenorphine.

Buprenorphine is—I know that there is talk about it being abused, and I would much rather see buprenorphine abused than fentanyl or OxyContin or oxycodone. And the people that are abusing it with substance use disorder are going to be abusing something, and so that is—it kind of falls into the same thing, almost like a harm-reduction thing.

Mr. BUCSHON. I understand.

Is there any evidence out there that the availability of naloxone facilitates ongoing illicit narcotics use?

For example, I mean, I have had in some counties, rural counties, where they have gone to the same house three, four, five times. And the law enforcement, at least, tell me some of the suspicion is that the people know that this is available and, you know, the cavalry is going to show up.

I don't personally believe that, but do you think there is any evidence of that, that the availability of naloxone could facilitate further use, or no?

Dr. WESTLAKE. No, I don't think there is.

But do you want to——

Mr. BUCSHON. Whoever wants to comment on that.

Dr. LOYD. Thank you, Dr. Westlake.

I don't think there is any evidence to that either. But I would tell you this: that if it is my son, I hope the cavalry continues to show up.

Mr. BUCSHON. And they do. But they run out. That is the problem, right? I have counties that are literally—the county sheriffs, they run out every month before the end of the month. And then the cavalry may not come.

So, with that, I yield back—oh, Mr. Johnson is here. I yield back. And I will now recognize the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman.

I appreciate the panel coming in.

I do have another fentanyl question. Then I will move on. So let me go quickly to Dr. Westlake.

Higher-dose pills from improperly mixed batches, known as hotspots, that lead to overdose and death in a given area are often the way the medical community and law enforcement learn that fentanyl or an analog has been introduced into a local drug market, which in turn would beget reactive scheduling in States.

Dr. Westlake, this helped you—if I understood it right, this helped lead you to work to target bioactive fentanyls as a class, in

order to remove the incentive that international drug traffickers had in modifying the drug molecule.

Can you discuss how fentanyl class scheduling is critical not only for law enforcement but for patient and community health as well?

Dr. WESTLAKE. Yes. It is critical to leave that spigot closed so that—you know, again, right now, there are no more new fentanyl-related substances that are being created, so no one is dying from new fentanyl-related substances. They are dying, you know, a lot from illicit fentanyl but not from fentanyl-related substances.

You know, what Congress can do is to pass a law that will stop the manufacture and creation of this and remove the incentive for it. If you take away the mandatory minimums, the incentive is going to creep back in, and I fear that that would come back into play.

Mr. JOHNSON. OK. So, should this scheduling ban expire, is it realistic to expect that we would see an increase, perhaps even a sharp increase, in overdose deaths?

Dr. WESTLAKE. So that is a good question. So there is really not—the fentanyl-related substances are not being created or researched in America at all. It is all from Chinese chemical labs and, you know, potentially from Indian chemical companies if they were to choose to do that. And so the key thing is to make sure that the Chinese stop, you know, creating these fentanyl-related substances.

So, yes, I mean, it is critical to get this passed.

Mr. JOHNSON. OK. All right.

And then I want to pivot to address another piece of legislation that we are considering today, this, quote, "quality-adjusted life years."

This concept is exactly what it sounds like. It is a calculation, not made by you or your loved ones, that decides how much, quote, "quality" remain in the remaining years of your life that you might have if you are diagnosed with an illness or a disability, and that then determines how much cost and coverage is going to be applied to that.

I mean, another term for that is called rationing healthcare. That is not what we do in the United States. In some countries with nationalized healthcare, like the United Kingdom, the government gets a say in this, when it is time to consider healthcare treatment options.

And some on the—not everybody, but some on the Democratic side want to emulate health systems like those in the United Kingdom. Well, I say, no, thanks, we don't want that here. This is a dystopian future that neither the people I represent nor I want any part of.

So, Ms. Pickard, thank you for being here and for your advocacy on this issue, because the public needs to learn more about this.

The legislation we are considering today prohibiting using quality-adjusted life years calculations in Federal programs, I fully support it. But, in addition, you mentioned other metrics and value assessments that also contribute to this type of discrimination or, as I refer to it, rationing.

Can you outline, Ms. Pickard, any other metrics or assessments here in the United States or overseas that as policymakers we need

to watch out for and work to mitigate the damage that they may cause?

Ms. PICKARD. Thank you for that question.

Yes. I mentioned a little bit earlier that our friends in the U.K. and in Canada do heavily rely on these QALYs to determine who is worth treating and who is too expensive to treat.

I think that, when we look at this, we really want to look at what is the best for people—in my case, the people with disabilities—and how do we make sure that we look at alternatives.

And I think that there has been a number of alternatives and supplements proposed to replace or improve the QALY, but there is still more research that needs to be done to determine what is the best route.

Mr. JOHNSON. OK. All right.

Mr. Chairman, I see that my time has expired. I yield back.

Mr. BUCSHON. The gentleman yields back.

I want to make a personal privilege here, that my wife is an anesthesiologist, and I have been using the term "illicit fentanyl." Let me tell you why. Because every day in her job she uses fentanyl. And she is having patients—this message is getting out, which is good, that this is a problem in our country, but it is actually a very useful anesthetic agent that we use every day legally. So I have been using the term "illicit fentanyl" rather than just saying "fentanyl," just FYI.

At this point, I ask unanimous consent to include in the record the following items on this list. It is my understanding these documents have been shared with the minority and approved by the minority.

Without objection, so ordered.

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

Mr. BUCSHON. Seeing there are no further Members wishing to ask questions, I would like to thank all of our witnesses—it has been a long day—again for testifying here. Very strong testimony from all of you. Very much appreciate it.

And, at this point, the committee stands adjourned.

[Whereupon, at 3:01 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

OPENING STATEMENT: HON. ROBERT E. LATTA
HOUSE COMMITTEE ON ENERGY AND COMMERCE

Health Hearing on Fentanyl, 2.1.23

I would like to thank the gentlemen from Kentucky our Chairman for holding this critically important hearing and for our witnesses' participation.

In 2021, the United States hit a truly dispiriting milestone by recording 107,735 drug poisoning. This number represents a 16% increase over 2020, which previously held the unfortunate record for poisoning deaths.

Let me repeat that – 107,735 of our fellow Americans, our brothers and sisters, husbands and wives, fathers and mothers, and our kids, died from drug poisoning in one years' time. This represents more

fatalities than the wars in Vietnam, Iraq, and Afghanistan combined.

The main culprit for this explosion in deaths is fentanyl. Abuse of this synthetic drug is now the leading cause of death in Americans aged 18 to 45.

After passage of H.R. 6, the SUPPORT Act, in the 115th Congress, we had a slight decline in poisoning, 62,172. However, after increased pressure at our southern border, there was an increase in poisoning for 2020 leading to 83,558 deaths.

Fentanyl is particularly popular with the criminal drug cartels that operate illicit labs in Mexico and other locations. This is mainly due to the basic nature of its production and utilization of cheap ingredients. Fentanyl

is also 50 times stronger than heroin and 100 times stronger than morphine, making it highly addictive and profitable for drug dealers.

According to DEA testimony, the Mexican cartels, are making fentanyl laced pills for ten cents. They are killing Americans for ten cents.

Due to President Biden's failed and hollow border policies, smugglers have been given the green light to take advantage of the situation by profiting off of the distribution of these weapons of mass destruction in our communities.

On top of these statistics, a recent Substance Abuse and Mental Health Services Administration (SAMHSA) report concluded that one in three Americans had a

mental illness or substance use disorder in 2021. Sadly, nearly 94% of those suffering did not receive the treatment they needed due to heavy handed and ill-advised lockdowns.

How many more lives will be lost before something is done to finally address this poison killing our communities?

We are tired of waiting and have been calling for swift action. That is why I introduced the HALT Fentanyl Act with my friend and colleague the gentlemen for the 8th district of Virginia,

Our legislation would permanently schedule fentanyl related substances as Schedule I and enable researchers to

continue to study Schedule I substances for possible medical benefits.

Again, I want to thank our witnesses for being here today and I look forward to working with you to end the decades old substance use crisis. I yield back.

Opening Remarks

Good morning, my name is Richard Hudson, and I represent North Carolina's 9th district.

Thank you to Chairman Guthrie and Ranking Member Eshoo for hosting this important hearing and thank you to the witnesses for their time and expert testimony this morning.

The threat of fentanyl plaguing our nation is very real and unfortunately has become the leading cause of death among adults ages 18-45.

Last year, it claimed the lives of more than 4,200 North Carolinians… many of whom were young folks who had no idea what they were using was laced with fentanyl.

This includes people like Matthew Thomas from Sanford who lost his life after an accidental exposure to fentanyl in 2020.

I am inspired by Matthew's mom, Wendy, who has turned her loss into advocacy to warn parents and students about the danger of fentanyl poisoning. Her mission should be one that no parent should experience ever again.

President Biden's open border policies are fueling the fentanyl crisis while they show no interest in changing these policies to solve the problem.

The DEA even shared in an unclassified intelligence report that the flow of fentanyl will continue to diversify with China,

Mexico and now India contributing to the supply of fentanyl to the U.S.

Today we have an opportunity to make the realities of the fentanyl crisis known and propose one solution.

Enacting the HALT Fentanyl Act to permanently classify fentanyl related substances as a schedule one drug under the Controlled Substances Act is one small step in curbing this crisis.

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[117H6184]

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Halt All Lethal Trafficking of Fentanyl Act" or the "HALT Fentanyl Act".

SEC. 2. CLASS SCHEDULING OF FENTANYL-RELATED SUBSTANCES.

Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

"(c)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of a fentanyl-related substance, or which contains the salts, isomers, and salts of isomers of a fentanyl-related substance whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

"(2) For purposes of paragraph (1), except as provided in paragraph (3), the term 'fentanyl-related substance' means any substance that is structurally related to fentanyl by 1 or more of the following modifications:

"(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, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

"(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, 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.

"(E) By replacement of the N–propionyl group with another acyl group.

"(3) A substance that satisfies the definition of the term 'fentanyl-related substance' in paragraph (2) shall nonetheless not be treated as a fentanyl-related substance subject to this schedule if the substance—

"(A) is controlled by action of the Attorney General under section 201; or

"(B) is otherwise expressly listed in a schedule other than this schedule.

"(4)(A) The Attorney General may by order publish in the Federal Register a list of substances that satisfy the definition of the term 'fentanyl-related substance' in paragraph (2).

"(B) The absence of a substance from a list published under subparagraph (A) does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term 'fentanyl-related substance' in paragraph (2).".

SEC. 3. REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) ALTERNATIVE REGISTRATION PROCESS FOR SCHEDULE I RESEARCH.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(m) SPECIAL PROVISIONS FOR PRACTITIONERS CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED SUBSTANCES.—

"(1) IN GENERAL.—Notwithstanding subsection (f), a practitioner may conduct research described in paragraph (2) of this subsection with 1 or more schedule I substances in accordance with subparagraph (A) or (B) of paragraph (3) of this subsection.

"(2) RESEARCH SUBJECT TO EXPEDITED PROCEDURES.—Research described in this paragraph is research that—

"(A) is with respect to a drug that is the subject of an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act; or

"(B) is—

"(i) conducted by the Department of Health and Human Services or the Department of Veterans Affairs; or

"(ii) funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services or the Department of Veterans Affairs.

"(3) EXPEDITED PROCEDURES.—

"(A) RESEARCHER WITH A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

"(i) IN GENERAL.—If a practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this subsection on and after the date that is 30 days after the date on which the practitioner sends a notice to the Attorney General containing the following information, with respect to each substance with which the practitioner will conduct the research:

"(I) The chemical name of the substance.

"(II) The quantity of the substance to be used in the research.

"(III) Demonstration that the research is in the category described in

paragraph (2), which demonstration may be satisfied—

"(aa) in the case of a grant, contract, cooperative agreement, or other transaction, or intramural research project, by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project; or

"(bb) in the case of an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, by supplying the application number and the sponsor of record on the application.

"(IV) Demonstration that the researcher is authorized to conduct research with respect to the substance under the laws of the State in which the research will take place.

"(ii) VERIFICATION OF INFORMATION BY HHS OR VA.—Upon request from the Attorney General, the Secretary of Health

and Human Services or the Secretary of Veterans Affairs, as appropriate, shall verify information submitted by an applicant under clause (i)(III).

"(B) RESEARCHER WITHOUT A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

"(i) IN GENERAL.—If a practitioner is not registered to conduct research with a controlled substance in schedule I or II, the practitioner may send a notice to the Attorney General containing the information listed in subparagraph (A)(i), with respect to each substance with which the practitioner will conduct the research.

"(ii) ATTORNEY GENERAL ACTION.—The Attorney General shall—

"(I) treat notice received under clause (i) as a sufficient application for a research registration; and

"(II) not later than 45 days of receiving such a notice that contains all information required under subparagraph (A)(i)—

"(aa) register the applicant; or

"(bb) serve an order to show cause upon the applicant in accordance with section 304(c).

"(4) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to permit a practitioner to submit a notification under paragraph (3) electronically.

"(5) LIMITATION ON AMOUNTS.—A practitioner conducting research with a schedule I substance under this subsection may only possess the amounts of schedule I substance identified in—

"(A) the notification to the Attorney General under paragraph (3); or

"(B) a supplemental notification that the practitioner may send if the practitioner needs additional amounts for the research, which supplemental notification shall include—

"(i) the name of the practitioner;

"(ii) the additional quantity needed of the substance; and

"(iii) an attestation that the research to be conducted with the substance is consistent with the scope of the research that was the subject of the notification under paragraph (3).

"(6) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this subsection alters the requirements of part A of title III, regarding the importation and exportation of controlled substances.".

(b) SEPARATE REGISTRATIONS NOT REQUIRED FOR ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following:

"(4) An agent or employee of a research institution that is conducting research with a controlled substance if—

"(A) the agent or employee is acting within the scope of the professional practice of the agent or employee;

"(B) another agent or employee of the institution is registered to conduct research with a controlled substance in the same schedule;

"(C) the researcher who is so registered—

"(i) informs the Attorney General of the name, position title, and employing institution of the agent or employee who is not separately registered;

"(ii) authorizes that agent or employee to perform research under the registration of the registered researcher; and

"(iii) affirms that any act taken by that agent or employee involving a controlled substance shall be attributable to the registered researcher, as if the researcher had directly committed the act, for purposes of any proceeding under section 304(a) to suspend or revoke the registration of the registered researcher; and

"(D) the Attorney General does not, within 30 days of receiving the information, authorization, and affirmation described in subparagraph (C), refuse, for a reason listed in section 304(a), to allow the agent or employee to possess the substance without a separate registration.".

(e) SINGLE REGISTRATION FOR RELATED RESEARCH SITES.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following:

"(3)(A) Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance

under section 303(f) may conduct the research under a single registration if—

"(i) the research occurs exclusively on sites all of which are—

"(I) within the same city or county; and

"(II) under the control of the same institution, organization, or agency; and

"(ii) before commencing the research, the researcher notifies the Attorney General of each site where—

"(I) the research will be conducted; or

"(II) the controlled substance will be stored or administered.

"(B) A site described in subparagraph (A) shall be included in a registration described in that subparagraph only if the researcher has notified the Attorney General of the site—

"(i) in the application for the registration; or

"(ii) before the research is conducted, or before the controlled substance is stored or administered, at the site.

"(C) The Attorney General may, in consultation with the Secretary, issue regulations addressing, with respect to research sites described in subparagraph (A)—

"(i) the manner in which controlled substances may be delivered to the research sites;

"(ii) the storage and security of controlled substances at the research sites;

"(iii) the maintenance of records for the research sites; and

"(iv) any other matters necessary to ensure effective controls against diversion at the research sites.".

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Section 302(f) of the Controlled Substances Act (21 U.S.C. 822(f)) is amended—

(1) by striking "(f) The" and inserting "(f)(1) The"; and

(2) by adding at the end the following:

"(2)(A) If a person is registered to conduct research with a controlled substance and applies for a registration, or for a modification of a registration, to conduct research with a second controlled substance that is in the same schedule as the first controlled substance, or is in a schedule with a higher numerical designation than the schedule of the first controlled substance, a new inspection by the Attorney General of the registered location is not required.

"(B) Nothing in subparagraph (A) shall prohibit the Attorney General from conducting an inspection that the

Attorney General determines necessary to ensure that a registrant maintains effective controls against diversion.''.

(e) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

''(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting research on a substance when the substance is added to schedule I, and the person is already registered to conduct research with a controlled substance in schedule I—

''(1) not later than 90 days after the scheduling of the newly scheduled substance, the person shall submit a completed application for registration or modification of existing registration, to conduct research on the substance, in accordance with regulations issued by the Attorney General for purposes of this paragraph;

''(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on the substance until—

''(A) the person withdraws the application described in paragraph (1) of this subsection; or

"(B) the Attorney General serves on the person an order to show cause proposing the denial of the application under section 304(c);

"(3) if the Attorney General serves an order to show cause as described in paragraph (2)(B) and the person requests a hearing, the hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time if so requested by the person; and

"(4) if the person sends a copy of the application described in paragraph (1) to a manufacturer or distributor of the substance, receipt of the copy by the manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive the substance.".

(f) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsection (e), is amended by adding at the end the following:

"(i) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—

"(1) IN GENERAL.—Except as provided in paragraph (3), a person who is registered to perform re-

search on a controlled substance may perform manufacturing activities with small quantities of that substance, including activities described in paragraph (2), without being required to obtain a manufacturing registration, if—

"(A) the activities are performed for the purpose of the research; and

"(B) the activities and the quantities of the substance involved in the activities are stated in—

"(i) a notification submitted to the Attorney General under section 303(l);

"(ii) a research protocol filed with an application for registration approval under section 303(f); or

"(iii) a notification to the Attorney General that includes—

"(I) the name of the registrant; and

"(II) an attestation that the research to be conducted with the small quantities of manufactured substance is consistent with the scope of the research that is the basis for the registration.

"(2) ACTIVITIES INCLUDED.—Activities permitted under paragraph (1) include—

"(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with—

"(i) the information provided as part of a notification submitted to the Attorney General under section 303(l); or

"(ii) a research protocol filed with an application for registration approval under section 303(f); and

"(B) dosage form development studies performed for the purpose of requesting an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

"(3) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) to manufacture substances does not include the authority to grow marihuana.".

(g) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by subsection (a), is amended by adding at the end the following:

"(n) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—

"(1) IN GENERAL.—If the Attorney General determines, with respect to a controlled substance, that an application by a practitioner to conduct research with the substance should be considered under a process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule, the Attorney General shall make public, including by posting on the website of the Drug Enforcement Administration—

"(A) the identities of all substances for which such determinations have been made;

"(B) the process and criteria that shall be applied to applications to conduct research with those substances; and

"(C) how the process and criteria described in subparagraph (B) differ from the process and criteria applicable to applications to conduct research with other controlled substances in the same schedule.

"(2) TIMING OF POSTING.—The Attorney General shall make information described in paragraph (1) public upon making a determination described in

that paragraph, regardless of whether a practitioner has submitted such an application at that time.''.

SEC. 4. RULEMAKING.

(a) INTERIM FINAL RULES.—The Attorney General—

(1) shall, not later than 1 year of the date of enactment of this Act, issue rules to implement this Act and the amendments made by this Act; and

(2) may issue the rules under paragraph (1) as interim final rules.

(b) PROCEDURE FOR FINAL RULE.—

(1) EFFECTIVENESS OF INTERIM FINAL RULES.—A rule issued by the Attorney General as an interim final rule under subsection (a) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor, notwithstanding subparagraph (B) of section 553(b) of title 5, United States Code.

(2) OPPORTUNITY FOR COMMENT AND HEARING.—An interim final rule issued under subsection (a) shall give interested persons the opportunity to comment and to request a hearing.

(3) FINAL RULE.—After the conclusion of such proceedings, the Attorney General shall issue a final

rule to implement this Act and the amendments made by this Act in accordance with section 553 of title 5, United States Code.

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend title XI of the Social Security Act to prohibit the use of quality-adjusted life years and similar measures in coverage and payment determinations under Federal health care programs.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act to prohibit the use of quality-adjusted life years and similar measures in coverage and payment determinations under Federal health care programs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protecting Health Care for All Patients Act of 2023".

SEC. 2. PROHIBITING THE USE OF QUALITY-ADJUSTED LIFE YEARS AND SIMILAR MEASURES IN COVERAGE AND PAYMENT DETERMINATIONS UNDER FEDERAL HEALTH CARE PROGRAMS.

(a) IN GENERAL.—Section 1182(e) of the Social Security Act (42 U.S.C. 1320e–1(e)) is amended—

(1) by striking "The Secretary shall not" and inserting "A Federal agency or State may not";

(2) by inserting ", including by using a price developed by any entity or government that is based on such an adjusted life year (or such a similar measure) or using averages or other pricing metrics that directly or indirectly take into account such prices," after "(or such a similar measure)"; and

(3) by striking "under title XVIII." and inserting the following: "under any Federal health care program (as defined in section 1128B, except that such term shall include the health program established under chapter 89 of title 5, United States Code).".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(A) in paragraph (86), by striking "and" at the end;

(B) in paragraph (87)(D), by striking the period and inserting "; and"; and

(C) by inserting after paragraph (87) the following new paragraph:

"(88) provide for compliance with the requirements of section 1182(e) (relating to prohibiting the use of certain measures in coverage determinations, reimbursement, and incentive programs).".

(2) CHIP.—Section 2102 of the Social Security Act (42 U.S.C. 1397bb) is amended by adding at the end the following new subsection:

"(d) PROHIBITION ON THE USE OF QUALITY-ADJUSTED LIFE YEARS AND SIMILAR MEASURES.—A State child health plan shall provide for compliance with the requirements of section 1182(e) (relating to prohibiting the use of certain measures in coverage determinations, reimbursement, and incentive programs).".

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend title V of the Public Health Service Act to secure the suicide prevention lifeline from cybersecurity incidents, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. OBERNOLTE introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title V of the Public Health Service Act to secure the suicide prevention lifeline from cybersecurity incidents, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "9-8-8 Lifeline Cybersecurity Responsibility Act".

SEC. 2. PROTECTING SUICIDE PREVENTION LIFELINE FROM CYBERSECURITY INCIDENTS.

(a) SUICIDE PREVENTION LIFELINE.—Section 520E–3(b) of the Public Health Service Act (42 U.S.C. 290bb–36c(b)) is amended—

(1) in paragraph (4), by striking ''and'' at the end;

(2) in paragraph (5), by striking the period at th end and inserting ''; and''; and

(3) by adding at the end the following:

''(6) coordinating with the Chief Information Security Officer of the Department of Health and Human Services to take such steps as may be necessary to ensure the program is protected from cybersecurity incidents and eliminates known cybersecurity vulnerabilities.''.

(b) REPORTING.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

''(f) CYBERSECURITY REPORTING.—

''(1) IN GENERAL.—The program's network administrator receiving Federal funding pursuant to subsection (a) shall report to the Assistant Sec-

retary, in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws—

"(A) any identified cybersecurity vulnerabilities to the National Suicide Prevention Lifeline; and

"(B) any identified cybersecurity incidents or potential incidents to the National Suicide Prevention Lifeline.

"(2) NOTIFICATION.—If an entity described in paragraph (1) discovers a cybersecurity vulnerability, incident, or potential incident, such entity shall immediately report that discovery to the Assistant Secretary.

"(3) CLARIFICATION.—The cybersecurity incident reporting requirements under this subsection shall supplement, and not supplant, cybersecurity incident reporting requirements under other provisions of applicable Federal law that are in effect on the date of the enactment of the 9-8-8 Lifeline Cybersecurity Responsibility Act.".

(c) STUDY.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall—

(1) conduct and complete a study that evaluates cybersecurity risks and vulnerabilities associated with the 9-8-8 National Suicide Prevention Lifeline; and

(2) submit a report of the findings of such study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Controlled Substances Act to require registrants to decline to fill certain suspicious orders, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MRS. HARSHBARGER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Controlled Substances Act to require registrants to decline to fill certain suspicious orders, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Block, Report, And Suspend Suspicious Shipments Act".

SEC. 2. BLOCK, REPORT, AND SUSPEND SUSPICIOUS ORDERS.

(a) CLARIFICATION OF PROCESS FOR REGISTRANTS TO EXERCISE DUE DILIGENCE UPON DISCOVERING A SUSPICIOUS ORDER.—Paragraph (3) of section 312(a) of the Controlled Substances Act (21 U.S.C. 832(a)) is amended to read as follows:

"(3) upon discovering a suspicious order or series of orders, and in a manner consistent with the other requirements of this section—

"(A) exercise due diligence as appropriate;

"(B) establish and maintain (for not less than a period to be determined by the Administrator of the Drug Enforcement Administration) a record of the due diligence that was performed;

"(C) decline to fill the order or series of orders if the due diligence fails to dispel all of the indicators that give rise to the suspicion that, if the order or series of orders is filled, the drugs that are the subject of the order or series of orders are likely to be diverted; and

"(D) notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area

in which the registrant is located or conducts business of—

"(i) each suspicious order or series of orders discovered by the registrant; and

"(ii) the indicators giving rise to the suspicion that, if the order or series of orders is filled, the drugs that are the subject of the order or series of orders are likely to be diverted.".

(b) RESOLUTION OF SUSPICIOUS INDICATORS.—Section 312 of the Controlled Substances Act (21 U.S.C. 832) is amended—

(1) by redesignating subsection (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

"(b) RESOLUTION OF SUSPICIOUS INDICATORS.—If a registrant resolves all of the indicators giving rise to suspicion about an order or series of orders under subsection (a)(3)—

"(1) notwithstanding subsection (a)(3)(C), the registrant may choose to fill the order or series of orders; and

"(2) notwithstanding subsection (a)(3)(D), the registrant may choose not to make the notification otherwise required by such subsection.".

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, for purposes of subsections (a)(3) and (b) of section 312 of the Controlled Substances Act, as amended or inserted by subsection (a), the Attorney General of the United States shall promulgate a final regulation specifying the indicators that give rise to a suspicion that, if an order or series of orders is filled, the drugs that are the subject of the order or series of orders are likely to be diverted.

(d) PENALTY.—Section 402(a)(5) of the Controlled Substances Act (21 U.S.C. 842(a)(5)) is amended by inserting before the semicolon at the end the following: "or otherwise violates section 312(a)(3)".

(e) APPLICABILITY.—Subsections (a)(3) and (b) of section 312 of the Controlled Substances Act, as amended or inserted by subsection (a), shall apply beginning on the day that is 1 year after the date of enactment of this Act. Until such day, section 312(a)(3) of the Controlled Substances Act shall apply as such section 312(a)(3) was in effect on the day before the date of enactment of this Act.

Autism Society

Autism Society of America
6110 Executive Blvd, Suite 305
Rockville, Maryland 20852

January 31, 2023

The Honorable Cathy McMorris Rodgers, Chair
Energy and Commerce Committee
House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
House of Representatives
Washington, D.C. 20515

Dear Chairwoman McMorris Rodgers and Ranking Member Pallone:

The Autism Society of America writes to thank you for introducing the Protecting Health Care for All Patients Act. This bill prohibits all federal health care programs, such as Medicaid, from using quality-adjusted-life-years (QALYs).

The Autism Society is the nation's oldest and largest grassroots organization representing individuals with Autism and their families.

QALYs are used by federal healthcare programs to calculate the costs of treatments or medications covered by insurance. If someone has pre-existing health conditions, they are given a QALY of a lesser value compared to someone without any health conditions, thereby covering less of the treatment. The use of QALYs discriminates against people with Autism and other disabilities by putting a lower numerical value on an individual's life. It is critical that Congress act to ban the use of QALYs for all federal healthcare programs.

Autism Society

Autism Society of America
6110 Executive Blvd, Suite 305
Rockville, Maryland 20852

We appreciate your leadership on this issue and pledge our support to help move this bill through this Session of Congress. Please contact me or Kim Musheno, Vice President of Public Policy at the Autism Society of America (kmusheno@autism-society.org or) if you have any questions or to follow up on this letter.

Sincerely,

Christopher Banks
President/Chief Executive Officer
cbanks@autism-society.org

CARING ACROSS GENERATIONS

January 30, 2023

The Honorable Cathy Mc-Morris Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington, DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington, DC 20510

Caring Across Generations writes to express our support for the Protecting All Health Care for Patients Act, to prohibit the use of Quality-Adjusted Life Years (QALYs) and similar measures in coverage and payment determinations under federal health care programs. This is an issue that impacts all levels of health care and prohibiting the use of these measures will positively impact the lives of millions of Americans.

Caring Across Generations is a national campaign of family caregivers, care workers, disabled people, and older adults working to transform the way we care in this country so that care is accessible, affordable, and equitable – and our systems of care enable everyone to live and age with dignity. Caring Across Generations convenes a diverse network of over 100 national, state, and local advocacy organizations, including in caregiving, aging, disability rights and justice, disease-based groups, and labor.

The logic inherent in the QALY is concerning on its face: it is designed to measure the extent to which a year of life with a disability is of lower quality and lower value than life without a disability. The disability rights movement seeks to show that not only do people with disabilities have a right to participate in society, but that they can have high quality lives. QALY-based assessments also do not account for outcomes that matter to people living with the relevant health condition. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We agree with the conclusions of the National Council on Disability, an independent federal agency, that Congress should disallow QALYs in state and federal health care programs.

The Protecting All Health Care for Patients Act will solidify a decades-long bipartisan track record of supporting disability rights in federal programs. Section 504 of the Rehabilitation Act of 1973, signed by President Nixon, ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or

otherwise be subjected to discrimination," under any program offered by any Executive Agency. Title II of the Americans with Disabilities Act of 1990, signed by President H.W. Bush, extended this protection to programs and services offered by state and local governments. In 2010, the Affordable Care Act, signed by President Obama, stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness. Finally the Inflation Reduction Act, signed by President Biden, prohibits the use of measures that devalue the lives of people with disabilities and others in Medicare prescription drug negotiations. Under both the Trump and Biden administrations, the HHS Office for Civil Rights has taken action on discriminatory allocation of health care resources.

Caring Across Generations urges you to support this important legislation and join the decades-long bipartisan initiative to advance the rights of disabled people.

Please contact our Legislative Manager Tory Cross at tory@caringacross.org with any questions or follow-up.

Sincerely,

Nicole Jorwic
Chief of Advocacy and Campaigns
Caring Across Generations

Disability Rights Education & Defense Fund DREDF

January 31, 2023
via electronic mail

The Honorable Cathy McMorris-Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington, DC 20510

Re: Support for the Protecting Health Care for All Patients Act of 2023

Dear Chair McMorris-Rodgers and Ranking Member Pallone:

The Disability Rights Education & Defense Fund ("DREDF") writes to support H.R.485, the Protecting Health Care for All Patients Act of 2023. The legislation prohibits the use of Quality-Adjusted-Life-Years (QALYs) and similar measures for determining coverage and payment decisions in federal health care programs, including Medicaid. Millions of people with disabilities and chronic conditions, across all ages and races/ethnicities in the US, are deeply impacted by how key federal programs such as Medicare, Medicaid, and CHIP make decisions on the effectiveness and value of health care treatments.

DREDF is a national cross-disability law and policy center that protects and advances the civil and human rights of people with disabilities through legal advocacy, training, education, and development of legislation and public policy. We are committed to increasing accessible and equally effective healthcare for people with disabilities and eliminating persistent health disparities that affect the length and quality of their lives. DREDF's work is based on the knowledge that people with disabilities of varying racial and ethnic backgrounds, ages, genders, and sexual orientations are fully capable of achieving self-sufficiency and contributing to their communities with access to needed services and supports and the reasonable accommodations and modifications enshrined in U.S. law.

At a time when federal and state governments face accelerating health care costs, DREDF appreciates the desire to have an "objective" means of evaluating the cost-effectiveness of current and new pharmaceutical treatments. Unfortunately, the QALY is **not** objective in how it purports to measure the value of a drug or therapy. This is because the QALY's base value is rooted in how a treatment would extend the life of a person in perfect non-disabled health. QALY values are derived from the general public's assignment of a score to living with such conditions as mobility limitations, self-care limitations, limits on engaging in usual activities, pain/discomfort, and anxiety/mental health. QALY values therefore doubly disadvantage individuals with disabilities and chronic conditions because the life years of disabled persons are automatically valued lower than the life years of non-disabled persons, and because most

members of the general public who are assigning value have negative stereotypes about the quality of life of people living with disabilities and chronic conditions.

Moreover, QALY valuations have implications for racial/ethnic health equity as well given how disability is experienced among distinct population groups. For example, the Centers for Medicare and Medicaid Services states that American Indians and Alaskan Native (AI/AN) populations experience markedly higher rates of disability in the US, and are 50.3% more likely to have a disability compared to the national average. When Medicaid programs use QALYs to develop guidelines on the economic "worth" of a particular pharmaceutical or drug treatment, the impact of those guidelines cascade down to multiple public and private program payer decisions on whether to include the drug in formularies, and the terms of its coverage when it comes to cost sharing, prior authorization, and other utilization management techniques.

In 2021, DREDF issued a legal memo that detailed our opinion that the use of QALYs violates existing disability rights laws. We agree with the recommendations made by the National Council on Disability (NCD) in its 2019 report on QALYs and the Devaluation of Life with Disability that Congress should ban the use of QALYs in federal and state programs that receive federal financial assistance.

The Protecting Health Care for All Patients Act will turn the NCD recommendations into concrete action. DREDF recognizes that this act can be the latest example of Congress' ability to achieve bi-partisan legislative victories on behalf of people with disabilities, from Section 504 of the Rehabilitation Act of 1973, through the Americans with Disabilities Act of 1990, to the Affordable Care Act of 2010 (ACA). The ACA stated that the Secretary of Health and Human Services could not deny coverage of items or services "solely on the basis of comparative effectiveness research" nor use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness.

DREDF supports the Protecting Health Care for All Patients Act as an important step toward recognizing the rights of people with disabilities and chronic conditions to equally effective healthcare. We urge all members of Congress to join the decades-long bipartisan effort to advance the rights of people with disabilities. Please contact Silvia Yee at syee@dredf.org if you have any questions.

Sincerely,

Silvia Yee
Senior Staff Attorney

January 27, 2023

The Honorable Cathy McMorris-Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Epilepsy Foundation writes to show our support for the Protecting All Health Care for Patients Act, to prohibit the use of Quality-Adjusted-Life-Years (QALYs) and similar measures in coverage and payment determinations under federal health care programs. This is an issue that impacts all levels of health care and prohibiting the use of these measures will positively impact the lives of millions of Americans.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of at least 3.4 million Americans with epilepsy and seizures. We foster the well-being of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, and people living with epilepsy must have meaningful and timely access to physician-directed care and specialists, to avoid breakthrough seizures and related complications and costs.

The logic inherent in the QALY is concerning on its face: it is designed to measure the extent to which a year of life with a disability is of lower quality and lower value than life without a disability. The disability rights movement seeks to show that not only do people with disabilities have a right to participate in society, but that they can have high quality lives. QALY-based assessments also do not account for outcomes that matter to people living with the relevant health condition. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We agree with the conclusions of the National Council on Disability, an independent federal agency, that Congress should disallow QALYs in state and federal health care programs.

The Protecting All Health Care for Patients Act will solidify a decades-long bipartisan track record of supporting disability rights in federal programs. Section 504 of the Rehabilitation Act of 1973, signed by President Nixon, ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency. Title II of the Americans with Disabilities Act of 1990, signed by President H.W. Bush, extended this protection to programs and services offered by state and local governments. In 2010, the Affordable Care Act, signed by President Obama, stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness. Finally the Inflation Reduction Act, signed by President Biden, prohibits the use of measures that devalue the lives of

EPILEPSY FOUNDATION
END EPILEPSY TOGETHER

people with disabilities and others in Medicare prescription drug negotiations. Under both the Trump and Biden administrations, the HHS Office for Civil Rights has taken action on discriminatory allocation of health care resources.

The Epilepsy Foundation urges you to support this important legislation and join the decades-long bipartisan initiative to advance the rights of people with disabilities.

Please contact Rachel Patterson at rpatterson@efa.org with any questions or follow-up.

Sincerely,

Allison Zetterquist
Acting Chief Executive Officer
Epilepsy Foundation

January 31, 2023

The Honorable Cathy McMorris Rodgers
Chairwoman
House Committee on Energy and Commerce
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
Washington, D.C. 20515

The Honorable Brett Guthrie
Chairman
House Committee on Energy and Commerce
Subcommittee on Health
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
Washington, DC 20515

Dear Chairwoman Rodgers, Ranking Member Pallone, Chairman Guthrie, and Ranking Member Eshoo,

In service of the neuromuscular disease (NMD) patient community, the Muscular Dystrophy Association (MDA) is pleased to support the Protecting Healthcare for All Patients Act of 2023, which would prohibit the use of Quality-Adjusted Life Years (QALYs) in determining the benefit of medical interventions for patients with disabilities under Medicare and Medicaid. We appreciate the opportunity to provide the House Energy & Commerce Subcommittee on Health with information about how the use of QALYs adversely affects individuals living with neuromuscular diseases.

The Muscular Dystrophy Association (MDA) is the #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and related neuromuscular diseases. For over 70 years, MDA has led the way in accelerating research, advancing care, and advocating for the support of our families. MDA's mission is to empower the people we serve to live longer, more independent lives.

Quality-Adjusted Life Years are used in health economic evaluations to quantify the health effect of a medical treatment and help payers allocate resources. QALYs evaluate how much a patient's life would improve from a given medical intervention, and for how long. However, the use of QALYs to determine the benefit of treatments for patients is flawed, as the "quality of life" metric relies on an inherently ableist and utilitarian concept of quality of life and assumes outcomes for able-bodied patients in perfect health. As an example, if a treatment results in one additional year of life in perfect health, that is counted as one QALY. If, however, a treatment buys an additional year of life for a patient with less than perfect health due to a neuromuscular disease, the QALY is reduced by a fraction determined by a subjective assumption of how that disease would reduce "perfect health." This can lead to the denial of treatments and interventions for patients with disabilities.

Such ableist assumptions about what constitutes a "good" quality of life in determining treatment effectiveness for patients with disabilities fail to consider other factors such as emotional well-being, the personal wishes, and aspirations of the patient, the will to live, the personal beliefs of the patient and more. Additionally, assessing "quality of life" through a subjective lens that places a higher value on people without disabilities only perpetuates prejudices within the medical profession and society writ large that see less worth and value in people with disabilities.

In 2019, the National Council on Disability (the Council) released a report entitled *Quality-Adjusted Life Years and the Devaluation of Life with Disability*[1], which found that continued devaluation of the lives of people with disabilities by society, the medical profession, and health economists leads to unequal access to medical care, poorer health outcomes, and reduced life expectancy for people with disabilities. As a result of these findings, the Council recommended Congress pass legislation to prohibit the use of QALYs in federally funded health programs.

The Protecting Healthcare Access for All Patients Act of 2023 reflects the recommendation made by the Council to prohibit the use of QALYs in Medicare and Medicaid. This bill is a great first step in recognizing that the lives of individuals with neuromuscular diseases and other disabilities are just as valuable as the lives of those without disabilities and will help address inequalities people with disabilities face in accessing healthcare.

MDA is proud to support this legislation, and we urge Members of the Energy and Commerce Health Subcommittee to support it. If you have any questions or desire additional information, please do not hesitate to contact me at mlewis@mdausa.org or (540) 447-9438.

Sincerely,

Michael Lewis

Michael Lewis
Director, Disability Policy
Muscular Dystrophy Association

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[1] National Council on Disability (2019). *Quality-Adjusted Life Years and the Devaluation of Life with Disability.* Washington, DC: National Council on Disability.e

January 31, 2023

The Honorable Brett Guthrie
Chairman
Health Subcommittee
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Health Subcommittee
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Chairwoman
Energy and Commerce Committee
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
Washington, DC 20515

Re: Statement Submission for Congressional Record on the Ban of QALYs in all government programs

Dear Chairman Guthrie, Ranking Member Eshoo, Chairwoman Rodgers, and Ranking Member Pallone,

As a health economist with links to pharmacy colleges in the US, I am impressed with the almost universal lack of understanding of measurement theory when it comes to arguments for or against quality adjusted life year (QALY) scores in health technology assessment (HTA). The QALY is a mathematical impossibility, yet it has a strange fascination for those with a limited understanding (or awareness) of modern measurement theory. The QALY debates are, clearly, a waste of time; the QALY must be discarded, not for issues such as disability, but for the incontrovertible fact that it is an impossible measure [1].

We have accepted for some 60 or more years that if a measure of response is required it must be a single attribute, unidimensional, interval measure [2] [3]. Nothing else will do. It must meet the standards of Rasch measurement, and the issue is straightforward: observations produce ordinal scales. To assess therapy response, we need an interval (or ratio) measure. This can only be achieved by applying Rasch rules to the ordinal counts of observations to transform them to interval measures. The point is made in a paper by Wight and Linacre in 1989 published before the QALY was developed to become a mainstay of HTA in the mid 1990s: *Quantitative observations are based on counting observed events or levels of performance. Meaningful measurement is based on the arithmetical properties of interval scales. The Rasch measurement model provides the necessary and sufficient means to transform ordinal counts into linear measures* [4].

Rasch measurement has been accepted for over 60 years as the basis for creating single attribute, unidimensional, linear, interval (as well as ratio) measures in the scores in the social sciences; it has just been ignored for over 30 years. Those advocating QALYs such as the Institute for Clinical

and Economic Review (ICER) with their assumption driven modelled simulations to support imaginary non-empirically evaluable claims just perpetuate the QALY myth. The issue is the failure of those creating multiattribute generic preference scores to understand the limitations of fundamental measurement. The preference scores are ordinal scales as sums over questionnaire items. There are, in fact, several software packages (RUMM2030, WINSTEPS) that undertake a Rasch assessment of patient reported outcomes and support interval scores. They were first introduced in the 1980s and are used extensively in the social sciences.

The QALY multiplies time spent in a disease state with a preference scale (range 0 to 1; but the algorithms create negative scores). This fails because: (i) no one thought they needed, not just an interval but a ratio scale (a measure with a true zero) to support multiplication; and (ii) that the scale had to represent a single unidimensional attribute not a bundle of symptoms and response levels. Typically applied are ordinal preference scores from a multiattribute instrument such as the EQ-5D-5L. This is where it all falls apart. The EQ-5D-5L as a multiattribute score fails the requirements of Rasch modelling for subjective responses. The entire exercise is a waste of time and resources.

The result, unfortunately, is that HTA is locked into a belief system that is unique among the physical and social science disciplines: putting to one side value claims that meet the standards of normal science for credibility, empirical evaluation, and replication together with a failure to recognize the importance of Rasch measurement [5]. Instead, HTA rests on the simulated creation of non-evaluable claims for pricing and product access which would be rejected out of hand in other disciplines.

Although the criticisms presented here have been voiced over the past 30 years, together with instruments developed in many disease areas to capture response in terms of Rasch requirements, they are largely ignored. The reason is obvious: a dominant belief system or meme that excludes criticism. Truth is consensus. I have no doubt the good ship QALY will sail on; too many people have too much to lose to make clear they were wrong. It is perhaps asking too much for the government to step in and make clear why it will no longer support the QALY in any program.

Sincerely,

Paul C. Langley, Ph.D., Adjunct Professor, College of Pharmacy University of Minnesota, Minneapolis, MN; Director, Maimon Research LLC, Tucson AZ

Contact: Email langley@maimonresearch.com
Tel: (520) 577-0436

References

[1] Langley PC and McKenna SP. Measurement, modeling and QALYs [version 1; peer review: 2 approved]. *F1000Research* 2020, **9**:1048 (https://doi.org/10.12688/f1000research.25039.1)

[2] Bond T, Yan Z, Heene M. Applying the Rasch Model: Fundamental Measurement in the Human Sciences (4th Ed.). New York: Routledge, 2021

[3] Andrich D, Marais I. A Course in Rasch Measurement Theory: Measuring the Educational, social and Health Sciences. Singapore, Springer: 2019

[4] Wright B, Linacre J. Observations are always ordinal; measurements, however, must be interval. *Arch Phys Med Rehabil*. 1989; 70(12):857-60

[5] Langley P. Nothing to Cheer About: Endorsing Imaginary Economic Evaluations and Value Claims with CHEERS 22 [version 1; peer review: 2 approved]. *F1000Research* 2022, **11**:248 (https://doi.org/10.12688/f1000research.109389.1)

October 3, 2022

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra:

As organizations representing patients, people with disabilities and chronic conditions and older adults, we appreciate the Administration's commitment to nondiscrimination and this comprehensive proposed rule seeking to strengthen civil rights protections in federally funded health programs and HHS programs. We agree that the ability to access needed health care fully and free from discrimination is critical and requires action to support and strengthen existing nondiscrimination laws.

As you move forward with the rulemaking process, we ask you to consider the following related to the agency's request for comments on the extent, scope and nature of value assessment methods that discriminate on the basis of race, color, national origin, sex, age, or disability; the use of clinical algorithms in health care decision-making; and nondiscrimination requirements and enforcement.

Nondiscrimination in health insurance coverage and other health-related coverage (§ 92.207): Use of Value Assessments

We appreciate this opportunity to provide comments on value assessment methods and the extent to which certain methodologies discriminate. Having worked for many years to raise awareness of our growing concerns regarding impermissible discrimination in the application of value assessment methodologies to set valuations for health care goods and services, we were pleased to see those concerns described in the proposed rule. We firmly believe that the examples provided in the proposed rule highlighting the potential risk posed by value assessments that place a lower value on life-extension for a group of individuals based on a protected basis or via inappropriate adjustment of clinical end points on a protected basis under Section 1557 are violations of existing nondiscrimination laws.

First, patients and people with disabilities have long-held deep concerns about reliance on cost-effectiveness assessments based on the Quality-Adjusted Life Year (QALY) to determine what treatments will be covered benefits for patients. QALYs and similar metrics relying on averages are referenced in other countries and in studies by third parties, such as the Institute for Clinical and Economic Review (ICER) to determine whether treatments are "cost-effective." The QALY metric puts a lower value on the life of an individual living with a disability, and, as such, value assessments using this metric devalue treatments for people with disabilities.

In a 2019 report, the National Council on Disability (NCD), an independent federal agency advising Congress and the administration on disability policy, concluded that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities and indicated that the use of QALYs in public programs would be contrary to United States disability policy and civil rights laws.

Recommendations:

- We urge the Office for Civil Rights to advance a rulemaking that codifies a ban on the use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability as part of utilization management, formulary design, price negotiations, alternative payment models and other incentive-based programs impacting access to care and affordability of care.
- We support the NCD's recommendation that the HHS Office for Civil Rights issue guidance stating that Section 504 and Section 1557 also apply to Medicaid programs and discuss how these authorities apply to benefits and reimbursement decisions, as well as their recommendation that payment decisions should not rely on cost-effectiveness research or reports that are developed using QALYs.
- More broadly, we also support the NCD recommendation that federal programs, including Medicaid, should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illnesses.[1]

The Precedent Against Use of QALYs and Similar Metrics

The United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.[2] Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[3] Based on the ADA's passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.[4]

The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research "in

[1] https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[2] 29 USC Sec 794, 2017.
[3] 42 USC Sec 12131, 2017.
[4] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. The New York Times.

a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[5] Additionally, the ACA specifically prohibits the development or use of a "dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended." The ACA also states, "The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII" (Medicare)."[6] The rationale for the ACA's provisions barring the use of QALYs was articulated by a bipartisan group of Senators in 2009 early in the debate over creation of what became the Patient-Centered Outcomes Research Institute (PCORI), expressing support for comparative clinical effectiveness research, not comparative cost effectiveness, as well as seeking reassurance that such work would be used to improve health decisions and not restrict coverage.[7]

More recently, the U.S. Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in value-based purchasing (VBP) arrangements.[8] Also, the recently-passed Inflation Reduction Act included language barring discriminatory evidence from being a factor in the negotiation process for determining a fair price for prescription drugs, stating, "In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[9]

The law and regulations governing federal health care programs have established clear precedent that QALY-based assessments of cost and clinical effectiveness are discriminatory against people with disabilities and contrary to federal nondiscrimination laws. The Disability Rights Education and Defense Fund (DREDF) published a report in 2021 discussing the elements of QALYs that rely on a set of discriminatory assumptions that devalue life with a disability, thereby disadvantaging people with disabilities seeking to access care based on subjective assessments of quality of life. DREDF concluded that, under disability nondiscrimination law, health care programs cannot use measures to determine the drugs worth covering that are based on discriminatory assumptions about the quality of life with a disability, nor can reliance on the measure produce a disproportionately negative impact on the health care services and treatments that people with disabilities uniquely rely on. DREDF stated, "The lives of all

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[5] 42 USC Sec 1320e, 2017.
[6] 42 USC Sec 1320e, 2017.
[7] 155 Cong. Rec. 1796, Feb 6, 2009.
[8] https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and
[9] Public Law No: 117-169.

individuals regardless of disability are equally valuable; this fundamental principle cannot be ignored for the sake of cost savings."[10]

Recommendation: Therefore, we encourage HHS to build on this precedent and make very clear across federal programs that QALYs discriminate and value assessments relying on them cannot be used in benefit design, including in designing utilization management and incentive program strategies.

Clinical Endpoints Should Represent Outcomes that Matter to Patients and People with Disabilities

We are similarly concerned about the clinical endpoints that define whether a studied treatment or service represents a therapeutic advance as compared to existing therapeutic alternatives, which provide the basis for determining its clinical or cost effectiveness. We strongly supported provisions in PCORI's statute emphasizing its duty to achieve preferred outcomes that matter to patients and to study the heterogeneity of impact of a studied treatment or service on subpopulations. Since its creation, PCORI has been at the forefront of efforts to improve the methods used to compare treatments and services to assure that the measured outcomes, including clinical endpoints, are defined by people with lived experience to improve their quality of life.

By contrast, we are concerned that studies comparing health care treatments and services using historic methods have strong potential to devalue outcomes that matter to people needing care. It is essential that the value assessments driving care decisions reflect the burdens experienced by people with lived experience, and place value on the outcomes that they determine to represent improved quality of life. For example, a child's ability to sit up independently in bed on treatment may seem small in academic terms, but significant to the child seeking independence and the family members that provide caregiving. ISPOR, the professional society for health economics and outcomes research, acknowledges this data gap and has stated that accurate measures of patient-centered outcomes are critical, and that there is a need for research to improve methodology for translating outcomes related to a disease or condition into utilities for use in value assessment, particularly for people with disabilities.[11]

Recommendation: HHS OCR should advance standards for nondiscriminatory value assessment that includes using clinical endpoints that indicate whether a studied treatment or service represents a therapeutic advance from the perspective of its end user, patients and people with disabilities.

To Avoid Discriminatory Impact, Value Assessments Must Consider Health Equity

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[10] DREDF, ICER Analyses Based on the QALY Violate Disability Nondiscrimination Law, September 21, 2021 at https://dredf.org/wp-content/uploads/2021/09/ICER-Analyses-Based-on-the-QALY-Violate-Disability-Nondiscrimination-Law-9-17-2021.pdf

[11] https://www.ispor.org/strategic-initiatives/science-strategy

We also are concerned that these comparisons have historically relied on health care data that excludes information on subpopulations, especially for people already experiencing health disparities, as well as excluding consideration of the social and structural determinants of health that are drivers of health inequity. Truly representative and non-discriminatory value assessments require high-quality data that includes the experiences of all affected patients and people with disabilities, including people historically excluded from clinical trials and other sources of patient experience data. Any value assessment will only be as strong as the data that underlies the model. High quality data provides information about the different responses to treatment among patient subpopulations, their preferred outcomes and health equity considerations, all of which are essential components of value assessment if it is to accurately capture treatment value to everyone and result in equitable care for everyone.

By contrast, the data that informs value assessments from entities such as ICER generally reflects population-level averages, omitting specific data on subpopulations such as people with disabilities and people of color. In a study of cost-effectiveness analyses published through 2016, only 19% reported patient subgroup results and only 4.4% reported on race or ethnicity specifically.[12] Relying on this type of data, value assessments are powered to show results for a patient population that is largely white, middle-aged, non-disabled, and male. This can lead to inherent discrimination by devaluing treatments that may have increased value specifically for people who do not fit that archetype, including people with disabilities or people of color. Inclusive data is essential to ensure that value assessments accurately represent treatment needs of people historically excluded from the data and therefore do not discriminate by deferring to data representative of white, non-disabled populations.[13]

Recommendation: We urge the HHS Office for Civil Rights to require that any use of value assessment in decisions related to utilization management, formulary design, price negotiations, alternative payment models and other incentives driving access to health care consider health equity and be built on high-quality, representative, patient-centered data.

Standardization is Needed to Advance Improved Methods for Valuing Health Care

PCORI is the standard-bearer in conducting high-quality research on outcomes that matter to patients. In 2019, PCORI was reauthorized by Congress and explicitly given authority to capture "the full range of clinical and patient centered outcomes" including "the potential burdens and economic impacts of healthcare services."[14] As part of this work, PCORI has published principles that define key factors demonstrating that their research has considered the potential burdens and economic impacts of healthcare utilization on "different stakeholders and decision-makers." Their principles are relevant to the value assessment enterprise and could inform standards that a value assessment should meet to demonstrate its quality and representation

[12] Lavelle TA, Kent DM, Lundquist CM, Thorat T, Cohen JT, Wong JB, Olchanski N, Neumann PJ. Patient variability seldom assessed in cost-effectiveness studies. Medical Decision Making 2018;38(4):487–94

[13] https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods

[14] *Further Consolidated Appropriations Act, 2020,* Pub L. No. 116-94 § 104 (e) (2019).

of diverse stakeholders with lived experience. For example, PCORI calls for consideration of the full range of outcomes important to patients and caregivers, including potential burdens and economic impacts. PCORI also calls for the collection of data on potential burdens and economic impacts of intervention options to be appropriate and relevant to the clinical aims of the study. PCORI describes its process as follows:

> PCORI requires applicants to engage relevant stakeholders in the formulation of the research question and the development of the study design, as well as the identification of outcomes to measure. This approach is intended to ensure that PCORI-funded research will provide evidence that is ultimately relevant and applicable for the end user; it also seeks to avoid the unnecessary capture of data that are not relevant to the aims of the study and may not be beneficial to the goals of the research. This same expectation should apply when considering whether and which potential burden and other economic impact data a research study should capture.

Similarly, the Innovation and Value Initiative (IVI) has developed consensus-based principles on the most effective methods for value assessment, seeking to define best practices in the applied use of value assessment and applying those principles to disease-specific models. IVI is working to cultivate modernized methods, including complementary approaches that address societal perspectives and broader cost parameters, as well as reduce discrimination and disparities based on patient heterogeneity or disability. We appreciate that IVI recognizes the need for improved clinical and real-world data, investment in it and standards for its generation. IVI is also working toward a value assessment process that supports health equity, which requires sub-group and distributional impact analyses, improved research methods reflecting diverse communities and experiences, and a policy dialogue about improving access and equity.[15]

The NCD report published in 2019 discussed alternative metrics that are less likely to be discriminatory. The NCD recommended use of well-established alternatives to QALYs, such as multi-criteria decision analysis (MCDA), a method capable of capturing the complexity of healthcare coverage decisions, or cost-benefit analysis.[16] NCD raised serious concerns about methods using health utilities relying on EQ-5D surveys, which take an extremely limited approach to measuring "quality of life" and fail to measure the wide variety of impacts a disability or illness could have on quality of life.

We are concerned that cultural barriers exist within the health economics and research establishment related to the incorporation and consideration of patient preferences into comparative research and value assessment. Research has shown that high-quality patient preference information can be collected in a manner that is systemic and scientifically

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[15] https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf
[16] https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf

rigorous,[17] and that it can be integrated into value assessments.[18] Many entities, including PCORI, have funded research on patient-preferences. By advancing a consistent policy throughout federal health care programs identifying safeguards against the use of discriminatory metrics in value assessment, the HHS Office for Civil Rights would be supporting culture change in the process of value assessment, similar to the efforts of PCORI to change the culture of comparative clinical effectiveness research to be patient centered.

Recommendation: As the HHS Office for Civil Rights seeks to define parameters for the use of value assessment in federal health care programs and policies, we urge collaboration with entities such as NCD and PCORI that are also invested in advancing nondiscriminatory research and methods for assessing value of health care. Entities engaged through contracts should not have a history of relying on QALYs or the equal value of life year gained that is based on the QALY for measuring value. Any third-party contributing data to HHS should have experience with alternative metrics unrelated to QALYs and a commitment to using representative data that captures outcomes that matter to people with lived experience. Regulations that call out the discriminatory implications of QALYs and similar average metrics failing to account for health equity will then drive investment in alternative metrics that do not rely on flawed data and surveys such as the EQ-5D. Ultimately, a combination of well-established metrics, as proposed by NCD, would be increasingly available for use.

Use of clinical algorithms in decision-making (§ 92.210): Potential to discriminate against people with disabilities

We appreciate HHS recognized that the use of clinical algorithms can lead to discriminatory decision-making. Guidelines based on "objective" point systems or algorithms can function to discriminate against people with disabilities, as many of these systems were designed and validated based on populations without disabilities.[19] As HHS stated in its Notice of Proposed Rulemaking, many Crisis Standards of Care used during the COVID-19 pandemic relied on discriminatory decision tools and assumptions of the life worth of people with disabilities. Some of these algorithms and "objective" standards may misinterpret disability-related characteristics. For example, the Sequential Organ Failure Assessment (SOFA), which was used throughout the COVID-19 pandemic as a factor in Crisis Standards of Care, would give someone a higher SOFA score which indicates a higher risk of mortality if they are unable to give a verbal response, regardless of whether they are typically able to do so, thereby increasing their risk of being denied care in a shortage.[20] One study found that SOFA is associated with overestimated

[17] Marsh K, Krucien N. Evaluating the Consistency of Patient Preference Estimates: Systematic Variation in Survival-Adverse Event Trade-Offs in Patients with Cancer or Cardiovascular Disease. Patient. 2022 Jan;15(1):69-75. doi: 10.1007/s40271-021-00513-3. Epub 2021 May 31. PMID: 34056700.

[18] Marsh, K., De Bekker-Grob, E., Cook, N., Collacott, H., & Danyliv, A. (2021). How to integrate evidence from patient preference studies into health technology assessment: A critical review and recommendations. International Journal of Technology Assessment in Health Care,37(1), E75. doi:10.1017/S0266462321000490

[19] https://dredf.org/disability-nondiscrimination-in-health-care-and-community-life-during-the-covid-19-pandemic/

[20] https://dredf.org/disability-nondiscrimination-in-health-care-and-community-life-during-the-covid-19-pandemic/

mortality among Black patients compared with White patients, suggesting that Crisis Standards of Care are associated with systematic deprioritization of care to Black patients.[21]

Recommendation: We urge HHS to learn from the pandemic and codify regulations that health care providers may not rely on clinical algorithms that function to discriminate against providing care to people based on race, color, national origin, sex, age, and disability.

Nondiscrimination Requirements Should Ensure Accessible Access to Information Used to Make Health Care Decisions

We appreciate that the HHS OCR outlined specific nondiscrimination requirements for health care programs and activities. Accessibility and effective communication are essential for people with disabilities and people with limited access to technology such as broadband. For example, it is difficult to hold health care decision-makers such as state Pharmacy and Therapeutic Committees and Drug Utilization Review Boards (DURB) accountable for decisions related to benefit design and coverage if their websites do not meet the accessibility requirements of the Americans with Disabilities Act (ADA) or clearly communicate to the public the information on which they have relied to make decisions. All people should be able to participate in P&T Committee or DURB meetings required to be public, with accessible teleconferencing capabilities and telephone capabilities, as well as sufficient notice to register to participate. The considerations being discussed at the meeting should be clearly stated to the participating public stakeholders, including copies of the evidence under discussion with the exception of legally protected material.

Recommendation: We urge the HHS OCR to provide guidance to state Medicaid program directors on the requirements of the ADA and their obligations to ensure their programs, including P&T Committees, DURBs and their outside contractors, are meeting the ADA's requirements for accessibility to the information on which they make decisions and communicating that information in a manner that does not disadvantage people with disabilities or people with limited access to technology.

Enforcement is Crucial for Health Equity and Nondiscrimination

We appreciate that the HHS OCR recognized the importance of enforcement of nondiscrimination laws. Because so much information is not publicly accessible to determine if a benefit design or coverage decision was based on evidence that itself discriminates, it is difficult to legally challenge coverage denials that may be discriminatory. We concur with the proposed rule that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate the appropriate enforcement procedure. We also would appreciate increased oversight from OCR of the activities of state-based Medicaid programs, particularly P&T Committees and

[21] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781190

DURBs, to better understand how they make decisions about benefit design, coverage and preferred drugs and whether they are relying on discriminatory value assessments.

We are concerned that many states very explicitly reference QALY-based evidence to make decisions within their Medicaid programs. Currently, HHS is reviewing Oregon's Medicaid waiver which will determine if the state's Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, will be authorized to continue to use a QALY-driven data and analysis in the formula for the prioritized list of services. In New York, their DURB has referenced QALY-based studies from ICER to make reimbursement decisions related to treatments for cystic fibrosis, migraines and spinal muscular atrophy. Similarly, Washington State's Heath Technology Clinical Committee routinely commissions QALY-based studies to make coverage determinations for selected health technologies which are followed by state purchased health care programs including Medicaid, Uniform Medical Plan and the Department of Labor and Industries.[22] [23]

Recommendation: We urge HHS OCR to increase oversight and enforcement of state Medicaid programs to determine the extent to which they are relying on discriminatory value assessments to make decisions impacting coverage and access to care.

Thank you for your consideration of our comments. We appreciate your commitment to nondiscrimination and stand ready to work with you as you work towards these goals. Please don't hesitate to reach out to Sara van Geerturyden, sara@pipcpatients.org if you have any questions or if we may provide additional information.

Sincerely,

ACMCRN Arachnoiditis and Chronic Meningitis Collaborative Research Network
Allergy & Asthma Network
Allfocus Technologies, Inc
Alliance for Aging Research
Allies for Independence
Alstrom Syndrome International
American Association of Kidney Patients (AAKP)
American Association of People with Disabilities
American Association on Health & Disability
American Behcet's Disease Association
Angelman Syndrome Foundation
Asthma and Allergy Foundation of America
Autistic Self Advocacy Network
Autistic Women & Nonbinary Network
Bone Health and Osteoporosis Foundation

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[22] https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-clinical-committee
[23] https://www.patientaccessproject.org/#State-Tracker

Cancer Support Community
Cancer*Care*
Caring Ambassadors Program
Center for Autism and Related Disorders
Center for Independence of the Disabled, NY
CFC International
Coalition to Cure CHD2
COMBINEDBrain, Inc.
COPD Foundation
Cure SMA
Cystic Fibrosis Research Institute
Davis Phinney Foundation
Derma Care Access Network
Disability Community Resource Center
Disability Policy Consortium
Disability Rights California
Disability Rights Education and Defense Fund (DREDF)
Disability Rights Oregon
Dup15q Alliance
Easterseals
Epilepsy Alliance America
Epilepsy Foundation
Familia Unida Living with MS
Genetic Alliance
GO2 Foundation for Lung Cancer
Haystack Project
Health Hats
HealthHIV
Hermansky-Pudlak Syndrome Network
Hope for HIE
Hydrocephalus Association
Hypertrophic Cardiomyopathy Association
ICAN, International Cancer Advocacy Network
International Pemphigus and Pemphigoid Foundation
Lennox-Gastaut Syndrome (LGS) Foundation
Lupus Foundation of America
Men's Health Network
Rosie Bartel
National Disability Rights Network (NDRN)
National Down Syndrome Society
NBIA Disorders Association
Not Dead Yet
Partnership to Improve Patient Care
Patient Partner

Pulmonary Hypertension Association
PXE International
Rare Epilepsy Network (REN) Coordinating Committee
RASopathies Network
SLC6A1 Connect
Syngap1 Foundation
The ALS Association
The Arc of the United States
The Assistance Fund
The Bonnell Foundation: living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
The Hepatitis C Mentor and Support Group-HCMSG
The Hepatitis C Mentor and Support Group-HCMSG
The Partnership to Advance Cardiovascular Health
TSC Alliance
U.S. Pain Foundation
United Spinal Association
VHL Alliance
Whistleblowers of America

NASDDDS
National Association of State Directors of Developmental Disabilities Services

January 31st, 2023

The Honorable Cathy McMorris Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The National Association of State Directors of Developmental Disabilities Services (NASDDDS) supports the Protecting All Health Care for Patients Act, which would prohibit the use of Quality-Adjusted-Life-Years (QALYs) and similar measures in coverage and payment determinations under federal health care programs. The use of QALYs is discriminatory and prevents people with disabilities from accessing much needed health care.

NASDDDS represents the nation's state agencies in 50 states and the District of Columbia providing services to children and adults with intellectual and developmental disabilities and their families. NASDDDS promotes visionary leadership, systems innovation, and the development of national policies that support home and community-based services for individuals with disabilities and their families. The NASDDDS mission is to assist member state agencies in building effective, efficient person-centered systems of services and supports for people with developmental disabilities and their families.

Access to healthcare for individuals with I/DD is a continual challenge. Medical professionals rarely have the requisite expertise and experience to serve these individuals, who may have communication and other challenges that require specific supports to ensure successful health care visits. Too, individuals with I/DD often need assistance with navigating the health care system, including finding practitioners, scheduling visits, and transportation. The application of QALY methodology introduces further barriers to access for this population.

The concept of the QALY is based on the premise that a year of life with a disability is of lower quality and value than a year of life without a disability. This perception is rooted in long-standing misconceptions about the lives of people with disabilities, which have never been accurate and are certainly out of touch with today's reality, in which it has become abundantly clear that people with disabilities can live high quality lives as valuable and contributing members of their communities. The QALY methodology flies in the face of this truth by assigning lower value to treatments that address an individual's immediate health need while not eliminating their disability. The National Council on Disability, an independent federal agency, in a 2019 report called on Congress to disallow QALYs in state and federal health care programs, noting that "the

NASDDDS
National Association of State Directors of Developmental Disabilities Services

QALY calculation reduces the value of treatments that do not bring a person back to 'perfect health,' in the sense of not having a disability and meeting society's definitions of 'healthy' and 'functioning'; uses simplified assessments of value that do not account for the complexity of patient experience; and does not to take into account clinical expertise on rare disorders that may not have an extensive research literature available for use." [1]

NASDDDS urges you to support this important legislation. Access to appropriate health care is crucial to successful outcomes in the long term services and supports programs our members administer. Please contact Dan Berland at dberland@nasddds.org with any questions or follow-up.

Sincerely,

Mary Sowers
Executive Director
NASDDDS

[1] National Council on Disability, "Quality-Adjusted Life Years and the Devaluation of Life with Disability," November 6, 2019.

PIPC Partnership to Improve Patient Care

FOR IMMEDIATE RELEASE January 30, 2023
Statement Supporting the Protecting Health Care for All Patients Act
Press Contact: Thayer Roberts, thayer@pipcpatients.org

The Protecting Health Care for All Patients Act represents an important step forward to strengthen and extend existing protections against use of the quality-adjusted life year (QALY) and similar metrics to all federal programs. The bill advances recent recommendations of the National Council on Disability and reflects longstanding, bipartisan concern with use of QALY standards in health care policy.

PIPC applauded the Protecting Health Care for All Patients Act and encouraged its swift passage into law. In 2010, the Affordable Care Act barred use of QALYs as a threshold to determine coverage, reimbursement and incentive programs in Medicare. The independent federal agency National Council on Disability recommended the bar be extended to all federal programs in its Health Equity Framework.

PIPC Chairman Tony Coelho stated, "As with the Americans with Disabilities Act, legislation barring QALYs in all federal programs can pass if Members of Congress on both sides of the aisle are determined to work together to get it done. Even in a divided Congress, there are issues such as ending disability discrimination in health care that everyone can agree on. I am grateful that Chair McMorris-Rodgers introduced the bill and is prioritizing its passage."

Maria Town, President and CEO of the American Association of People with Disabilities, expressed similar optimism and support, stating, "Ensuring that health care policy decisions are focused on the individual needs of people with disabilities is something everyone can agree on. Over two administrations, Republican and Democratic, the National Council on Disability and disability advocates across the country have called for the bar on using QALYs to make Medicare decisions to be consistent across federal programs and this bill advances that."

Laura Weidner, Vice President of Government Relations & Advocacy at the Epilepsy Foundation, noted broad support across the patient and disability communities for the policy, stating, "Concerns about QALYs are longstanding in the disability community. We urge swift passage of this legislation to ensure that that this discriminatory tool is not used in our nation's health care programs."

Debbie Weir, CEO of Cancer Support Community, stated support for the bill, "The bill is consistent with our efforts to work towards a health care system that is truly centered on the experiences, preferences, and values of cancer patients and their loved ones. Too often, patients are caught in the middle of efforts to reduce health system costs by denying or restricting access to care, shifting the cost of care to patients and their families in the process."

Patricia Goldsmith, CEO of Cancer*Care*, noted the importance of Congress taking this step, stating, "For too long, cancer patients and their families have fought access barriers based on black-box algorithms that treat us like numbers and not individuals. This bill represents an important step forward in advancing patient-centered decision-making across the care continuum."

PATIENTS RISING NOW

February 1, 2023

The Honorable Brett Guthrie
Chairman
Health Subcommittee
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Health Subcommittee
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Chairwoman
Energy and Commerce Committee
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
Washington, DC 20515

Dear Chairman Guthrie, Ranking Member Eshoo, Chairwoman Rodgers, and Ranking Member Pallone,

On behalf of Patients Rising Now, thank you for holding a legislative hearing focused on the *Protecting Health Care for All Patients Act*. Patients Rising Now is a national nonprofit patient advocacy organization driving efforts at the federal, state, and local level to ensure all people in the United States have **access** to high-value healthcare services and treatments with **transparent** and **affordable** pricing. Since our founding eight years ago, Patients Rising has provided people with chronic, rare, and life-threatening illnesses the information and services to best access affordable care.

We unequivocally support the full ban of Quality Adjusted Life Years (QALYs) in all government programs and Medicare valuations, which was, unfortunately, not included in the Inflation Reduction Act (IRA). QALY is not a household term, but its influence over patients' access to treatments and services looms large for the patient community.

The IRA sidesteps the problem of QALY use in value assessments by only prohibiting any measurement that "treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally." This ambiguous wording is open to misinterpretation and fails to protect patients and their families from rationing and discrimination.

While care valuations may not directly discriminate against the elderly, disabled, or terminally ill, my fear is government programs will indirectly prejudice the most vulnerable. For example, Centers for Medicare and Medicaid Services currently restricts brain imaging in connection with diagnosing Alzheimer's disease to a single scan during a person's lifetime, which is contingent on that person's enrollment in a clinical trial. Many in underserved communities do

not have access to clinical trials. As a result, CMS has taken the advice of an FDA Advisory Committee and the Institute for Clinical and Economic Review (ICER) review in determining an entire class of current and future medications are not available to those who lack access to a clinical trial. This is just one example of the massive discrimination against seniors in underserved communities. Rationing decisions such as this set a dangerous precedent against future innovation.

In the absence of a national Health Technology Assessment (HTA) program, private entities like the Institute for Clinical and Economic Review (ICER) evaluate and determine the "value" of new therapies using QALY-based assessments. ICER and similar groups have a troubling pattern of ignoring the needs of patients living with rare diseases, resulting in decisions that would limit access and affordability for approved therapies.

Steve Pearson, ICER's President states that orphan drug spending places an "*undue burden ... on others for the sake of a few*." Specifically, ICER asserts "*The opportunity cost of supporting the use of ultra-orphan drugs necessitates that patients with a more common disease, for which a cost-effective treatment is available, are denied treatment.*"

ICER's reports reduce every patient to a dollar amount, prioritizing the least costly patients rather than those with the greatest healthcare needs. And it isn't just academic economists like ICER that use the QALY. ICER is systematically leveraging its influence to use this model for care decisions for our veterans and Medicaid recipients.

QALY-based models view life as more valuable with a "perfect" body, in "perfect" health. If a patient does not meet HTA's desired characteristics, they will be disadvantaged in QALY-based equations. This is a payer-centric approach to healthcare finance, not a patient-centered model. Cancer patients and survivors, Rare Disease patients, the elderly, and disabled are disadvantaged by QALYs because lives are automatically discounted.

The QALY is a controversial metric that should be banned, but this issue of undervaluing patient's lives will require further action. There are more patient-centered and scientifically accurate ways to approach the value of treatments to the patient populations. We can start by including patients in developing new metrics. Their experiences will provide vital insights beyond the cold mathematical formula too often used in health care-design.

At the end of 2022, Patients Rising released a set of best practices for health technology assessment for rare disease treatments. This was developed over several months with our Patient Access and Affordability Project Working Group, and then endorsed by our Patient Delegates.

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It is a set of core principles, which we hope you will consider as you move forward in determining the most equitable ways to assess the value of treatments for patients. These best practices include:

Patients Need a Transparent, Collaborative, Adaptive and Equitable Process

- Regulators, HTA bodies and payers should collaborate throughout the development and lifecycle of a therapy with patients, caregivers, clinicians, and manufactures.

- HTA organizations should state in their final report how patient experience and related data - including information from a product sponsor or a patient advocacy organization - were quantitatively applied in the assessment of an FDA-approved treatment.

- Disease specific specialists that understand what constitutes patient value should be active participants in any drug assessment.

- HTA value assessment frameworks should aim to improve health equity and consider the value new medical technologies provide in terms of reducing health disparities among racial and ethnic minority groups, and people with disabilities.

Science-Based Value Claims Should be the Basis for Pricing and Access Decisions

- HTA value assessment frameworks should abandon the quality adjusted life year (QALY) and similar discriminatory tools when determining economic value or to set a value-based price.

- The foundation of an HTA framework should be the evaluation of science-based value claims, proposed in both pivotal clinical trials and for ongoing real world data collection, that are used as the basis for coverage and access decisions.

- Value frameworks must be adaptable to the disease and based on what matters to patients and caregivers.

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- Manufacturers should begin establishing value claims for rare disease treatments prior to FDA-approval with a detailed assessment of the target patient population, along with the unmet medical and evidence needs.

- All value claims, including Patient Reported Outcome measures, should be scientifically valid - expressed in ratio or interval form- and disease-specific to collect credible, empirical, and replicable evidence of benefit and value.

Encourage Evidence Generation

- Given the limited data at approval, manufacturers, HTA bodies, payers and policymakers should focus on long term research programs that generate a scientifically robust evidence base overtime with manufactures commitment to ongoing value claim assessments.

- Post-approval commitments, like confirmatory trials, should be a simple, collaborative, and realistic effort with manufacturers and stakeholders to increase evidence generation.

- Data systems and patient registries should be developed so that they can capture patient-reported outcomes reflecting broader patient and family effects of treatment.

- It is the role of the payer to weigh the totality evidence of value claims for a target patient population and to factor these claims into pricing and access recommendations.

- Payers should uphold the FDA's authority in determining safety and efficacy of the population included in the drug's FDA-approved indication statement.

- The price of a new rare disease treatment should be mutually agreed upon between the payer and manufacturer - and any cost sharing with patients should be minimal.

- Manufacturers should be open to disease area and therapeutic class reviews as evidence builds over its patent life or life cycle of a therapy.

In closing, I ask members of this committee to work across the aisle to find policy solutions that do not erect additional barriers to care for patients with rare and chronic diseases. We have a lot of work to do in creating *equitable and affordable healthcare for all patients in America*. This

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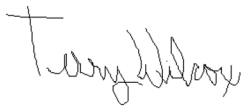
starts with the design of the benefits that determine a patient's cost and access. Keep the QALY metric out of public benefits like Medicare.

Patients Rising Now strongly encourages the Energy and Commerce Committee to pass the *Protecting Health Care for All Patients Act* and ban the QALY from being used in any government program.

Sincerely,



Terry Wilcox

CEO and Founder

The Arc
For people with intellectual and developmental disabilities

January 31, 2023

The Honorable Cathy McMorris-Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Arc writes to show our support for prohibiting the use of Quality-Adjusted-Life-Years (QALYs) and similar measures in coverage and payment determinations under federal health care programs. This is an issue that impacts all levels of health care and prohibiting the use of these measures will positively impact the lives of millions of Americans.

The Arc is the largest national community-based organization advocating for and serving people with intellectual and developmental disabilities (I/DD) and their families. We have more than 140,000 members and more than 600 state and local chapters nationwide. The Arc has a longstanding history of opposing the use of QALYs due to the discriminatory impact on people with Intellectual and Developmental Disabilities.

QALYs design inherently relays a deeply troubling message, a year of life with a disability is of lower quality and lower value than life without a disability. The disability rights movement seeks to highlight that people with disabilities have a right to be included in society and that they can have high quality lives. QALY-based assessments do not accurately account for outcomes related to people with relevant health conditions. Applying QALYs to health care decision-making can alter access to care. In fact, some people with disabilities and chronic illnesses are not seen as worthy enough to treat. We agree with the conclusions of the National Council on Disability, that Congress should disallow QALYs in state and federal health care programs.

The Protecting All Health Care for Patients Act will solidify a decades-long bipartisan track record of supporting disability rights in federal programs. Section 504 of the Rehabilitation Act of 1973 ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency. Title II of the Americans with Disabilities Act of 1990 extended this protection to programs and services offered by state and local governments. In 2010, the Affordable Care Act, stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness. Finally, the Inflation Reduction Act prohibits the use of measures that devalues the lives of people with disabilities and others in Medicare prescription drug negotiations. Under both the Trump and Biden administrations, the HHS Office for Civil Rights has taken action on discriminatory allocation of health care resources.

The Arc urges you to support this important legislation and join the decades-long bipartisan initiative to advance the rights of people with disabilities.

Please contact Brittany Owens at owens@thearc.org with any questions or follow-up.

Sincerely,

Julie Ward
Senior Executive Officer, Public Policy
The Arc

Make today a breakthrough.

January 31, 2023

The Honorable Cathy McMorris Rodgers
Chair, Energy and Commerce Committee
United States House of Representatives
Washington DC 20515

Dear Chair McMorris Rodgers,

Cure SMA, which represents individuals with a neuromuscular disease known as spinal muscular atrophy (SMA), **is pleased to support the Protecting Health Care for All Patients Act to prevent health care discrimination on the basis of disability.** Your legislation would prohibit Medicaid and other federal health programs from using discriminatory measurements, such as quality-adjusted life years (QALYs), when determining coverage or payment for life-saving treatments, services, and devices.

SMA is a progressive neurodegenerative disease that is caused by a mutation in the survival motor neuron gene 1 (SMN1) that is critical to the function of the nerves that control our muscles. Without it, those nerve cells cannot properly function and eventually die, leading to debilitating and often fatal weakness in muscles used for breathing, crawling, walking, head and neck control, and swallowing. In contrast to the progressive motor weakness, individuals with SMA have normal cognition and excel in school and the workforce and are contributing greatly to society.

Access to healthcare, including treatments, caregiving, and medical devices, is vitally important to children and adults with SMA. Three U.S. Food and Drug Administration-approved treatments exist that are targeting the underlying genetics of SMA and stopping or slowing future degeneration. Medical devices, such as ventilators (BiPAP machines) and power wheelchairs, are making it possible for children and adults with SMA to live independently and navigate their communities. And many individuals with SMA rely on personal care attendants (PCAs) and other in-home aides to assist with everyday living activities, such as bathroom transfers, meal preparation, and getting out of bed and dressed in the morning to attend work or school. Despite research and real world evidence that concludes timely and full access to these treatments, health care services, and devices improves the health and well-being of individuals with SMA, many report that they struggle to access these essential services. Individuals with SMA and their families shared in a 2022 report that *"battling insurance and state Medicaid programs is frustrating and requires time and energy."* Cure SMA's Community Survey found that a majority of adults with SMA (56%) and parents of children with SMA (61%) have had to appeal an insurance denial related to SMA treatment coverage, the majority of whom receive coverage through Medicaid. *"Please advocate on behalf of the SMA community to ensure that we are able to continue receiving treatment and care,"* an adult with SMA shared as a concern during a recent health-related survey.

The use of QALYs and other measurement tools that devalue a person with a disability can contribute toward negative coverage determinations. The National Council on Disability, in its 2019 report to Congress, found that QALY measurements, which *"may have a negative impact on the health and welfare of people with disabilities,"* are increasingly used in reimbursement and drug pricing decisions. ICER, for example, regularly uses QALYs to determine what it considers fair market value of drugs, including life-saving treatments for ultra-rare diseases such as SMA. In addition, during the COVID-19 pandemic, several states released rationing of care guidelines that excluded or deprioritized people with SMA and other disabilities from accessing ventilators and other medical care based solely on their disabilities. *"People with SMA need equal treatment in medical triage settings,"* a SMA community member shared during the height of the pandemic.

The Protecting Health Care for All Patients Act would stop this discriminatory practice against people with SMA and other disabilities by prohibiting the use of QALYs and similar measurements under any federal health care program. We stand ready to assist you and your team in securing passage of this important legislation during the 118th Congress. For more information, your staff can contact Maynard Friesz, Vice President for Policy and Advocacy at Cure SMA, at maynard.friesz@curesma.org or 202-871-8004.

Sincerely,

Kenneth Hobby
President
Cure SMA

January 31, 2023

The Honorable Cathy McMorris-Rodgers
Chair
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

The Honorable Frank Pallone Jr.
Ranking Member
Energy and Commerce Committee
US House of Representatives
Washington DC 20510

Dear Chair McMorris-Rodgers and Ranking Member Pallone:

The National Disability Rights Network (NDRN) writes to show our support for the Protecting All Health Care for Patients Act, to prohibit the use of Quality-Adjusted-Life-Years (QALYs) and similar measures in coverage and payment determinations under federal health care programs. This is an issue that impacts all levels of health care and prohibiting the use of these measures will positively impact the lives of millions of Americans.

NDRN is the non-profit membership association of Protection and Advocacy (P&A) and Client Assistance Program (CAP) agencies located in all 50 States, the District of Columbia, and the United States Territories. In addition, there is a P&A and CAP affiliated with the Native American Consortium which includes the Hopi, Navajo, and San Juan Southern Paiute Nations in the Four Corners region of the Southwest.

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P&A and CAP agencies are authorized under various federal statutes to provide legal representation and related advocacy services, and to investigate abuse and neglect of individuals with disabilities in a variety of settings. The P&A / CAP Network comprises the nation's largest provider of legally-based advocacy services for persons with disabilities. NDRN and the P&A / CAP Network have heard and write today to convey the concerns of people with disabilities, the P&A's and CAP's clients, on the use of QALYs.

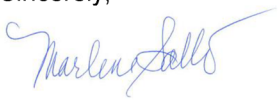
The logic inherent in the QALY is concerning on its face: it is designed to measure the extent to which a year of life with a disability is of lower quality and lower value than life without a disability. The mission and vision of the P&A / CAP Network is to advocate that not only do people with disabilities have a right to participate in society, but that they can have high quality lives. QALY-based assessments also do not account for outcomes that matter to people living with the relevant health condition. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We agree with the conclusions of the National Council on Disability, an independent federal agency, that Congress should disallow QALYs in state and federal health care programs.

The Protecting All Health Care for Patients Act will solidify a decades-long bipartisan track record of supporting disability rights in federal programs. Section 504 of the Rehabilitation Act of 1973, signed by President Nixon, ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency. Title II of the Americans with Disabilities Act of 1990, signed by President H.W. Bush, extended this protection to programs and services offered by state and local governments. In 2010, the Affordable Care Act, signed by President Obama, stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness. Finally the

Inflation Reduction Act, signed by President Biden, prohibits the use of measures that devalue the lives of people with disabilities and others in Medicare prescription drug negotiations. Under both the Trump and Biden administrations, the HHS Office for Civil Rights has taken action on discriminatory allocation of health care resources.

NDRN and the nationwide network of P&A and CAP agencies urges you to support this important legislation and join the decades-long bipartisan initiative to advance the rights of people with disabilities. Please contact Eric Buehlmann, Deputy Executive Director for Public Policy at eric.buehlmann@ndrn.org with any questions or follow-up.

Sincerely,



Executive Director
National Disability Rights Network

December 14, 2021

The Honorable Bill Cassidy
United States Senate
520 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Bob Latta
United States House of Representatives
2448 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Morgan Griffith
United States House of Representatives
2202 Rayburn House Office Building
Washington, D.C. 20515

RE: S. 3336 / H.R. 6184 the Halt Lethal Trafficking (HALT) Fentanyl Act - Active Support

Dear Senator Cassidy, Senator Burr, Representative Latta, and Representative Griffith,

I write to you today on behalf of the Peace Officers Research Association of California (PORAC), representing 75,000 public safety members and 930 public safety associations. PORAC is very pleased to support the recently introduced *Halt Lethal Trafficking (HALT) Fentanyl Act*, which would permanently classify fentanyl and its analogs as a Schedule I substance under the Controlled Substances Act (CSA).

This important legislation would enable law enforcement to prosecute the distribution of fentanyl and fentanyl analogs, which continue to devastate communities nationwide. This is particularly important in California, where we have seen opioid-related overdoses rise significantly in recent years. In 2020 alone, Fentanyl accounted for 36 percent of overdose deaths in our State, an increase of 89 percent from 2019. As the law enforcement community continues working to reverse these trends, the HALT Fentanyl Act would help to bolster these efforts by ensuring the current Schedule 1 classification of fentanyl under the CSA does not expire.

PORAC sincerely appreciates your work in developing and introducing this legislation. Making this classification permanent will enhance the vital role our law enforcement officers play in removing these deadly and harmful substances from our streets. Should you have any questions, please do not hesitate to call the PORAC Headquarters (916) 928-3777 or contact our legislative advocates at Steptoe & Johnson LLP (202) 429-6457.

Very Truly Yours,
BOARD OF DIRECTORS
Peace Officers Research Association of California

Brian R. Marvel
President

Brian R. Marvel	Damon Kurtz	Tim Davis	Randy Beintema
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Principles for allocation of scarce medical interventions

Govind Persad, Alan Wertheimer, Ezekiel J Emanuel

Allocation of very scarce medical interventions such as organs and vaccines is a persistent ethical challenge. We evaluate eight simple allocation principles that can be classified into four categories: treating people equally, favouring the worst-off, maximising total benefits, and promoting and rewarding social usefulness. No single principle is sufficient to incorporate all morally relevant considerations and therefore individual principles must be combined into multiprinciple allocation systems. We evaluate three systems: the United Network for Organ Sharing points systems, quality-adjusted life-years, and disability-adjusted life-years. We recommend an alternative system—the complete lives system—which prioritises younger people who have not yet lived a complete life, and also incorporates prognosis, save the most lives, lottery, and instrumental value principles.

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In health care, as elsewhere, scarcity is the mother of allocation.[1] Although the extent is debated,[2,3] the scarcity of many specific interventions—including beds in intensive care units,[4] organs, and vaccines during pandemic influenza[5]—is widely acknowledged. For some interventions, demand exceeds supply. For others, an increased supply would necessitate redirection of important resources, and allocation decisions would still be necessary.[6]

Allocation of scarce medical interventions is a perennial challenge. During the 1940s, an expert committee allocated—without public input—then-novel penicillin to American soldiers before civilians, using expected efficacy and speed of return to duty as criteria.[7] During the 1960s, committees in Seattle allocated scarce dialysis machines using prognosis, current health, social worth, and dependants as criteria.[7] How can scarce medical interventions be allocated justly? This paper identifies and evaluates eight simple principles that have been suggested.[8–12] Although some are better than others, no single principle allocates interventions justly. Rather, morally relevant simple principles must be combined into multiprinciple allocation systems. We evaluate three existing systems and then recommend a new one: the complete lives system.

Simple allocation principles

Eight simple ethical principles for allocation can be classified into four categories, according to their core ethical values: treating people equally, favouring the worst-off, maximising total benefits, and promoting and rewarding social usefulness (table 1). We do not regard ability to pay as a plausible option for the scarce life-saving interventions we discuss.

Some people wrongly suggest that allocation can be based purely on scientific or clinical facts, often using the term "medical need".[13,14] There are no value-free medical criteria for allocation.[15,16] Although biomedical facts determine a person's post-transplant prognosis or the dose of vaccine that would confer immunity, responding to these facts requires ethical, value-based judgments.

When evaluating principles, we need to distinguish between those that are insufficient and those that are flawed. Insufficient principles ignore some morally relevant considerations. Conversely, flawed principles recognise morally irrelevant considerations: inherently flawed principles necessarily recognise irrelevant considerations, whereas practically flawed principles allow irrelevant considerations to affect allocation. Principles that are individually insufficient could form part of an acceptable multiprinciple system, whereas systems that include flawed principles are untenable because they will always recognise irrelevant considerations.

Treating people equally

Many scarce medical interventions, such as organ transplants, are indivisible. For indivisible goods, benefiting people equally entails providing equal chances at the scarce intervention—equality of opportunity, rather than equal amounts of it.[1] Two principles attempt to embody this value.

Lottery

Allocation by lottery has been used, sometimes with explicit judicial and legislative endorsement, in military conscription, immigration, education, and distribution of vaccines.[10,17,18]

Lotteries have several attractions. Equal moral status supports an equal claim to scarce resources.[19] Even among only roughly equal candidates, lotteries prevent small differences from drastically affecting outcome.[18] Some people also support lottery allocation because "each person's desire to stay alive should be regarded as of the same importance and deserving the same respect as that of anyone else".[20] Practically, lottery allocation is quick and requires little knowledge about recipients.[18] Finally, lotteries resist corruption.[18]

The major disadvantage of lotteries is their blindness to many seemingly relevant factors.[21,22] Random decisions between someone who can gain 40 years and someone who can gain only 4 months, or someone who has already lived for 80 years and someone who has lived only 20 years, are inappropriate. Treating people equally often fails to treat them as equals.[23] Ultimately, although allocation solely by lottery is insufficient, the lottery's

	Advantages	Disadvantages	Examples of use	Recommendation
Treating people equally				
Lottery	Hard to corrupt; little information about recipients needed	Ignores other relevant principles	Military draft; schools; vaccination	Include
First-come, first-served	Protects existing doctor-patient relationships; little information about recipients needed	Favours wealthy, powerful, and well-connected; ignores other relevant principles	ICU beds; part of organ allocation	Exclude
Favouring the worst-off: prioritarianism				
Sickest first	Aids those who are suffering right now; appeals to "rule of rescue"; makes sense in temporary scarcity; proxy for being worst off overall	Surreptitious use of prognosis; ignores needs of those who will become sick in future; might falsely assume temporary scarcity; leads to people receiving interventions only after prognosis deteriorates; ignores other relevant principles	Emergency rooms; part of organ allocation	Exclude
Youngest first	Benefits those who have had least life; prudent planners have an interest in living to old age	Undesirable priority to infants over adolescents and young adults; ignores other relevant principles	New NVAC/ACIP pandemic flu vaccine proposal	Include
Maximising total benefits: utilitarianism				
Number of lives saved	Saves more lives, benefiting the greatest number; avoids need for comparative judgments about quality or other aspects of lives	Ignores other relevant principles	Past ACIP/NVAC pandemic flu vaccine policy; bioterrorism response policy; disaster triage	Include
Prognosis or life-years saved	Maximises life-years produced	Ignores other relevant principles, particularly distributive principles	Penicillin allocation; traditional military triage (prognosis) and disaster triage (life-years saved)	Include
Promoting and rewarding social usefulness				
Instrumental value	Helps promote other important values; future oriented	Vulnerable to abuse through choice of prioritised occupations or activities; can direct health resources away from health needs	Past and current NVAC/ACIP pandemic flu vaccine policy	Include but only in some public health emergencies
Reciprocity	Rewards those who implemented important values; past oriented	Vulnerable to abuse; can direct health resources away from health needs; intrusive assessment process	Some organ donation policies	Include only irreplaceable people who have suffered serious losses

Table 1: Simple principles and their core ethical values

simplicity and resistance to corruption suggests that it could be incorporated into a multiprinciple system.[22]

First-come, first-served

Within health care, many people endorse a first-come, first-served distribution of beds in intensive care units[24] or organs for transplant.[25] The American Thoracic Society defends this principle as "a natural lottery—an egalitarian approach for fair [intensive care unit] resource allocation."[24] Others believe it promotes fair equality of opportunity,[25] and allows physicians to avoid discontinuing interventions, such as respirators, even when other criteria support moving those interventions to new arrivals.[26] Some people simply equate it to lottery allocation.[19]

As with lottery allocation, first-come, first-served ignores relevant differences between people, but in practice fails even to treat people equally. It favours people who are well-off, who become informed, and travel more quickly, and can queue for interventions without competing for employment or child-care concerns.[27] Queues are also vulnerable to additional corruption. As New York State's pandemic influenza planners stated, "Those who could figuratively (and sometimes literally) push to the front of the line would be vaccinated and stand the best chance for survival".[28] First-come, first-served allows morally irrelevant qualities—such as wealth, power, and connections—to decide who receives scarce interventions, and is therefore practically flawed.

Favouring the worst-off: prioritarianism

Franklin Roosevelt argued that "the test of our progress is not whether we add more to the abundance of those who have much; it is whether we provide enough for those who have too little".[29] Philosophers call this preference for the worst-off prioritarianism.[30] Some define being worst-off as currently lacking valuable goods, whereas others define it as lacking valuable goods throughout one's entire life.[8] Two principles embody these two interpretations.

Sickest first

Treating the sickest people first prioritises those with the worst future prospects if left untreated. The so-called rule of rescue, which claims that "our moral response to the imminence of death demands that we rescue the doomed", exemplifies this principle.[31] Transplantable livers and hearts, as well as emergency-room care, are allocated to the sickest individuals first.[21]

Some people might argue that treating the sickest individuals first is intuitively obvious.[32] Others claim that the sickest people are also probably worst off overall, because healthier people might recover unaided or be saved later by new interventions.[33] Finally, sickest-first allocation appeals to prognosis if untreated—a criterion clinicians frequently consider.[14]

On its own, sickest-first allocation ignores post-treatment prognosis: it applies even when only minor gains at high cost can be achieved. To circumvent this result, some

misleadingly claim that sick people with a small but clear chance of benefit do not have a medical need.[15] Sick recipients' prognoses are wrongly assumed to be normal, even though many interventions—such as liver transplants—are less effective for the sickest people.[34]

If the failure to take account of prognosis were its only problem, sickest-first allocation would merely be insufficient. However, it myopically bases allocation on how sick someone is at the current time—a morally arbitrary factor in genuine scarcity.[16] Preferential allocation of a scarce liver to an acutely ill person unjustly ignores a currently healthier person with progressive liver disease, who might be worse off when he or she later suffers liver failure.[8,22] Favouring those who are currently sickest seems to assume that resource scarcity is temporary: that we can save the person who is now sickest and then save the progressively ill person later.[8,22] However, even temporary scarcity does not guarantee another chance to save the progressively ill person. Furthermore, when interventions are persistently scarce, saving the progressively ill person later will always involve depriving others. When we cannot save everyone, saving the sickest first is inherently flawed and inconsistent with the core idea of priority to the worst-off.

Youngest first

Although not always recognised as such, youngest-first allocation directs resources to those who have had less of something supremely valuable—life-years.[8] Dialysis machines and scarce organs have been allocated to younger recipients first,[35] and proposals for allocation in pandemic influenza prioritise infants and children.[36] Daniel Callahan[37] has suggested strict age cut-offs for scarce life-saving interventions, whereas Alan Williams[38] has suggested a system that allocates interventions based on individuals' distance from a normal life-span if left unaided.

Prioritising the youngest gives priority to the worst-off—those who would otherwise die having had the fewest life-years—and is thus fundamentally different from favouritism towards adults or people who are well-off.[8,9] Also, allocating preferentially to the young has an appeal that favouring other worst-off individuals such as women, poor people, or minorities lacks: "Because [all people] age, treating people of different ages differently does not mean that we are treating persons unequally."[39] Prudent planners would allocate life-saving interventions to themselves earlier in life to improve their chances of living to old age.[39] These justifications explain much of the public preference for allocating scarce life-saving interventions to younger people.[40,41]

Strict youngest-first allocation directs scarce resources predominantly to infants. This approach seems incorrect.[3] The death of a 20-year-old young woman is intuitively worse than that of a 2-month-old girl, even though the baby has had less life.[40] The 20-year-old has a much more developed personality than the infant, and has drawn upon the investment of others to begin as-yet-unfulfilled projects. Youngest-first allocation also ignores prognosis,[42] and categorically excludes older people.[34] Thus, youngest-first allocation seems insufficient on its own, but it could be combined with prognosis and lottery principles in a multiprinciple allocation system.[34]

Maximising total benefits: utilitarianism

Maximising benefits is a utilitarian value, although principles differ about which benefits to maximise.

Save the most lives

One maximising strategy involves saving the most individual lives, and it has motivated policies on allocation of influenza vaccine[5] and responses to bioterrorism.[43] Since each life is valuable, this principle seems to need no special justification. It also avoids comparing individual lives. Other things being equal, we should always save five lives rather than one.[44]

However, other things are rarely equal. Some lives have been shorter than others; 20-year-olds have lived less than 70-year-olds.[40] Similarly, some lives can be extended longer than others. How to weigh these other relevant considerations against saving more lives—whether to save one 20-year-old, who might live another 60 years if saved, or three 70-year-olds who could only live for 10 years each—is unclear.[45] Although insufficient on its own, saving more lives should be part of a multiprinciple allocation system.

Prognosis or life-years

Rather than saving the most lives, prognosis allocation aims to save the most life-years. This strategy has been used in disaster triage and penicillin allocation, and motivates the exclusion of people with poor prognoses from organ transplantation waiting lists.[7,21,46] Maximising life-years has intuitive appeal. Living more years is valuable, so saving more years also seems valuable.[8]

However, even supporters of prognosis-based allocation acknowledge its inability to consider distribution as well as quantity.[46] Making a well-off person slightly better off rather than slightly improving a worse-off person's life would be unjust; likewise, why give an extra year to a person who has lived for many when it could be given to someone who would otherwise die having had few?[8,47] Similarly, giving a few life-years to many differs from giving many life-years to a few.[8] As with the principle of saving the most lives, prognosis is undeniably relevant but insufficient alone.

Promoting and rewarding social usefulness

Unlike the previous values, social value cannot direct allocation on its own.[20] Rather, social value allocation prioritises specific individuals to enable them to promote other important values, or rewards them for having promoted these values.

In view of the multiplicity of reasonable values in society and in view of what is at stake, social value allocation must

not legislate socially conventional, mainstream values.[1] When Seattle's dialysis policy favoured parents and church-goers, it was criticised: "The Pacific Northwest is no place for a Henry David Thoreau with kidney failure."[48] Allocators must also avoid directing interventions earmarked for health needs to those not relevant to the health problem at hand, which covertly exacerbates scarcity.[8,49] For instance, funeral directors might be essential to preserving health in an influenza pandemic, but not during a shortage of intensive-care beds.[5]

Instrumental value

Instrumental value allocation prioritises specific individuals to enable or encourage future usefulness. Guidelines that prioritise workers producing influenza vaccine exemplify instrumental value allocation to save the most lives.[5] Responsibility-based allocation—eg, allocation to people who agree to improve their health and thus use fewer resources—also represents instrumental value allocation.[50]

This approach is necessarily insufficient, because it derives its appeal from promoting other values, such as saving more lives: "all whose continued existence is clearly required so that others might live have a good claim to priority".[20] Prioritising essential health-care staff does not treat them as counting for more in themselves, but rather prioritises them to benefit others. Instrumental value allocation thus arguably recognises the moral importance of each person, even those not instrumentally valuable.

Student military deferments have shown that instrumental value allocation can encourage abuse of the system.[51] People also disagree about usefulness: is saving all legislators necessary in an influenza pandemic?[20] Decisions on usefulness can involve complicated and demeaning inquiries.[52] However, where a specific person is genuinely indispensable in promoting morally relevant principles, instrumental value allocation can be appropriate.

Reciprocity

Reciprocity allocation is backward-looking, rewarding past usefulness or sacrifice. As such, many describe this allocative principle as desert or rectificatory justice, rather than reciprocity. For important health-related values, reciprocity might involve preferential allocation to past organ donors,[8] to participants in vaccine research who assumed risk for others' benefit,[53] or to people who made healthy lifestyle choices that reduced their need for resources.[50] Priority to military veterans embodies reciprocity for promoting non-health values.[54]

Proponents claim that "justice as reciprocity calls for providing something in return for contributions that people have made".[53] Reciprocity might also be relevant when people are conscripted into risky tasks. For instance, nurses required to care for contagious patients could deserve reciprocity, especially if they did not volunteer.

Reciprocity allocation, like instrumental value allocation, might potentially require time-consuming, intrusive, and demeaning inquiries, such as investigating whether a person adhered to a healthy lifestyle.[52,22] Furthermore, unlike instrumental value, reciprocity does not have the future-directed appeal of promoting important health values. Ultimately, the appropriateness of allocation based on reciprocity seems to depend in a complex way on several factors, such as seriousness of sacrifice and irreplaceability. For instance, former organ donors seem to deserve reciprocity since they make a serious sacrifice and since there is no surplus of organ donors. By contrast, laboratory staff who serve as vaccine production workers do not incur serious risk nor are they irreplaceable, so reciprocity seems less appropriate for them.

Assessing principles: allocation systems

Which principles best embody morally relevant values? First-come, first-served is flawed in practice because it unwittingly allows irrelevant considerations, such as wealth, to affect allocation decisions, whereas a lottery is insufficient but not flawed. Similarly, sickest-first allocation is inherently flawed, whereas the youngest-first principle, though insufficient, recognises the important value of priority to the worst-off. Both utilitarian principles—maximising lives saved and prognosis—are relevant but insufficient, and usefulness and reciprocity are relevant where irreplaceable individuals make serious sacrifices, such as those during public health emergencies.

Ultimately, no principle is sufficient on its own to recognise all morally relevant considerations. Combining principles into systems increases complexity and controversy, but is inevitable if allocations are to incorporate the complexity of our moral values (table 2). People disagree about which principles to include and how to balance them. Many allocation systems do not make their content explicit, nor do they justify their choices about inclusion, balancing, and specification.[1] Elucidating, comparing, and evaluating allocation systems should be a research priority.[3]

United Network for Organ Sharing (UNOS) points systems

The UNOS points systems are used for organ allocation (table 2). They combine three principles: sickest-first (current medical condition); first-come, first-served (waiting time); and prognosis (antigen, antibody, and blood type matching between recipient and donor). UNOS weights principles differently depending on the organ distributed. Kidney and pancreas allocation is mainly by waiting time, with some weight given to sickest-first and prognosis.[55] Conversely, heart allocation weights sickest-first principles heavily and waiting time less so.[55] Lung and liver allocation takes into account waiting time, sickest-first, and prognosis.[55] Historically, no UNOS system has emphasised prognosis, although

	Principles included	Advantages	Objections
UNOS points systems for organ allocation in the USA	First-come, first-served; sickest-first; prognosis	Can combine all possible principles; flexible	Includes least justifiable principles: first-come, first-served and sickest-first; low priority given to prognosis; vulnerable to bias and manipulation, such as being listed on multiple transplantation lists and misrepresentation of health status; allows multiple organ transplants, thus saving fewer lives
QALY allocation	Prognosis; excludes save the most lives	Maximises future benefits; considers quality of life; used in many existing, quantitatively sophisticated frameworks	Outcome measure disadvantages disabled people; incorrect conception of equality by focusing on equality of QALYs rather than equality of persons; does not incorporate many relevant principles
DALY allocation	Prognosis; instrumental value; excludes save the most lives	Maximises future benefits; includes instrumental value, saving people whose productivity is key to a flourishing society	Outcome measure disadvantages disabled people; age considered as modifying value of individual life-years, rather than from standpoint of distributive justice; definition of instrumental value is too focused on economic worth, and could justify bias towards heads of household and other "traditional" social positions; does not incorporate many relevant principles
Complete lives system	Youngest-first; prognosis; save the most lives; lottery; instrumental value, but only in public health emergency	Matches intuition that death of adolescents is worse than that of infants or elderly; everyone has an interest in living through all life stages; incorporates the largest number of relevant principles; resistant to corruption	Reduced chances for persons who have lived many years; life-years are not a relevant health care outcome; unable to deal with international differences in life expectancy; need lexical priority rather than balancing; complete lives system is not appropriate for general distribution of health care resources

UNOS=United Network for Organ Sharing. QALY=quality-adjusted life-years. DALY=disability-adjusted life-years.

Table 2: Four multiprinciple systems

UNOS's most recent policy discussions on lung allocation suggest such a change.[56]

The UNOS point systems are flexible: conceivably, they could include any simple principle by translating it into a points framework. The systems are easily revisable to weight one principle more heavily than others.

Current UNOS systems incorporate two flawed simple principles: first-come, first-served and sickest first. They are also vulnerable to additional exploitation. Taking advantage of the first-come, first-served principle, well-off patients place themselves on multiple waiting lists.[57] Exploiting the sickest-first element, some transplant centres have temporarily altered or misrepresented their patients' health state to get them scarce organs, making sickest-first both practically and inherently flawed.[58,59]

Furthermore, UNOS points systems do not appropriately consider the benefit-maximising principles, prognosis, and saving the most lives, nor do they include youngest-first allocation. Most dramatically, multiple-organ transplants to one individual are permitted, even when a heart-lung-liver combination could save three lives if transplanted separately.[8,60] Similarly, policy revisions during the 1990s de-emphasised organ-recipient matching even though poorer matching leads to fewer lives saved.[61]

Attempts to remedy these deficiencies have been covert and haphazard. In an effort to implement prognosis allocation tacitly, ill or old people have been excluded from supposedly first-come, first-served waiting lists.[62] Physicians can misdiagnose comorbidities as contra-indications, wrongly implying that transplants will harm recipients, rather than explicitly practising prognosis-based allocation.[63] Some have proposed so-called old-for-old policies that match donor organ age to recipient age—misrepresenting both youngest-first and prognosis-based allocation as biological fact.[64] Others have advocated local rather than national waiting lists to circumvent sickest-first allocation.[60,65] Explicit and public acknowledgment of allocation strategies would be preferable to this surreptitious and piecemeal approach.

Quality-adjusted life-years

Allocation systems based on quality-adjusted life-years (QALY) have two parts (table 2). One is an outcome measure that considers the quality of life-years. As an example, the quality-of-life measure used by the UK National Health Service rates moderate mobility impairment as 0·85 times perfect health.[66] QALY allocation therefore equates 8·5 years in perfect health to 10 years with moderately impaired mobility.[67] The other part of QALY allocation is a maximising assumption: that justice requires total QALYs to be maximised without consideration of their distribution.[46,68] QALY allocation initially constituted the basis for Oregon's Medicaid coverage initiative, and is currently used by the UK's National Institute for Health and Clinical Excellence (NICE).[69,70] Both the ethics and efficacy of QALY allocation have been substantially discussed.[46]

The QALY outcome measure has problems. Even if a life-year in which a person has impaired mobility is worse than a healthy life-year, someone adapted to wheelchair use might reasonably value an additional life-year in a wheelchair as much as a non-disabled person would value an additional life-year without disability.[71] Allocators have struggled with this issue.[72]

More importantly, maximising the number of QALYs is an insufficient basis for allocation. Although QALY advocates appeal to the idea that all QALYs are equal,

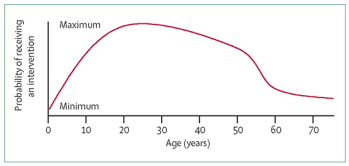

Figure: **Age-based priority for receiving scarce medical interventions under the complete lives system**

people, not QALYs, deserve equal treatment.[73] Treatment of a serious disease such as appendicitis gives a few people many more QALYs, whereas treatment of a minor problem like uncapped teeth gives many people a few more QALYs.[70] Even though the two strategies produce equal numbers of QALYs, they treat individuals very differently.[8] Likewise, giving QALYs to someone who has had few life-years differs morally from giving them to someone who has already had many.[8,47] Ultimately, QALY allocation systems do not recognise many morally relevant values—such as treating people equally, giving priority to the worst-off, and saving the most lives—and are therefore insufficient for just allocation.

Disability-adjusted life-years

WHO endorses the system of disability-adjusted life-year (DALY) allocation (table 2).[74] As with QALY allocation, DALY allocation does not consider interpersonal distribution. DALY systems also incorporate quality-of-life factors—for instance, they equate a life-year with blindness to roughly 0·6 healthy life-years.[74] Additionally, DALY allocation ranks each life-year with the age of the person as a modifier: "The well-being of some age groups, we argue, is instrumental in making society flourish; therefore collectively we may be more concerned with improving health status for individuals in these age groups."[74] This argument, although used to justify age-weighting, would equally justify counting the life-years of economically productive people and those caring for others for more.

DALY allocation wrongly incorporates age into the outcome measure, claiming that a year for a younger person is in itself more valuable. Priority for young people is better justified on grounds of distributive justice.[41] Also, the use of instrumental value to justify DALY allocation resembles that used in Seattle's dialysis allocation, which inappropriately favoured wage earners and carers of dependants.[7,48]

The complete lives system

Because none of the currently used systems satisfy all ethical requirements for just allocation, we propose an alternative: the complete lives system. This system incorporates five principles (table 2): youngest-first, prognosis, save the most lives, lottery, and instrumental value.[5] As such, it prioritises younger people who have not yet lived a complete life and will be unlikely to do so without aid. Many thinkers have accepted complete lives as the appropriate focus of distributive justice: "individual human lives, rather than individual experiences, [are] the units over which any distributive principle should operate."[1,75,76] Although there are important differences between these thinkers, they share a core commitment to consider entire lives rather than events or episodes, which is also the defining feature of the complete lives system.

Consideration of the importance of complete lives also supports modifying the youngest-first principle by prioritising adolescents and young adults over infants (figure). Adolescents have received substantial education and parental care, investments that will be wasted without a complete life. Infants, by contrast, have not yet received these investments. Similarly, adolescence brings with it a developed personality capable of forming and valuing long-term plans whose fulfilment requires a complete life.[77] As the legal philosopher Ronald Dworkin argues, "It is terrible when an infant dies, but worse, most people think, when a three-year-old child dies and worse still when an adolescent does";[78] this argument is supported by empirical surveys.[41,79] Importantly, the prioritisation of adolescents and young adults considers the social and personal investment that people are morally entitled to have received at a particular age, rather than accepting the results of an unjust status quo. Consequently, poor adolescents should be treated the same as wealthy ones, even though they may have received less investment owing to social injustice.

The complete lives system also considers prognosis, since its aim is to achieve complete lives. A young person with a poor prognosis has had few life-years but lacks the potential to live a complete life. Considering prognosis forestalls the concern that disproportionately large amounts of resources will be directed to young people with poor prognoses.[42] When the worst-off can benefit only slightly while better-off people could benefit greatly, allocating to the better-off is often justifiable.[1,30] Some small benefits, such as a few weeks of life, might also be intrinsically insignificant when compared with large benefits.[8]

Saving the most lives is also included in this system because enabling more people to live complete lives is better than enabling fewer.[8,44] In a public health emergency, instrumental value could also be included to enable more people to live complete lives. Lotteries could be used when making choices between roughly equal recipients, and also potentially to ensure that no individual—irrespective of age or prognosis—is seen as beyond saving.[34,80] Thus, the complete lives system is complete in another way: it incorporates each morally relevant simple principle.

When implemented, the complete lives system produces a priority curve on which individuals aged between roughly 15 and 40 years get the most substantial chance, whereas the youngest and oldest people get chances that are attenuated (figure).[78] It therefore superficially resembles

the proposal made by DALY advocates; however, the complete lives system justifies preference to younger people because of priority to the worst-off rather than instrumental value. Additionally, the complete lives system assumes that, although life-years are equally valuable to all, justice requires the fair distribution of them. Conversely, DALY allocation treats life-years given to elderly or disabled people as objectively less valuable.

Finally, the complete lives system is least vulnerable to corruption. Age can be established quickly and accurately from identity documents. Prognosis allocation encourages physicians to improve patients' health, unlike the perverse incentives to sicken patients or misrepresent health that the sickest-first allocation creates.[58,59]

Objections

We consider several important objections to the complete lives system.

The complete lives system discriminates against older people.[81,82] Age-based allocation is ageism.[82] Unlike allocation by sex or race, allocation by age is not invidious discrimination; every person lives through different life stages rather than being a single age.[8,39] Even if 25-year-olds receive priority over 65-year-olds, everyone who is 65 years now was previously 25 years.[16] Treating 65-year-olds differently because of stereotypes or falsehoods would be ageist; treating them differently because they have already had more life-years is not.

Age, like income, is a "non-medical criterion" inappropriate for allocation of medical resources.[14,83] In contrast to income, a complete life is a health outcome. Long-term survival and life expectancy at birth are key health-care outcome variables.[84] Delaying the age at onset of a disease is desirable.[85,86]

The complete lives system is insensitive to international differences in typical lifespan. Although broad consensus favours adolescents over very young infants, and young adults over the very elderly people, implementation can reasonably differ between, even within, nation-states.[87,88] Some people believe that a complete life is a universal limit founded in natural human capacities, which everyone should accept even without scarcity.[37] By contrast, the complete lives system requires only that citizens see a complete life, however defined, as an important good, and accept that fairness gives those short of a complete life stronger claims to scarce life-saving resources.

Principles must be ordered lexically: less important principles should come into play only when more important ones are fulfilled.[10] Rawls himself agreed that lexical priority was inappropriate when distributing specific resources in society, though appropriate for ordering the principles of basic social justice that shape the distribution of basic rights, opportunities, and income.[1] As an alternative, balancing priority to the worst-off against maximising benefits has won wide support in discussions of allocative local justice.[1,8,10] As Amartya Sen argues, justice "does not specify how much more is to be given to the deprived person, but merely that he should receive more".[89]

Accepting the complete lives system for health care as a whole would be premature. We must first reduce waste and increase spending.[81,90] The complete lives system explicitly rejects waste and corruption, such as multiple listing for transplantation. Although it may be applicable more generally, the complete lives system has been developed to justly allocate persistently scarce life-saving interventions.[39,80] Hearts for transplant and influenza vaccines, unlike money, cannot be replaced or diverted to non-health goals; denying a heart to one person makes it available to another. Ultimately, the complete lives system does not create "classes of *Untermenschen* whose lives and well being are deemed not worth spending money on",[91] but rather empowers us to decide fairly whom to save when genuine scarcity makes saving everyone impossible.

Legitimacy

As well as recognising morally relevant values, an allocation system must be legitimate. Legitimacy requires that people see the allocation system as just and accept actual allocations as fair. Consequently, allocation systems must be publicly understandable, accessible, and subject to public discussion and revision.[92] They must also resist corruption, since easy corruptibility undermines the public trust on which legitimacy depends. Some systems, like the UNOS points systems or QALY systems, may fail this test, because they are difficult to understand, easily corrupted, or closed to public revision. Systems that intentionally conceal their allocative principles to avoid public complaints might also fail the test.[93]

Although procedural fairness is necessary for legitimacy, it is unable to ensure the justice of allocation decisions on its own.[94,95] Although fair procedures are important, substantive, morally relevant values and principles are indispensable for just allocation.[96,97]

Conclusion

Ultimately, none of the eight simple principles recognise all morally relevant values, and some recognise irrelevant values. QALY and DALY multiprinciple systems neglect the importance of fair distribution. UNOS points systems attempt to address distributive justice, but recognise morally irrelevant values and are vulnerable to corruption. By contrast, the complete lives system combines four morally relevant principles: youngest-first, prognosis, lottery, and saving the most lives. In pandemic situations, it also allocates scarce interventions to people instrumental in realising these four principles. Importantly, it is not an algorithm, but a framework that expresses widely affirmed values: priority to the worst-off, maximising benefits, and treating people equally. To achieve a just allocation of scarce medical interventions, society must embrace the challenge of implementing a coherent multiprinciple framework rather than relying on simple principles or retreating to the status quo.

Conflict of interest statement
We delare that we have no conflict of interest.

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CORONAVIRUS

People With Intellectual Disabilities May Be Denied Lifesaving Care Under These Plans as Coronavirus Spreads

Disaster preparedness plans in Washington and Alabama say people with cognitive issues are a lower priority for lifesaving treatment. Disability advocacy organizations have asked the federal government to clarify the plans.

by Amy Silverman, Arizona Daily Star, March 27, 2020, 5 a.m. EDT

A medical assistant and nurse check paperwork during a drive-up COVID-19 screening in Seattle on March 17. (Karen Ducey/Getty Images)

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Advocates for people with intellectual disabilities are concerned that those with Down syndrome, cerebral palsy, autism and other such conditions will be denied access to lifesaving medical treatment as the COVID-19 outbreak spreads across the country.

Several disability advocacy organizations filed complaints this week with the civil rights division of the U.S. Department of Health and Human Services, asking the federal government to clarify provisions of the disaster preparedness plans for the states of Washington and Alabama.

The advocates say the plans discriminate against people with intellectual disabilities by deprioritizing this group in the event of rationing of medical care — specifically, access to ventilators, which are in high demand in treating COVID-19 cases. More than 7 million people in the U.S. have some form of cognitive disability.

Some state plans make clear that people with cognitive issues are a lower priority for lifesaving treatment. For instance, Alabama's plan says that "persons with severe mental retardation, advanced dementia or severe traumatic brain injury may be poor candidates for ventilator support." Another part says that "persons with severe or profound mental retardation, moderate to severe dementia, or catastrophic neurological complications such as persistent vegetative state are unlikely candidates for ventilator support."

Other plans include vague provisions, which advocates fear will be interpreted to the detriment of the intellectually disabled community. For instance, Arizona's emergency preparedness plan advises medical officials to "allocate resources to patients whose need is greater or whose prognosis is more likely to result in a positive outcome with limited resources." Between a person with cognitive difficulties and a person without them, who decides whose needs come first?

Medical triage always forces hard decisions about who lives and dies. For instance, older people with shorter life expectancy or those with severe dementia are often deemed less deserving of scarce medical resources than younger, healthier individuals. The state plans make clear that the fate of those with intellectual disabilities is part of the wrenching debate.

HHS officials said they were opposed to rationing care for people with any kind of disability.

“Persons with disabilities should not be put at the end of the line for health services based on stereotypes or discrimination, especially during emergencies. Our civil rights laws protect the equal dignity of every human being from ruthless utilitarianism,” said Roger Severino, the director of the agency’s civil rights office.

“What we’re seeing here is a clash between disability rights law and ruthless utilitarian logic,” said Ari Ne’eman, a visiting scholar at the Lurie Institute for Disability Policy at Brandeis University. “What this is really about at the end of the day is whether our civil rights laws still apply in a pandemic. I think that’s a pretty core question as to who we are as a country.”

Advocates and families of those with intellectual disabilities say their community is especially vulnerable to the disease because many of those with significant impairments live in group homes or other congregate settings.

It can sometimes be difficult for people with intellectual disabilities to understand the pandemic and its demands, such as the need to wear masks and heightened protocols for social distancing and hand-washing.

The death of Emily Wallace, a 67-year-old with Down syndrome in a group home in Georgia, was an early warning sign of the dangers facing the community, advocates say.

Wallace was a woman of firsts. She and her husband, Richard, were the first couple with intellectual disabilities to marry in the state. They were the first to live independently in their own home in Albany, a small town in the southwestern part of the state. In mid-March, Emily was the first person with an intellectual disability in her community — and possibly one of the first in the nation — to be diagnosed with COVID-19.

She was taken to a local hospital where she died alone.

“Mrs. Wallace is once again the first, but this isn’t what we wanted to celebrate,” said Stacey Ramirez, state director for The Arc of Georgia, a nonprofit advocacy group that serves people with intellectual disabilities.

Richard and Emily Wallace, shown in this photo from 2015, are believed to have been the first couple with intellectual disabilities to marry in Georgia. Both had Down syndrome. Emily died this month after contracting COVID-19. Richard died in 2018. (Courtesy of Albany Arc)

Emily and Richard Wallace were married for 18 years. A 1992 story in the Albany Herald depicted their life as happily domestic, mentioning that Richard hated to vacuum, while Emily didn't like to dust, and that she did most of the cooking while he raked the leaves. They made payments on their home and both held down jobs. After Richard, who also had Down syndrome, died in 2018 at 65, Emily moved to a group home operated by The Albany Arc.

After a caregiver apparently brought the coronavirus into the home, Wallace fell ill. So did another resident, who was hospitalized.

Emily Wallace had a do not resuscitate order, so a ventilator would not have been an issue even if care were being rationed, said DeAnna Julian, executive director of The Albany Arc.

But as more people are getting sick, Julian said she worries that not enough testing for the virus is being done in Albany. She's seeing individuals — both with and without intellectual disabilities — who appear to have mild symptoms of COVID-19.

"They're just turning them around and sending them home, they're putting them on" antibiotics, she said. "We live here in southwest Georgia where right now, all the cars are covered in yellow pollen and everyone has some kind of seasonal allergies. ... Is it just your springtime cold or is it COVID-19?"

Julian doesn't have masks, gloves or other safety equipment. She doesn't have enough staff.

“It’s a difficult and critical situation here,” she said.

But no, Julian said, she didn’t see Wallace or the other group home resident receive treatment any different than anyone else. She said she wouldn’t stand for it.

“I’d take it all the way to the top, to the governor! They have every right to be treated like human beings,” Julian said.

With the Americans with Disabilities Act celebrating its 30th birthday this year, activists are questioning whether policymaking has come far enough in what some consider to be the final battle in the fight for civil rights.

In a March 18 letter to Wisconsin Gov. Tony Evers, the Survival Coalition, a group of advocacy organizations, wrote, “‘Quality of life’ has long been a pretext for denying treatment, including life-sustaining treatment, to vulnerable populations, particularly people with intellectual disabilities.”

Michael Bérubé and his wife, Janet, live in State College, Pennsylvania, with their son Jamie, who is 28 and has Down syndrome. Bérubé, a professor of literature at Pennsylvania State University and the author, most recently, of the book “Life as Jamie Knows It,” studies disability. He was not surprised to learn about state rationing plans that single out people with intellectual disabilities and other cognitive conditions.

“It would be a very rare person who sees a person with Down syndrome as innately as valuable and as able to contribute to society as anybody else,” Bérubé said.

Pennsylvania is among those states now scrambling to write up guidelines to determine who will have access to ventilators in case of medical rationing, according to media reports.

“In two weeks, when the resources get truly stressed out, we’ll see how much of this draconian stuff goes into practice,” he said.

Hearing Entitled "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"
House Energy and Commerce Subcommittee on Health
2123 Rayburn House Office Building
February 1, 2023

Statement for the Record

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O'Neill Institute for National and Global Health Law
Georgetown University Law Center
Washington, DC

Introduction

Chairman Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, thank you for the opportunity to provide this statement for the record.

I am Regina LaBelle, and I currently direct the Addiction and Public Policy Initiative at the O'Neill Institute for National and Global Health Law at Georgetown Law Center. We use the law and policy to promote access to quality addiction treatment, harm reduction, and recovery support services. In addition, I direct Georgetown's Master of Science in Addiction Policy program, a unique program where we train future addiction policy professionals.

At the beginning of the Biden-Harris Administration in 2021, I was privileged to be appointed as the Acting Director of the White House Office of National Drug Control Policy (ONDCP). I oversaw the development of this Administration's first-year drug policy priorities.[1] I previously served as Chief of Staff at ONDCP during the Obama Administration.

Scope of the Overdose Crisis

In January, the Centers for Disease Control and Prevention (CDC) released data reporting that it projects over 107,000 deaths in the United States from drug overdoses during the 12-month period ending August 2022.[2] Although this figure represents a five-month levelling off from the peak estimated 12-month overdose death rate for the 12 months ending March 2022, it is still unacceptably high.

[1] EXECUTIVE OFFICE OF THE PRESIDENT, THE BIDEN-HARRIS ADMINISTRATION'S STATEMENT OF DRUG POLICY PRIORITIES FOR YEAR ONE (2021) (https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf).
[2] Centers for Disease Control and Prevention, National Center for Health Statistics. Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts (https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm).

CDC also reports that provisional data for 2021 show that most drug overdose deaths involved synthetic opioids, the drug class that includes fentanyl and fentanyl-related substances (FRS). Of the estimated 107,622 drug overdose deaths in 2021, an estimated 80,816 (75%) involved opioids, and an estimated 71,238 (66%) involved synthetic opioids.[3] It is obvious, then, that we need to address synthetic opioid use in order to reduce overdose deaths.

Addressing Substance Use

We know that substance use disorder is a chronic condition that requires a coordinated public health-based response. At the O'Neill Institute, we advocate for a public health approach to addressing substance use across the continuum of care. The continuum of care includes enhancing evidence-based prevention, improving harm reduction services to prevent risky substance use and reduce overdose deaths, increasing access to quality, evidence-based treatment by reducing barriers to treatment, and increasing access to recovery support services to sustain long-term recovery.

- Prevention – We need to enhance efforts to educate parents and schools about common warning signs indicating that an adolescent or young adult child may be struggling with a mental health condition. Untreated mental health conditions in young people can be a risk factor in engaging in problematic drug use at an early age.[4] Young people report that they can access illicitly manufactured fentanyl over social media platforms. Parents need to be ready to have open, honest, and difficult conversations with their children about the dangers of drugs found online or in other interactions and about their mental health. The Substance Abuse and Mental Health Services Administration (SAMHSA) gives parents helpful guidance on how to talk to their children about drugs.[5] There is still more that can be done to improve mental health supports in school districts nationwide.

- Treatment – Congress has dedicated considerable funding for treating people with substance use disorder, but quality treatment and coordinated funding are ongoing needs. In the context of opioid use disorder, we need to ensure that treatment providers are employing evidence-based treatment, including medications for opioid use disorder (MOUD). We applaud Congress for passing the Mainstreaming Addiction Treatment Act as part of the FY 2023 omnibus funding measure. This eliminates the "X-waiver" additional education requirements for providers who wish to prescribe MOUD that are not needed to prescribe other Controlled Substances Act (CSA) scheduled drugs.

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[3] Centers for Disease Control and Prevention, National Center for Health Statistics. U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15%, May 11, 2022 (https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm).

[4] Over 2 in 5 young adults with mental health disorders are untreated, and nearly 9 in 10 young adults with substance use disorders are untreated. Mental Illness and Substance Use in Young Adults, Substance Abuse and Mental Health Services Administration, September 22, 2022. (https://www.samhsa.gov/young-adults).

[5] Substance Abuse and Mental Health Services Administration, Why You Should Talk With Your Child About Alcohol and Other Drugs. (https://www.samhsa.gov/sites/default/files/talk-with-your-child-about-alcohol-drugs.pdf)

Eliminating the X-waiver, coupled with the Medication Access and Training Expansion (MATE) Act, will encourage more providers to screen and treat their patients with substance use disorder. In addition, by placing substance use treatment on par with treatment of other chronic diseases, it will help address the stigma that discourages people from seeking treatment for their substance use disorder.

Another critical area for intervention, both to reduce overdose deaths and strengthen communities, is through a greater focus on addressing substance use and mental health conditions in corrections. According to the Bureau of Justice Statistics, in 2019, suicide was the leading cause of death in jail. From 2000 to 2019, the rate of jail deaths due to drug or alcohol intoxication more than quadrupled.[6] Research we conducted at Georgetown's O'Neill Institute found that withdrawal-related deaths are preventable if correctional settings provide withdrawal management upon intake, as well as access to longer-term treatment. The Bureau of Justice Assistance used this research to develop a set of recommendations for preventing harms from unsupervised withdrawal in jails.[7] Lack of treatment during incarceration and a lack of community-based care places individuals leaving corrections and reentering their communities at increased risk of overdose and death. State and local prison officials need to be educated about the benefits of providing MOUD during incarceration, and they need to be provided resources to provide such treatment. We encourage Congress to modify SAMHSA's Substance Abuse Prevention and Treatment Block Grant program to remove restrictions that limit states' ability to provide substantive Block Grant funds to pay for treatment in prisons and jails.

- Recovery – Successful recovery involves deterring return to use by fostering social connections, community integration, and other recovery support services. There are numerous actions that impact successful recovery. More obviously, stigma towards people with substance use disorder can deter people from receiving necessary services. To prevent risky substance use and limit stigma's harmful impact, we must move to limit the stigmatization and treat addiction like any other chronic disease. In addition, we must improve environmental factors that help sustain successful recovery, such as removing barriers to housing, jobs, and education. And since many of those in recovery have limited personal resources, we must ensure opportunities are afforded to those who are just getting back on their feet.

<u>The "HALT Fentanyl Act"</u>

In 2021, during my tenure as ONDCP Acting Director, ONDCP, in conjunction with the Department of Health and Human Services (HHS) and the Department of Justice (DOJ),

[6] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Mortality in Local Jails, 2000–2019 – Statistical Tables, Dec. 2021. (https://bjs.ojp.gov/content/pub/pdf/mlj0019st.pdf)
[7] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance. Managing Substance Withdrawal in Jails: A Legal Brief. Feb. 2022. (https://bja.ojp.gov/doc/managing-substance-withdrawal-in-jails.pdf)

submitted recommendations to Congress for legislation to reduce the supply and availability of illicitly manufactured FRS, while protecting civil rights and reducing barriers to scientific research for all CSA Schedule I substances. This proposal included the following recommendations:

- Permanently place FRS into Schedule I of the CSA.
- Establish a simplified process that would align research registration for all Schedule I substances, including FRS, more closely with the research registration process for Schedule II substances.
- Exclude those FRS that are scheduled by class from all quantity-based mandatory minimum penalties (normally associated with domestic trafficking offenses of CSA Schedule I compounds).
- Create a streamlined process overseen by HHS to identify and remove or reschedule any individual FRS that is found to not have a high potential for abuse as defined in the CSA.
- Ensure that a federal court can vacate or reduce the sentence of an individual convicted of an offense involving an individual FRS that is subsequently removed or rescheduled from Schedule I.
- Direct the Government Accountability Office to analyze the implementation and impact of permanent class scheduling of FRS, including its impact on research, civil rights and the illicit manufacturing and trafficking of FRS.[8]

The "Halt All Lethal Trafficking of (HALT) Fentanyl Act" (Act), as introduced, only would address the first two recommendations.

We appreciate that the Act would make it easier for researchers to obtain access to and conduct work on Schedule I substances. The research community has long asserted that burdensome requirements placed on these substances has slowed ongoing research progress on them and sometimes has discouraged researchers from conducting research on them at all. The modifications proposed in the Act would ease the burden on researchers while ensuring appropriate safeguards of these substances by DOJ.

However, we are concerned that, without the civil rights protections contained in the Administration's proposal, judges are robbed of their discretion to impose appropriate sentences based on the facts of the individual case. Imposing harsh sentences on people with substance use

[8] Office of National Drug Control Policy, Biden-Harris Administration Provides Recommendations to Congress on Reducing Illicit Fentanyl-Related Substances, Sept. 2, 2021. (https://www.whitehouse.gov/ondcp/briefing-room/2021/09/02/biden-harris-administration-provides-recommendations-to-congress-on-reducing-illicit-fentanyl-related-substances/)

disorder who have been convicted under statutes involving Schedule I substances due to circumstances, where the activities were conducted to address their addiction, only serves to further stigmatize these people because of their illness. Similarly, to permanently schedule the class of FRS into CSA Schedule I without providing a mechanism to deal with those substances that are subsequently found to not have a high potential for abuse subverts the intent of the statute and violates basic principles of justice.

Closing

Action to expand the ability for researchers to work on CSA Schedule I substances is laudable and would create greater opportunities for scientific discoveries, possibly helping to address the overdose crisis itself; however, the Subcommittee should take a more holistic approach to legislation that attempts to address the issue, particularly as the temporary scheduling order is in effect until the end of the 118th Congress. This is especially important as new synthetic substances are being identified in the nation's drug supply, and these new synthetic opioids may not fall into any definition of FRS.

Permanent scheduling is not enough. Federal law enforcement representatives contend that temporary scheduling action has helped to reduce the proliferation of new types of fentanyl analogs;[9] however, if that were enough, we would not be experiencing the increases in overdose deaths since the DOJ's temporary scheduling action in February 2018. We hope the Subcommittee continues to work with the Administration and interested constituent groups like the O'Neill Institute on solutions to end the tragedy of overdoses related to illicit drug use.

Thank you for the opportunity to provide this statement for the record.

[9] *See* Government Accountability Office, *Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substance*s, GAO-21-499, April 2021. (https://www.gao.gov/assets/gao-21-499.pdf)

March 8, 2017

To Members of the U.S. Senate and House of Representatives:

On behalf of the National Down Syndrome Society, the leading human rights organization for all individuals with Down syndrome, I am writing to express the views of our organization on Budget Reconciliation legislative recommendations relating to the repeal and replacement of the Affordable Care Act (ACA). As you know, vital provisions contained in the ACA and Medicaid continue to be critical to people with Down syndrome. NDSS supports several provisions in ACA - such as an expansion of health coverage reforms to the insurance market, nondiscrimination provisions, and long-term services and supports – that are important to the ability of people with Down syndrome to live healthy, independent and fulfilling lives.

As this legislation is considered in the coming weeks, we urge legislators to work in a bipartisan manner to: 1) continue to address and strengthen the ACA priorities outlined below; 2) enact additional reforms to promote independence and self-determination for individuals with Down syndrome and other disabilities; and 3) protect and preserve Medicaid's current funding structure by removing from the legislation provisions to convert Medicaid to a block grant system and establish a per capita spending cap for the disability community.

Existing ACA Policies Benefiting All Individuals with Down Syndrome

The following are policies in existing law that are critical to people with Down syndrome, and NDSS urges the Administration and Congress to sustain or enhance them:

Maintain dependent coverage: People with Down syndrome follow a longer transition period going from youth to adulthood. Their vocational, domestic, and social and personal skills take longer to develop, and the responsibilities of identifying, locating and coordinating appropriate health care resources and services for the complex medical conditions facing young adults with Down syndrome fall primarily on their families. Allowing individuals with Down syndrome to stay on their parents' private health insurance plan until age 26 is essential to their ability to achieve independence and community integration.

Guarantee availability and renewal: All individuals with Down syndrome have pre-existing and co-occurring medical conditions that could undermine access to universal and continuous health insurance coverage. These includes cognitive impairment, congenital heart defects, leukemia, obstructive sleep apnea, seizure disorders, neurobehavioral problems, pulmonary hypertension, thyroid diseases, celiac disease, gastrointestinal defects, Type 1 diabetes, immune system dysfunction, metabolic dysfunction and mental health disorders, to name a few. As a result of the ACA's prohibition on exclusions for pre-existing conditions, combined with guaranteed renewability

of coverage, individuals with Down syndrome now have access to affordable private health insurance coverage.

Ensure affordable access to habilitative and preventative services: Since the implementation of the ACA, developmental screening is now a covered preventive service for children. In addition, non-grandfathered health plans in the individual and small-group markets are required to cover rehabilitative and habilitative services and devices. This is particularly important for individuals with Down syndrome, who typically face delays in basic physical, cognitive, language, social and self-help skills. Their having access to early intervention and habilitative services is critical for achieving optimal health outcomes, improving skills and functioning for daily living, and becoming active and productive participants in their communities.

Maintain the Community First Choice State Plan Option: This program expands Medicaid opportunities for the provision of home and community-based long-term services and supports (LTSS), and facilitates community integration. Many people with Down syndrome are not in the labor force and lack access to employer sponsored health insurance. Many others are employed but have grandfathered private insurance plans that do not cover many disability related therapies and services. Without access to LTSS, individuals with Down syndrome will be denied opportunities to work in meaningful and competitive employment settings.

Prohibit annual and lifetime caps in private insurance policies: The ACA prohibits health plan and insurance policies from imposing annual and lifetime dollar limits on total benefits the amount of coverage an individual may receive. According to the National Institutes of Health, at least one-half of all children with Down syndrome also have co-occurring conditions that contribute to their medical complexity. Limits on benefits would prevent people with Down syndrome from obtaining needed, but costly, surgeries, therapies, medical equipment and prescription drugs.

In addition to continuing certain provisions of current law, NDSS urges the Administration and Congress to support additional reforms that can improve the health and wellbeing of individuals with Down syndrome in a cost-effective way. Such reforms include:

Enact the Advancing Care for Exceptional (ACE) Kids Act: Because their complex medical conditions can be costly, many children with Down syndrome depend on state-based Medicaid programs. They also require specialized care in centers of excellence, often times outside of their state. Unfortunately, current Medicaid rules can limit access to coordinated care and restrict options to receive medical treatment by out-of-state specialists. The ACE Kids Act is legislation to create a mechanism for states to participate in a national framework for children with medical complexities to receive cost-effective and coordinated health care and support. This framework could significantly reduce the necessity for more extensive medical interventions later in life, thus improving the long-term financial viability of the Medicaid program.

Incentivize productivity and work: The current eligibility framework for Medicaid penalizes work and employment for individuals with Down syndrome. Future reforms should incorporate changes that improve opportunities for people with Down syndrome and other disabilities to obtain integrated employment and reduce their relegation to subminimum wages and segregated environments. Medicaid reforms should include incentives for states to meeting certain benchmarks for expanding employment opportunities for people with Down syndrome and other disabilities within the state,

and offer cost-effective supports and services that promote self-determination, independence, productivity, and integration and inclusion.

Address lifespan needs: Due to advances in medical technology, individuals with Down syndrome are living longer than ever before. Today, as many as 80 percent of adults with Down syndrome reach the age of 60, and many live even longer. This necessitates access to affordable health care and long-term services and supports throughout an increased lifespan. Efforts to reform the Medicaid program should seek to address the gaps and barriers to health care that prevent individuals with Down syndrome from experience a high quality of life as they transition from childhood to working adult to senior citizen. This includes access to wellness and prevention services, health and health disparities research, patient-centered care models, and increased professional training for health care providers.

How Block Granting Medicaid Funding and Per Capita Payment Caps Could Impact People with Down Syndrome

Medicaid is vitally important for people with Down syndrome who generally do not have access to employer-based or other private coverage. Moreover, people with Down syndrome can have significant medical needs, and often require assistance with activities of daily living throughout their lives. In addition, Medicaid is a program that reaches far beyond the scope of healthcare for individuals with Down syndrome. It encourages people with Down syndrome to live and work in their communities, develop assets that reduce dependence on public benefits, and avoid costly and segregated nursing homes or institutions. For example, through Medicaid Long-Term Services and Supports (LTSS), people with Down syndrome can also receive employment supports that enable them to both attain and maintain gainful employment. Home and community-based services (HCBS) also provide opportunities for Medicaid beneficiaries to receive services in their own home or community rather than institutions or isolated settings.

Specifically, proposals that provide for block grants and per capita payment caps, including those that fund high-risk pools, must account for the many combinations of complicated health care needs that people with Down syndrome will face throughout their lifespan. According to the National Institutes of Health (NIH), at least one-half of all people with Down syndrome also have co-occurring conditions that contribute to their medical complexity. For example, approximate half of all children with Down syndrome are born with congenital heart disease. A person with Down syndrome may also be defined as a person with a disability, a person with cancer, and a person with Autism, and a person with Alzheimer's disease. ***Therefore, unless calibrated correctly, block grants and per capita spending caps – even those that establish high-risk pools, define subpopulations and/or set fixed amounts – could be complex, arbitrary, and detrimental to people with Down syndrome, many of whom would not fit neatly into one category of complexity or subpopulation.***

In closing, NDSS supports constructive federal health care reforms that promote home and community-based services, improve the coordination of care and services due resulting from medical complexities and facilitate economic independence for people with Down syndrome. As Congress considers reforms to the ACA and Medicaid, we urge you to fully address the health needs, access to care and vast scope of services (i.e., housing, job supports, and employment) that programs like Medicaid offer to all individuals with Down syndrome.

We, at NDSS, continue to appreciate the opportunity to work with you to work with you to fashion health care reforms that improve health outcomes and increase access to quality care, while also promoting independence and self-determination for individuals with Down syndrome.

Thank you for all you do for individuals with Down syndrome and their families!

Sincerely,

Sara Hart Weir, MS
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NOVEMBER 2022

QUICK TAKE

ILLICITLY MANUFACTURED FENTANYL AS A WEAPON OF MASS DESTRUCTION: RHETORIC AND REALITY

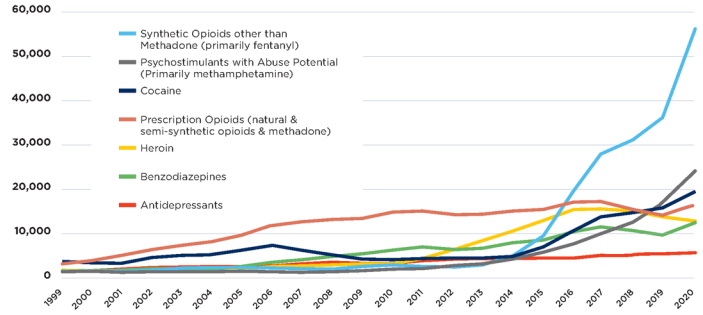
RECENTLY, MEMBERS OF CONGRESS[1] AND EIGHTEEN STATE AND TERRITORY ATTORNEYS GENERAL[2] have called for action that would require the federal government to treat illicitly manufactured fentanyl as a "weapon of mass destruction (WMD)." The letter from the attorneys general called for an "unorthodox" response to illicitly manufactured fentanyl, fearing that it could be used as a weapon against Americans.

Tragically, synthetic opioids, primarily illicitly manufactured fentanyl, were involved in over 71,000 overdose deaths in 2021.[3] Americans need a smart, long-term, and aggressive response to save lives and dramatically reduce the damage that illicitly manufactured fentanyl does to our communities, families, and loved ones. While classifying illicitly manufactured fentanyl as a weapon of mass destruction has some intuitive and emotional appeal, it is ultimately counterproductive in efforts to stem overdose deaths.

WHILE CLASSIFYING ILLICITLY MANUFACTURED FENTANYL AS A WEAPON OF MASS DESTRUCTION HAS SOME INTUITIVE AND EMOTIONAL APPEAL, IT IS ULTIMATELY COUNTERPRODUCTIVE IN EFFORTS TO STEM OVERDOSE DEATHS.

NATIONAL DRUG-INVOLVED OVERDOSE DEATHS*

NUMBER AMONG ALL AGES, 1999-2020



*Includes deaths with underlying causes of unintentional; drug poisoning (X40-X44), suicide drug poisoning (X60-X64), homicide drug poisoning (X85), or drug poisoning of undermined intent (Y10-Y14), as coded in the international Classification of Disease, 10th Revision.

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, release 12/2021.

A WEAPON OF MASS DESTRUCTION IS CURRENTLY DEFINED AS A CHEMICAL, BIOLOGICAL, OR RADIOACTIVE AGENT OR ANY EXPLOSIVE OR GAS THAT IS DESIGNED TO INJURE OR KILL A LARGE NUMBER OF PEOPLE.

WHAT WOULD IT MEAN TO CLASSIFY ILLICITLY MANUFACTURED FENTANYL AS A WEAPON OF MASS DESTRUCTION?

Proposed Congressional legislation would require the Department of Homeland Security (DHS) to treat illicitly manufactured fentanyl as a weapon of mass destruction under 6 U.S.C. § 590 et seq. A weapon of mass destruction is currently defined as a chemical, biological, or radioactive agent or any explosive or gas that is designed to injure or kill a large number of people. See 50 U.S.C. § 1801.

The legislation would require the Department of Homeland Security's Countering Weapons of Mass Destruction Office to spend resources combatting illicitly manufactured fentanyl. This Office's responsibilities, as laid out in 6 U.S.C. § 592, are nearly all related to the prevention of a nuclear attack on the United States. The legislation does not appropriate new financial resources to tackle the overdose epidemic, nor does it provide the government any additional regulatory tools that could help combat the crisis.

WHY DECLARING ILLICIT FENTANYL A "WEAPON OF MASS DESTRUCTION" IS A MISTAKE.

We must use every available and effective tool to combat the overdose epidemic. This legislation will not get us closer to ending the overdose epidemic for several reasons.

Declaring Illicitly Manufactured Fentanyl a WMD Distracts from DHS's Countering Weapons of Mass Destruction Office's Mission of Preventing a Nuclear Attack

First, it dangerously expands, and potentially distracts from, the mission of one of the most critically important offices in the government. DHS's Countering Weapons of Mass Destruction Office is nearly solely focused on preventing a nuclear, biological, or chemical attack on our country and American nationals around the world. To add a new mission to this office, without providing additional resources or expertise, could take crucial staff away from their fulltime duties protecting our nation from a devastating nuclear attack. With nuclear aggression from Russia and North Korea, now is not the time to fundamentally restructure this office. Additionally, while this office has expertise in preventing a nuclear, biological, or chemical attack, it does not currently have expertise in how to respond to the overdose epidemic—a medical, public health, and criminal justice issue. Many instruments of the federal government, including different divisions of DHS, are currently coordinating on the response to illicitly manufactured fentanyl.

Declaring Illicitly Manufactured Fentanyl a WMD would duplicate and needlessly increase punitive and ineffective criminal consequences for people who use drugs

Defining illicitly manufactured fentanyl as a weapon of mass destruction could also have unnecessarily punitive, and ultimately ineffective, criminal consequences. Federal criminal law prohibits the use or attempted use of a weapon of mass destruction "against any person or property within the United States" in any way that affects interstate commerce, or in the case of an attempt, any way that would have affected interstate commerce. 18 U.S.C. § 2332a(a)(2).[4] The statute goes on to impose a maximum sentence of life in prison for violation of the weapons of mass destruction statute, and, if death results, permits bringing the death penalty. This punishment is duplicative of other federal statutes[5] in addition to being disproportionate[6] and overbroad. Studies have shown no relationship between increased punishment and lower rates of problematic drug use, while costing the United

COUNTERING WEAPONS OF MASS DESTRUCTION OFFICE

Mission Statement: The [Countering Weapons of Mass Destruction] Office shall be responsible for coordinating Federal efforts to detect and protect against the unauthorized importation, possession, storage, transportation, development, or use of a nuclear explosive device, fissile material, or radiological material in the United States, and to protect against attack using such devices or materials against the people, territory, or interests of the United States" 6 U.S.C. § 592(a).

A PUBLIC HEALTH APPROACH TO REDUCING ILLICITLY MANUFACTURED FENTANYL USE.

Instead of declaring illicitly manufactured fentanyl a weapon of mass destruction, we need to boost evidence-based resources to combat overdose deaths. This can be accomplished by taking a public health approach to substance use across the continuum of care. The continuum of care includes enhancing evidence-based prevention, improving harm reduction services to prevent risky substance use and reduce overdose deaths, increasing access to quality, evidence-based treatment by reducing barriers to treatment, and increasing access to recovery support services to sustain long-term recovery.

In addition, the federal government should undertake efforts to educate parents about common warning signs indicating that their adolescent or young adult child may be struggling with a mental health condition. Untreated mental health conditions in young people can be a risk factor in engaging in problematic drug use at an early age.[15] Young people report that they can access illicitly manufactured fentanyl over social media platforms forms like Snapchat. Parents need to be ready to have open, honest, and difficult conversations with their children about the dangers of drugs found online. Parents should read SAMHSA's guidance on how to talk to their children about drugs here: https://www.samhsa.gov/talk-they-hear-you/parent-resources/why-you-should-talk-your-child.

States over $1 trillion since 1971.[7] Applying this statute to illicitly manufactured fentanyl could impose a life sentence on any person who uses drugs laced with illicitly manufactured fentanyl, or anyone who gives drugs laced with illicitly manufactured fentanyl to their friend. It could also impose the death penalty on someone who gives their friend drugs laced with illicitly manufactured fentanyl, and the friend dies of an overdose.[8] Sadly, illicitly manufactured fentanyl and other synthetic opiates are remarkably common in the drugs circulating the country today, killing over 71,000 people in 2021.[9] Illicitly manufactured fentanyl is found not just in heroin, but also in cocaine, methamphetamine, and MDMA, among other drugs.[10]

Existing Law and Regulations Allow Appropriate Action Against Weaponized Fentanyl

The state attorneys general's letter to President Biden requesting that he declare illicitly manufactured fentanyl a weapon of mass destruction points to one example of Russia using carfentanil (a derivative of fentanyl) in a counterterrorism operation that ended up killing over 100 people.[11] While tragic, this is the sole known example of fentanyl being used as a weapon of war. Devising an entire strategy on one incident isn't good policymaking. **Further, to the extent that it could be used as a chemical weapon again in the future, both current domestic law[12] and the Chemical Weapons Convention authorizes appropriate action to be taken.[13]**

Increasing rates of overdose death are a national tragedy and frustration and anger at the deaths are justified, however the weapon of mass destruction designation for illicitly manufactured fentanyl is not a solution. Neither the attorneys general nor the members of Congress in favor of this action have pointed to new, effective government resources that would result from this action. As discussed above, the proposed legislation would expand and distract from the mission of a critical national security office within DHS. Large amounts of illicitly manufactured fentanyl have already been seized by agencies like DOJ through existing resources.[14] Continued strategic law enforcement activity is necessary to reduce the flow of illicitly manufactured fentanyl around the country. However, this specific intervention does not address shortcomings in our response to the crisis, risks bureaucratic confusion in some of the most important offices in government, and needlessly punishes people struggling with a substance use disorder. We need a robust, evidence-based public health response to the overdose crisis.

INCREASING RATES OF OVERDOSE DEATH ARE A NATIONAL TRAGEDY. HOWEVER, THE WEAPON OF MASS DESTRUCTION DESIGNATION FOR ILLICITLY MANUFACTURED FENTANYL IS NOT A SOLUTION.

ENDNOTES

1 Fentanyl is a WMD Act, H.R. 8030, 117th Cong. § 2 (2022).

2 Letter from Eighteen Attorneys General to President Joseph R. Biden (Sept. 14, 2022), http://myfloridalegal.com/webfiles.nsf/WF/GPEY-CJ9SJ9/$file/Multistate+WMD+Policy+Letter_9.15.22_18+AGs.pdf.

3 Press Release, Centers for Disease Control and Prevention, *U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020—But Are Still Up 15%* (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

4 If this statute were applied to illicitly manufactured fentanyl, federal courts would likely find that use of illicitly manufactured fentanyl substantially affects interstate commerce. *Gonzales v. Raich*, 545 U.S. 1, 18, 25 (2005) (holding that marijuana is "a fungible commodity for which there is an established, albeit illegal, interstate market" and that this economic activity substantially affects interstate commerce sufficient to justify Congressional regulation under the Commerce Clause).

5 *See* 21 U.S.C. § 844 (prohibiting use of illicitly manufactured fentanyl and imposing a maximum one year sentence, which could be enhanced with prior convictions); 21 U.S.C. § 841(a)(1) (prohibiting possession with the intent to distribute or distribution of illicitly manufactured fentanyl, with a twenty year maximum sentence).

6 The Supreme Court has left very little room for vacating a non-death penalty sentence on proportionality grounds under the Eighth Amendment. *See, e.g., Harmelin v. Michigan*, 501 U.S. 957, 996 (1991) (upholding a mandatory life sentence without possibility of parole for someone convicted of possessing 672 grams of cocaine); *but see Graham v. Florida*, 560 U.S. 48, 82 (2010) (holding that the Constitution prohibits life sentence without parole for juveniles convicted of non-homicide offenses).

7 Adam Gelb, et al., *More Imprisonment Does Not Reduce State Drug Problems*, Pew Charitable Trusts (Mar. 8, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems; Nathaniel Lee, *American has spent over a trillion dollars fighting the war on drugs*, CNBC (June 17, 2021), https://www.cnbc.com/2021/06/17/the-us-has-spent-over-a-trillion-dollars-fighting-war-on-drugs.html.

8 The Supreme Court has held that major participation in a felony "combined with reckless indifference to human life" can amount to sufficient culpability for a death sentence in the context of felony murder, even where the defendant did not intend to murder the victim and the defendant did not strike the fatal blow. *Tison v. Arizona*, 481 U.S. 137, 158 (1987).

9 Press Release, Centers for Disease Control and Prevention, *U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020—But Are Still Up 15%* (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

10 *Fentanyl*, National Institute on Drug Abuse (June 2021), https://nida.nih.gov/publications/drugfacts/fentanyl.

11 Letter from Eighteen Attorneys General to President Joseph R. Biden (Sept. 14, 2022), http://myfloridalegal.com/webfiles.nsf/WF/GPEY-CJ9SJ9/$file/Multistate+WMD+Policy+Letter_9.15.22_18+AGs.pdf.

12 Defining a weapon of mass destruction "*any* weapon that is designed, intended, or has the capability to cause death or serious bodily injury to a significant number of persons through the release, dissemination, or impact of toxic or poisonous chemicals or their precursors." 50 U.S.C. § 1801(p)(1) (emphasis added). A weaponized version of fentanyl that proves toxic or poisonous fits neatly under this definition. Cf. Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 21 C.F.R. 1310 (2020) (federal rule classifying precursor chemicals to illicitly manufactured fentanyl as List I Chemicals).

13 *See* John P. Caves, Jr., *Fentanyl as a Chemical Weapon*, Center for the Study of Weapons of Mass Destruction (Dec. 2019), https://wmdcenter.ndu.edu/Portals/97/CSWMD%20Proceedings%20Dec%202019.pdf.

14 Press Release, Department of Justice, *Department of Justice Announces Results of Enforcement Surge to Reduce the Fentanyl Supply Across the United States* (Sept. 27, 2022), https://www.justice.gov/opa/pr/department-justice-announces-results-enforcement-surge-reduce-fentanyl-supply-across-united#:~:text=As%20part%20of%20the%20One,through%20Sept.%208%2C%202022.

15 Over 2 in 5 young adults with mental health disorders are untreated and nearly 9 in 10 young adults with substance use disorders are untreated. *Mental Illness and Substance Use in Young Adults*, Substance Abuse and Mental Health Services Administration (Sept. 22, 2022), https://www.samhsa.gov/young-adults.

O'NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW
GEORGETOWN LAW

NOVEMBER 2022

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https://oneill.law.georgetown.edu/initiatives/addiction-public-policy

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White House Office of National Drug Control Policy
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

Dear Mr. Chester:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 1, 2023, to testify at the hearing entitled "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, March 8, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

[Mr. Chester did not answer submitted questions for the record by the time of publication. Replies received after publication will be retained in committee files and made available at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=115361.]

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment 1—Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

1. According to the Government Accountability Office (GAO), the 2022 Office of National Drug Control Policy's National Drug Control Strategy does not comply with certain statutory requirements. For example, the Strategy is required to contain a systematic plan for increasing data collection, including to enable real time surveillance of drug control threats. However, as of December 2022, ONDCP has not created such a plan. What is the timeline ONDCP has established for creating and implementing this plan?

2. What percent of ONDCP staff work in person five days per week? What percentage of meetings are held virtually versus in-person?

The Honorable Greg Pence

The opioid and Fentanyl crisis is having a devastating impact on families across my district. State and local law enforcement agencies in Indiana's Sixth Congressional District are on the front lines, and they consistently communicate to me that they are overwhelmed by the illicit drugs flooding our community. According to the CDC, "there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before." Our state and local partners need more resources to combat the ruthless cartels that are trafficking illicit drugs across our southern border and killing family members, friends, and neighbors in our communities.

1. How can federal law enforcement agencies, such as the DEA, leverage their resources to more closely coordinate with local law enforcement agencies to increase the detection and prevention of illicit drugs in Hoosier communities?

We know these violent cartel criminals are intentionally altering the chemical structure of prescription-grade Fentanyl to create synthetic opioids with the intention to evade federal law enforcement.

2. How do you think drug traffickers weigh the legal risks of using specific synthetic Fentanyl analogues and how can our federal law enforcement agencies best hold these criminals accountable for their actions?

The Honorable Dan Crenshaw

1. How would ONDCP respond to proposals of an expedited approval process for fentanyl-related treatments/Opioid Use Disorder treatments given the enormity of the fentanyl problem?

    - For context--One of the concerns is legislative language that deems any fentanyl-related substance Schedule 1. The DEA passed an edict a few years back designating anything that looked like fentanyl to be a Schedule 1 substance although fentanyl itself is Schedule II. What we don't want is unnecessary restraint in the ability to conduct research and develop therapeutics (or the potential fentanyl vaccine). For example, there is ample evidence that research on hapten, a fentanyl-like molecule, has no biological activity related to fentanyl-induced effects (e.g. analgesia). The hapten, in simple terms, is the "backbone" of the fentanyl molecule that is also common to fentanyl derivatives. How would the designation apply to fentanyl type molecules.

2. How important is additional funding for future fentanyl-related research to the work being done by ONDCP; and, if appropriated, how would they prioritize directing that funding?

The Honorable Frank Pallone, Jr.

1. We on this subcommittee remain committed to addressing the opioid crisis. Illicit fentanyl and fentanyl-related substances remain a critical threat to the public health and safety of our country. According to the CDC, over 150 people continue to die daily from fentanyl overdoses. A refresher on some of the nuances of fentanyl would be helpful. Can you briefly remind us of the differences between Fentanyl, Fentanyl-Related Substances (FRS), and Fentanyl analogues?

2. Does the proposal to permanently schedule FRS change the current classification of fentanyl if used and regulated for medical purposes?

3. How many FRS have we encountered? Does chemical structure alone determine the pharmacological effect of an FRS?

4. Are the rates of fentanyl-related deaths continuing to increase?

5. Research and evidence-based approaches are a key component of the president's proposal on how to address FRS. In order to conduct quality research, investigators need access to fentanyl analogues as they might be useful in enhancing current treatments or developing new ones. A key component of the Administration's proposal involves how FRS are classified or subsequently reclassified if found to have a lower-risk profile. Can you explain the importance of the provision for "off-ramping" an FRS?

6. How would off-ramping assist researchers and science?

7. What is your understanding of how the current administration's proposal differs from the HALT Fentanyl approach?

8. How did the Administration consult with external stakeholders and what was their response to the Administration's proposal?

9. How does the administration proposal change mandatory minimum penalties for offenses involving fentanyl-related substances?

10. To your knowledge, how many Schedule I fentanyl-related substance trafficking offenses have been pursued since the temporary scheduling order has been in place?

11. Can you describe novel approaches in Dr. Gupta's inaugural National Drug Control Strategy and why it is critical to maintain robust resources for these activities?

12. The Biden Administration's proposal to address FRS exempts those charged with an FRS offense from quantity-based mandatory minimum penalties, unless the offense results in death or serious bodily injury. Is there any indication that permanent scheduling of FRS, with exemptions for quantity-based mandatory minimums, will lead to an increase in new FRS being created?

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

Honorable Cathy McMorris Rodgers

1. Congress relies on agencies such as SAMHSA to collect relevant data to inform our oversight efforts and policy making. What data does SAMHSA collect with regard to mental health conditions in the pediatric population?

SAMHSA collects data through our grant programs and SAMHSA's Center for Behavioral Health Statistics Quality (CBHSQ), which is the lead Federal government agency for behavioral health data and research. CBHSQ issues reports such as "Mental Health Annual Report 2015–2020 Use of Mental Health Services: National Client-Level Data" which is a compilation of the demographic, clinical, and outcome data of individuals served by the state mental health agencies (SMHAs) within a state-defined 12-month reporting period.[1] SAMHSA's CBHSQ also collects and reports data in the Uniform Reporting System for the pediatric population. SMHAs report annual data as part of their application package for SAMHSA's Community Mental Health Services Block Grant. State reports on how many clients they have served include information about children and adolescents (aged 17 and younger). Data collected for youth include: sociodemographic characteristics of clients served, outcomes of care, use of selected evidence-based practices, client assessment of care, insurance status, living situation, and readmission to state psychiatric hospitals within 30 and 180 days.[2] Additionally, as part of the National Survey on Drug Use and Health (NSDUH), SAMHSA collects information regarding major depressive episodes (MDEs) in adolescents aged 12 to 17, including whether reported MDEs severely impaired adolescents' lives. Finally, SAMHSA collects ICD-10 mental health diagnoses for children that are reported through the Government Performance and Results Act (GPRA) for SAMHSA's Center for Mental Health Services and Center for Substance Abuse Treatment non-formula-based grant programs.

Grant Programs

SAMHSA grantees are required to collect and report GPRA data. Categories of data collected from grantees include training, mental health awareness, organizational changes, outreach, partnerships, referrals, screening, access to services, and workforce development. SAMHSA's Center for Mental Health Services (CMHS) grantees comply with GPRA requirements by providing National Outcome Measures, which is client-level data collected by grantees by interviewing their clients and reporting on their behavioral health diagnosis, demographics, functioning, employment, education, housing, and measures specific to the grant program. In addition, CMHS grantees, with the goal of improving the infrastructure of mental health prevention, services and promotion, collect quantitative data on each infrastructure development, prevention and mental health promotion (IPP) indicators as assigned in the grant's Notice of Funding Opportunity or Notice of Award. IPP data is collected quarterly and includes a short narrative description of the results achieved.

Child-serving grant programs that collect both National Outcomes Measures and IPP data include Certified Community Behavioral Health Centers Expansion, Clinical High-Risk for

[1] https://www.samhsa.gov/data/sites/default/files/reports/rpt38666/2020_MH-CLD%20Annual%20Report-508%20compliant_10212022_final.pdf

[2] Link for 2021 data https://www.samhsa.gov/data/report/2021-uniform-reporting-system-urs-output-tables

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

Psychosis, Healthy Transitions, Children's Mental Health Initiative (CHMI), and National Child Traumatic Stress Initiative Category III, Community Treatment and Service Centers. Child-serving grant programs that collect IPP data include Project Advancing Wellness and Resiliency in Education (AWARE), Project Linking Actions for Unmet Needs in Children's Health (LAUNCH), Resiliency in Communities After Stress and Trauma (ReCAST), Trauma-Informed Services in Schools, Circles of Care, Mental Health Awareness Training, Garrett Lee Smith Campus Suicide Prevention, Garrett Lee Smith State/Tribal Suicide Prevention, Tribal Behavioral Health/Native Connections, and Infant and Early Childhood Mental Health Consultation.

2. Among children with mental health conditions, many have co-occurring developmental or other conditions that exacerbate and complicate providing them with the best care. What gaps does SAMHSA see with regard to children with co-occurring conditions?

Youth and young adults with co-occurring conditions need treatment that addresses the whole person. Such person-centered services may include psychosocial interventions, family behavioral therapy, medication, proactive outreach, and use of specialized applications that can assist or provide an intervention and track symptoms. Youth and young adults experiencing co-occurring conditions commonly face difficulties accessing integrated services or specialty care designed to assess and treat their needs. This is due to a lack of access to health insurance or adequate insurance benefits; provider shortages and/or narrow provider networks; fragmented or uncoordinated care, especially for youth and young adults in foster, juvenile justice, or residential settings, or those experiencing homelessness; limited cross training and education for mental health and substance use professionals; separate and geographically distinct Serious Emotional Disturbance (SED) / Serious Mental Illness (SMI) and Substance Use Disorder (SUD) treatment systems; and different and separate financing and reimbursement policies for each treatment option. Additionally, there are challenges in finding appropriate places of care for children and youth with neurodevelopmental disorders and mental health disorders. These children and youth need higher levels of care, but due to system challenges, including workforce shortages and cross training of specialty services, these children and youth often end up experiencing the longest emergency department boarding times.

However, progress has been made. There has been increased integration of effective and evidence based behavioral health services in primary care and school settings, where youth access treatment and clinical services most often; greater access to telehealth services; and expanded capacity to identify and treat co-occurring issues through more educational training. Implementation of systematic and integrated approaches for this population are critical to increasing the availability of, and access to, services. The following SAMHSA grant programs include a focus on youth and young adults with co-occurring conditions and have helped ameliorate some of the gaps: The Infant and Early Childhood Mental Health program (IECMH), CHMI, the Mental Health Block Grant, the Family Support Technical Assistance Center, and the Statewide Family Network.

3. What programs and resources are available to working families struggling to navigate complex systems to get help for children with mental health conditions (beyond an online

treatment finder, families need help understanding different types of care, what's available, how to access, how to partner with providers in treatment planning, understanding MH conditions, etc.)?

FindTreatment.gov provides information on location, treatment options, payment and insurance information, and access to over 13,000 state-licensed facilities. A redesigned and improved FindTreatment.gov was launched earlier this year by SAMHSA. FindTreatment.gov uses age-based filters to search for mental health services for the pediatric population aged 17 and under. Additionally, SAMHSA administers several grant programs that assist working families in navigating complex systems to help their children with mental health conditions. Examples include: the Statewide Family Network, ReCAST, the Family Support Technical Assistance Center, Project AWARE, Project LAUNCH, the Children's Mental Health Initiative, and the Clinical High Risk for Psychosis programs.

4. What percent of SAMHSA staff work in person five days per week? What percentage of meetings are held virtually versus in-person?

Right now, SAMHSA employees are working onsite, remotely, and on official travel. Our employee responsibilities and roles at SAMHSA vary with regard to whether they must be in person or remote to be able to do their work. Our employees who need to be in person to do their work, are, while those who can do their jobs remotely are generally allowed the flexibility to do so. While COVID-19 is no longer a determining factor for how we do our work, the pandemic has forever changed both the public and private sectors' approaches to the way work is done.

The Honorable Michael Burgess

1. How does SAMHSA currently deal with cybersecurity threats?

SAMHSA takes several approaches to deal with cybersecurity threats. This includes: (1) establishment of a cybersecurity program that is reviewed annually; (2) deployment of solutions to detect, prevent and respond to cyber threats; (3) conducting risk assessments; (4) use of National Institute of Standards and Technology (NIST) Cybersecurity Framework and other cybersecurity frameworks; (5) establishment of secure baselines for SAMHSA systems, in alignment with OMB Memorandum M-22-09, that allows for architecting toward a Zero Trust model; (6) regularly conducting risk assessments; (7) following HHS and NIST data-protection guidance; (8) regularly monitoring and auditing networks to detect potential threats; (9) enforcement of a strict patching policy for software updates to protect against known vulnerabilities; (10) maintaining awareness on the latest threats and vulnerabilities through multiple partnerships with cybersecurity firms; and (11) involvement with the Department of Homeland Security's Continuous Diagnostics and Mitigation (CDM) Program which provides a dynamic approach to fortifying the cybersecurity of government networks and systems.

2. Do you believe that SAMHSA, and HHS in general, are ill-equipped to deal with cyber threats?

HHS possesses a robust ability to identify, protect, detect, respond to, and recover from cyber events. As the threats to HHS and its Divisions continue to evolve, HHS continues to focus on strengthening and modernizing Department information technology systems to bolster our

cybersecurity posture. Increased and consistent funding is critical for HHS to be able to stay current with the necessary tools and technologies to keep the threats at bay.

3. Aside from implementing H.R. 498, what can SAMHSA do in the future to combat domestic and international cyber threats?
SAMHSA is actively working to protect the agency from cyber threats, including by:

- Periodically evaluating cybersecurity needs: SAMHSA periodically evaluates cybersecurity needs against emerging cyber threats and adjusts its investment in cybersecurity tools and technologies to adequately protect its data, and systems, in accordance with the Federal Information Technology Acquisition Reform Act and the Federal Information Security Modernization Act.
- Creating a secure hosting environment: SAMHSA is working to leverage a secure hosting environment for all systems that provide security by default, encompassing the latest security practices and frameworks.
- Partnering with cybersecurity experts: SAMHSA is working to partner with cybersecurity experts to ensure that SAMHSA's networks and systems are secure and provide channels to stay up-to-date on emerging cyber threats so SAMHSA can respond quickly and effectively when needed.
- Ensuring oversight and accountability of all new contracts by requiring sign-off from SAMHSA's Chief Information Officer and/or Chief Information Security Officer to ensure that information technology services are expended meaningfully, employing security best practices, avoiding shadow IT and removing duplicative applications and work effort.

The Honorable Dan Crenshaw
1. How important is additional funding for future fentanyl-related research to the work being done by SAMHSA; and, if appropriated, how would they prioritize directing that funding?
As I mentioned in my testimony, SAMHSA is implementing the HHS Overdose Prevention Strategy, which supports substance use prevention by prioritizing expanded research of new and improved prevention efforts, investment in community resources to help prevent harms related to substance use, increased access to high-quality pain management to reduce preventable suffering, and responsible prescription of medications to protect patient safety.

In addition, SAMHSA is currently working with the National Institutes of Health on the Healing Communities Consortium Stay Safe Study, a multi-site observational study that will assess the effect of fentanyl test strip (FTS) use on overdose risk reduction behaviors among people who use drugs (PWUD) over a 28-day observation period. Simultaneously, the study will examine facilitators and barriers to FTS distribution at individual and organizational levels and how these contextual factors may interact to promote or impede FTS use and overdose risk reduction behaviors among PWUD.

2. For SAMSHA: how does fentanyl impact families and broader communities.

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

As I indicated in my testimony, over the past few years, drug overdose deaths have reached a historic high, devastating families and communities.[3] The 2021 National Survey on Drug Use and Health found that among people who used prescription fentanyl products for any reason in the past year, 20.9 percent misused them.[4] Moreover, findings from SAMHSA's analysis of 2021 data from drug-related emergency department visits show that fentanyl-related emergency department visits rose throughout 2021.[5] Overdose of an individual due to fentanyl, whether fatal or non-fatal has a lasting impact, not just on the individual themselves, but also on their family, friends, and communities. Sadly, data show that of those who are treated for an overdose in the emergency room and survive, about 1 in 20 patients die within one year of their visit, many within two days of discharge.[6] The reverberation of an overdose death of a friend or family member, colleague or neighbor is immense. Provisional data from the Centers for Disease Control and Prevention predicts that more than 107,000 Americans died due to a drug overdose in the 12-month period ending in August 2022. Of these drug overdoses, the same source predicts that 81,231 involved opioids, and approximately 73,102 were attributable to fentanyl and other synthetic opioids (excluding methadone).[7]As fentanyl continues to proliferate, the pain and grief that families and broader communities shoulder with each overdose death continues to grow.

The Honorable Richard Hudson

1**. Dr. Gandotra, as you outlined in your testimony, SAMHSA's mission is to "lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes." As SAMHSA's annual National Surveys on Drug Use and Health have made clear – the country is sadly struggling under a mental health and substance misuse crisis, both of which were heightened by the COVID-19 pandemic lockdowns. According to the 2019 National Survey, 20.4 million people aged 12 or older suffered from a substance use disorder. By 2021, which are the most recent figures we have available, the number for substance use disorders has more than doubled to 46.3 million people. The numbers for mental health are no better. In 2019, 20.6%, or 51.5 million adults over 18 years of age, suffered from any mental health disorder. This number increased to nearly 58 million adults (57.7 million) in 2021, with the rate of serious mental illness also increasing. Over**

[3] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data
[4] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data

[5] Substance Abuse and Mental Health Services Administration. (2022). Drug Abuse Warning Network: Findings from Drug-Related Emergency Department Visits, 2021 (HHS Publication No. PEP22-07-03-002). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/
[6] https://nida.nih.gov/news-events/nida-notes/2020/04/many-people-treated-opioid-overdose-in-emergency-departments-die-within-1-year
[7] Id.

one-fifth of our middle-school and high-school aged youth are suffering from a mental illness. This is unacceptable. It is my opinion the harsh school closures and community lockdowns have only exacerbated this problem, and your data largely reflect that.

2. Dr. Gandotra – you have served as the Chief Medical Officer at SAMHSA since July 2019. Could you speak to the role you and your agency, including any specific interactions with other partner agencies such as the CDC, played in the crafting of COVID-19 response policies?

During the COVID-19 pandemic, agencies across HHS including SAMHSA and the CDC, coordinated on crafting the country's COVID-19 response policies. We worked together, as we always do, to follow the science with regards to prevention, treatment and overall mitigation protocol and policy. As we learned more about COVID-19 through research, we collaborated across HHS to update policies accordingly.

3. Do you believe the detrimental impact of these lockdowns on mental health and substance use disorders were considered in finalizing and implementing administration recommendations? Should they have been a higher priority, particularly when the policies included mandates?

Data show that across a broad range of social, emotional, and cognitive outcomes, allowing students to attend school in person is incredibly important. Accordingly, the Biden Administration has prioritized in-person schooling in its COVID-19 response plan. Recommendations, for mask wearing, like those put forth by the Biden Harris Administration[8] were a crucial part of a layered prevention strategy, particularly before adults and children had widespread access to safe and effective COVID-19 vaccines, and wearing masks has been shown to reduce school and day care closures.

The Honorable Neal Dunn

1. **Please provide a breakdown of provider type (nonprofit, for profit, health system, independent BHOs, residential vs inpatient) that are subrecipients of the Substance Abuse Prevention and Treatment Block Grant (SABG).**
   Substance Use Prevention, Treatment and Recovery Services (SUPTRS) Block Grant (formally SABG) grantees are required to provide information regarding the subrecipient name, address, and amount of block grant funds received. SAMHSA does not collect information regarding subrecipient's provider type.

   • **What percentage of grant subrecipients serve urban areas? Rural areas?**
   SAMHSA does not collect this information. Grantees are required to report the address and funding amounts received for each subrecipient during the specified fiscal year (three years prior to the current federal fiscal year's award). However, we do not collect information regarding the geographic coverage for each subrecipient. During the FY 2022 reporting

[8] https://www.ed.gov/coronavirus

period, block grant awardees reported that they used a total of 5,413 entities to provide block grant services during federal fiscal year 2019.

• What percentage of grant subrecipients offer Medication Assisted Treatment or partner with a facility that offers Medication Assisted Treatment services?

SAMHSA does not collect information regarding the percentage of subrecipients that offer medications for substance use disorder. However, SAMHSA does collect this information at the grantee level. During the latest reporting period, among grantees for which data was available, 77 percent (44 of 57) reported serving a combined total of 279,391 clients with medication treatment for substance use disorder during state fiscal year 2021.

• Please also provide the percentage of funds dedicated to recovery housing by state.
SAMHSA does not collect this information. SAMHSA has proposed including this element as part of its 2024-2025 program application and reporting requirements.

• Please provide the total number of subgrant applications, and what percentage of applications receive funding by state.
SAMHSA does not collect this information.

The Honorable Frank Pallone, Jr.
Addressing the opioid epidemic, stemming the flow of illicit fentanyl, and ensuring individuals with substance use disorder are connected to services are important issues that deserve thoughtful, bipartisan solutions. This Committee has worked together to tackle these problems under past Republican and Democratic Chairs. I hope that we can continue that tradition at future hearings to find common ground on these and the other issues in our jurisdiction. One bill that would have been a great addition to this hearing today is the Medicaid Reentry Act. This bipartisan legislation would extend Medicaid eligibility to incarcerated individuals 30 days prior to their release. It's my understanding that individuals newly released from incarceration are at a much higher risk of overdose and suicide. Can you describe some of the reasons for that?

Yes, individuals newly released from incarceration are at much higher risk of overdose and suicide because of many of the challenges they face with re-entry from incarceration to society. Pre and post-release support services and continuity of care are key to help incarcerated individuals re-enter successfully into the community, which often means establishing or re-establishing relationships and support systems, finding work and stable housing, connecting to health care, and finding other needed supports. These challenges, many of which may have existed prior to entering incarceration, are often stressful and can lead to substance misuse and or depression, anxiety, and other mental health challenges, which, without access to services pre and post release, can prove deadly. In addition, newly released individuals often have decreased tolerance for opioids as a result of incarceration-induced abstinence or because they begin treatment for OUD while incarcerated. When individuals are released from incarceration after either abstinence from opioid use or being on tapering managed withdrawal, this population face a higher risk of overdose because of decreased tolerance. These individuals are also more

susceptible to overdose after treatment if they attempt to use the same amount or dose of opioids that they used prior to treatment because of decreased tolerance. In addition, many individuals who began OUD treatment while incarcerated, do not continue treatment once released, leading to relapse and potential overdose.

2. It sounds like ensuring newly-released individuals have continuity of access is incredibly important, especially for individuals with substance use disorder; would you agree with that?
Yes.

3. What are some of the barriers to care that recently-incarcerated individuals may face when reentering society?
As I mentioned above, there are many challenges that recently-incarcerated individuals face with reentering successfully into the community, and these challenges include finding places to access care, paying for care and prescriptions, obtaining health insurance, etc. In addition to finding and paying for medical care, incarcerated individuals must learn to re-enter their lives outside of incarceration and often that means establishing or re-establishing relationships and support systems, finding work and stable housing, and finding other needed supports. These challenges are often stressful, many of which may have existed prior to entering incarceration, and can lead to substance misuse and or depression, anxiety, and other mental health challenges, which, without access to services pre and post release, can prove deadly.

4. Medicaid Reentry Act would extend Medicaid eligibility to individuals 30 days prior to their release, promoting continuity of coverage and access to care during their transition into the community. Given the enormous risk of overdose during this time period and the importance of continuity of care, do you think enrolling individuals in health insurance, like Medicaid, prior to their release could help to address some of the issues you identified that make transitioning in the community a challenge?
Yes, enrolling individuals who are incarcerated in health insurance prior to their release would likely facilitate a more successful transition to the community. SAMHSA is actively engaging individuals who are currently incarcerated and soon to be transitioning back into the community using the Sequential Intercept Model (SIM). The SIM model encourages:

- Transition planning by jail or in-reach providers, starting at intake, that shape reentry outcomes to a person's needs prior to release including resources for behavioral health, physical health, and other related needs;
- States to allow individuals coming back into the community to have access to services and medications;
- Warm handoffs between release and service providers, ideally as a follow-up from in-reach services through the SIM;
- Necessary medication and prescription access for those being released to bridge the gap between their release and their next meeting with a medical provider; and
- Peer support services to help those being released to plan for reentry, identify quality stable housing, and diverting from the criminal justice system.

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

5. As you know, the recently passed omnibus addressed many of the gaps in substance use disorder treatment and mental healthcare—one of those being access to treatment, namely medication assisted therapy (MAT). MAT has been shown to keep people in treatment for their substance use disorder for longer periods of time leading to better chances of recovery. I'd like to take a moment to examine the implications of this law and how it will benefit people struggling with opioid use disorder. What is buprenorphine-naloxone and how does it work?

Buprenorphine is a partial agonist at the mu-opioid receptor, which means that it has similar effects to other opioids, such as pain relief, but it does not produce the same degree of effects as full agonists, such as heroin or fentanyl. Naloxone is an opioid antagonist that blocks the effects of opioids and is added to buprenorphine to deter misuse of the medication. Buprenorphine works by binding to the mu-opioid receptors in the brain, which reduces the craving and withdrawal symptoms associated with opioid use disorder. As a partial agonist, buprenorphine produces weaker effects than full agonists, which reduces the risk of overdose and misuse. Naloxone is included in the medication to discourage misuse by injection, as the antagonist effects of naloxone can precipitate withdrawal symptoms if the medication is injected. Buprenorphine-naloxone is typically taken under the tongue or inside the cheek, where the medication dissolves and is absorbed into the bloodstream. Buprenorphine-naloxone has been found to be an effective treatment for opioid use disorder, and has been shown to reduce illicit opioid use, improve retention in treatment, and decrease overdose deaths. It's an important tool in the treatment of opioid use disorder and can help individuals achieve and maintain long-term recovery.

6. Is there abuse potential for buprenorphine-naloxone? In other words, could someone use it to achieve a "high?"

While any opioid can produce euphoric effects, buprenorphine as a partial opioid agonist may not act as strongly as other opioids for its euphoric effects and many individuals do not report experiencing any euphoric effects which with its long half-life, makes it an ideal medication for withdrawal management. Opioids have variable effects on opioid receptors such as 1. pain relief, 2. autonomic nervous effects like heart rate, temperature control, blood pressure, digestive functions, etc., and 3. euphoric effects. Buprenorphine works very well for autonomic regulation, which is why it works for withdrawal, less so for pain management over 4-6 hours, and even less for euphoria. In fact, most individuals do not feel euphoric effects; rather, they simply have withdrawal relief. As buprenorphine still has partial agonist effects on opioid receptors, there is some abuse risk, albeit lower than other full agonist opioids.

7. Can you explain what the X-waiver was and how its removal makes it easier to deal with the fentanyl crisis and treating OUD overall?

The X-Waiver (also known as the Data-Waiver) was established under the Drug Addiction Treatment Act of 2000 (DATA 2000) to allow qualified practitioners to prescribe certain opioid treatment medications for the treatment of opioid use disorder (OUD). Under DATA 2000, qualifying practitioners received waivers from the Drug Enforcement Administration (DEA) after SAMHSA determined that they met certain statutory conditions. Qualifying practitioners were permitted to dispense, including prescribe, Schedule III, IV, and V controlled medications approved by the Food and Drug Administration (FDA) specifically for maintenance or

detoxification treatment without being separately registered as a narcotic treatment program by the DEA, otherwise known as an Opioid Treatment Program. "DATA-Waived" practitioners were not permitted to prescribe the Schedule II medication methadone for the treatment of OUD. Qualifying practitioners were subject to certain conditions. For example, practitioners were authorized to prescribe only opioid medications specifically approved by the FDA for the treatment of a use disorder, and that are controlled in Schedules III through V. Also, only practitioners in certain disciplines were eligible for a waiver and they had to be "qualified" by satisfying certain credentialing, training or experience requirements. Practitioners were also subject to limits on how many patients they could treat at any one time.

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023. Section 1262 of the Act amended the Controlled Substances Act to remove the requirement that practitioners obtain a special waiver to prescribe buprenorphine for the treatment of OUD, and section 1263 added substance use disorder training requirements for all DEA registrants. Section 1262 also made several conforming changes throughout the Controlled Substances Act, the Public Health Service Act, and the Social Security Act. These amendments expand the pool of potential buprenorphine prescribers from 114,000 (the number of practitioners with an X-Waiver in December 2022) to 1.8 million DEA-registered practitioners. Expansion in capacity to prescribe buprenorphine is significant because any practitioner, subject to applicable state law, with a valid medical license and DEA registration can now prescribe buprenorphine, assuming that they have completed requisite substance use disorder training. This means that those with OUD in rural areas and areas previously classified as having low access to treatment for OUD, can receive intervention. This change also has the potential to reduce the stigma associated with prescribing buprenorphine, and to establish OUD as a chronic medical condition that is manageable with treatment.

8. What do you believe is the next step in addressing the Opioid Crisis?
In response to the COVID-19 pandemic, in October 2021 the Department of Health and Human Services (HHS) released its Overdose Prevention Strategy (The Strategy). The Strategy aims to combat opioid overdoses by applying the best-available data and evidence to maximize health equity, inform SUD-related policy and actions, integrate SUD into other types of health care and social services, and reduce stigma. The Strategy includes elements from the full continuum of care including prioritization of prevention, harm reduction, expanding evidence-based quality treatment and sustaining recovery through support. Key to supporting those activities and The Strategy are SAMHSA's grant programs such as the Substance Use Prevention, Treatment and Recovery Services (SUPTRS) Block Grant, the State Opioid Response grants, and the Building Communities of Recovery and Partnerships for Success programs, all of which received major investments in the FY 2023 Omnibus. This Administration believes that investing in and expanding elements of the Strategy will ultimately help save lives.

9. What is SAMHSA doing to reduce disparities in substance use and mental health in the United States?
SAMHSA is committed to addressing health disparities by supporting culturally and linguistically appropriate mental health, substance misuse prevention, treatment and recovery support programs. This commitment is reinforced through SAMHSA's Behavioral Health

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

Disparity Impact Statement (DIS), which monitors programs and activities to ensure that access, use, and outcomes are equitable across racial, ethnic, and other under resourced populations. SAMHSA requires all non-formula-based grant recipients to prepare a DIS. In addition, SAMHSA administers information sharing, training and technical assistance towards the goal of promoting behavioral health equity through the National Network to Eliminate Disparities in Behavioral Health, which is a network of community-based organizations focused on the mental health and substance use issues of diverse racial and ethnic communities. Examples of grant programs and technical assistance centers focused on reducing disparities include the Minority Fellowship Program, the Tribal Behavioral Health grant program (also known as Native Connections), the Tribal Opioid Response Grants, and the Circles of Care program.

In addition, SAMHSA's Minority AIDS program supports activities that build a strong foundation for delivering and sustaining high-quality and accessible substance misuse and HIV prevention services. The program aims to engage community-level domestic public and private non-profit entities, tribes, and tribal organizations to prevent and reduce the onset of substance misuse and transmission of HIV/AIDS among at-risk populations, including racial/ethnic minority youth and young adults. SAMHSA also has Technology Transfer Centers that are dedicated to American Indian and Alaska Native and Hispanic and Latino populations. These Centers work with organizations and treatment practitioners involved in the delivery of behavioral health services to American Indian and Alaska Native individuals, families, and tribal and urban Indian communities and Hispanic and Latino communities respectively. SAMHSA also supports three Centers of Excellence, which are dedicated to providing training and technical assistance related to the evidence-based and evidence-informed prevention, treatment and recovery services specific to Black or African Americans, LGBTQI+ and older adult populations respectively. SAMHSA likewise funds the Historically Black Colleges and Universities Center of Excellence in Behavioral Health program, which recruits students to careers in the behavioral health field to address mental and substance use disorders, providing training that can lead to careers in the behavioral health field, and/or preparing students to obtain advanced degrees in the behavioral health field. Finally, SAMHSA administers the Centers of Excellence for Behavioral Health Disparities program. This program funds three Centers of Excellence that develop and disseminate training and technical assistance for healthcare providers related to addressing behavioral health disparities in the Black or African American, LGBTQI+ and aging populations.

10. How is SAMHSA addressing social determinants of health and their impact on human well-being?
Some examples of SAMHSA's work related to addressing social determinants of health include: our Office of Behavioral Health Equity, which coordinates SAMHSA's efforts to reduce disparities in mental and/or substance use disorders across populations; our Office of Recovery, which was established to evaluate and initiate policy, programs and services with a recovery focus and ensure that the voices of individuals in recovery are represented. The Office of Recovery addresses key social determinants that support recovery including access to housing, education, social support, and employment. In addition, SAMHSA works collaboratively with the United States Interagency Council on Homelessness and we administer programs like the Projects for Assistance in Transition from Homelessness program, which collaborates with the

SAMHSA Responses to 2/1/2023
Energy & Commerce Health Subcommittee Hearing on Fentanyl
Questions for the Record

Department of Housing and Urban Development as part of local continuums of care to comprehensively address the needs of individuals with serious mental illness and a co-occurring disorder who are experiencing homelessness or are imminently homeless. Finally, SAMHSA also administers the Transforming Lives Through Supported Employment program, which aims to increase evidence-based, supported employment programs for individuals with co-occurring mental and substance use disorders.

11. What agencies is SAMHSA collaborating with to address health inequities?
SAMHSA collaborates with several other agencies to address health inequities. Some examples of our collaborative work to promote health equity include: leading the Interdepartmental Serious Mental Illness Coordinating Committee and the Interdepartmental Substance Use Disorders Coordinating Committee, both of which include representatives from a combination of the Department of Justice, the Department of Veterans Affairs, the Department of Defense, the Department of Housing and Urban Development, the Department of Education , the Department of Labor, Centers for Medicare & Medicaid Services , the Administration for Community Living, the Social Security Administration, and the White House Office of National Drug Control Policy. In addition, SAMHSA works with the Office of Refugee Resettlement and National Institute of Mental Health to improve mental health outcomes for refugee and migrant populations. SAMHSA also participates in the Department of Justice's monthly coordinating meeting to discuss ongoing Olmstead[9] cases and issues related to Olmstead implementation for states, as well as Olmstead-related initiatives and resources across agencies. Finally, SAMHSA administers the Asian American, Native Hawaiian, and Pacific Islander Center of Excellence (AANHPI-CoE). The AANHPI-CoE is tasked with developing and disseminating culturally informed, evidence-based behavioral health information and providing technical assistance on training on issues related to addressing behavioral health disparities in the Asian American, Native Hawaiian, and Pacific Islander communities.

[9] *The 1999 Supreme Court's decision in Olmstead v. L.C. requires states to eliminate unnecessary segregation of persons with disabilities and to ensure that persons with disabilities receive services in the most integrated setting appropriate to their needs. The Department of Justice's Civil Rights Division work with state and local governments officials, disability rights groups and attorneys around the country, and with representatives of the HHS, to fashion an effective, nationwide program to enforce the integration mandate of the Department's regulation implementing title II of the Americans with Disabilities Act (ADA). For more information, see https://archive.ada.gov/olmstead/index.html.*

CATHY McMORRIS RODGERS,
WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY,
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
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February 22, 2023

Mr. Jon C. DeLena
Associate Administrator, Business Operations
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. DeLena:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 1, 2023, to testify at the hearing entitled "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, March 8, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

[Mr. DeLena did not answer submitted questions for the record by the time of publication. Replies received after publication will be retained in committee files and made available at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=115361.]

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment 1—Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

1. Has DEA identified any trends in illicit drug shipments? Is there international coordination to prevent fentanyl analogues and counterfeit drugs from crossing borders?

2. Understanding that most of the precursor chemicals needed to produce illicit fentanyl and fentanyl related substances come from China. Are there other countries who also supply these chemicals? Do the cartels in Mexico have the ability to produce these raw chemicals?

3. Transnational criminal organizations are adeptly shifting tactics to ensure that a steady supply of deadly drugs continues to flow into our communities.

- Does DEA have a sense of how expansive the cartels are? For example, are drug dealers in our communities part of or associated with the cartels who are smuggling fentanyl and FRS into the U.S.?
- Do the dealers in our communities know that street drugs like cocaine are adulterated with fentanyl / FRS?

4.What percent of DEA staff work in person five days per week? What percentage of meetings are held virtually versus in-person?

The Honorable Michael Burgess

1. Do you believe that the southern border is secure?

2. Is it possible that normal policies and procedures are not currently being enforced due to the record-breaking number of migrants coming into the country?

3. What are the specific policies and procedures for agricultural products?

4. Could agricultural products and other specimens be of worry in the future?

The Honorable Richard Hudson

1. Mr. DeLena, you've had a lot of experience overseeing DEA operations. We see fentanyl seizures daily at the southern border…but how much fentanyl do you predict gets *through* to the U.S. from outside countries?

The Honorable Greg Pence

The opioid and Fentanyl crisis is having a devastating impact on families across my district. State and local law enforcement agencies in Indiana's Sixth Congressional District are on the front lines, and they consistently communicate to me that they are overwhelmed by the illicit drugs flooding our community. According to the CDC, "there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before." Our state and local partners need more resources to combat the ruthless cartels that are trafficking illicit drugs across our southern border and killing family members, friends, and neighbors in our communities.

1. How can federal law enforcement agencies, such as the DEA, leverage their resources to more closely coordinate with local law enforcement agencies to increase the detection and prevention of illicit drugs in Hoosier communities?

We know these violent cartel criminals are intentionally altering the chemical structure of prescription-grade Fentanyl to create synthetic opioids with the intention to evade federal law enforcement.

2. How do you think drug traffickers weigh the legal risks of using specific synthetic Fentanyl analogues and how can our federal law enforcement agencies best hold these criminals accountable for their actions?

The Honorable Robert Latta

1. A new report has been released that shows 1 in 3 adults aged 18 to 25 suffered from a mental illness in the past year. However, through the successful rollout of telehealth services, many medications are now able to be prescribed to treat mental illness. Given the current mental health crisis in this country, what controlled medications will clinicians with the proposed Special Registration be permitted to prescribe through telehealth? More specifically, would there be any medications that are used to treat mental illness that would be excluded by the proposed Special Registration?

2. Is there a timeline for the release of the Special Registration proposed rulemaking?

3. What happens if this proposed rule is not finalized by the Administration's expiration of the Public Health Emergency on May 11, 2023?

The Honorable Dan Crenshaw

1. How would the DEA respond to proposals of an expedited approval process for fentanyl-related treatments/Opioid Use Disorder treatments given the enormity of the fentanyl problem?

    - For context--One of the concerns is legislative language that deems any fentanyl-related substance Schedule 1. The DEA passed an edict a few years back designating anything that looked like fentanyl to be a Schedule 1 substance although fentanyl itself is Schedule II. What we don't want is unnecessary restraint in the ability to conduct research and develop therapeutics (or the potential fentanyl vaccine). For example, there is ample evidence that research on hapten, a fentanyl-like molecule, has no biological activity related to fentanyl-induced effects (e.g. analgesia). The hapten, in simple terms, is the "backbone" of the fentanyl molecule that is also common to fentanyl derivatives. How would the designation apply to fentanyl type molecules.

2. How important is additional funding for future fentanyl-related research to the work being done by DEA; and, if appropriated, how would they prioritize directing that funding?

3. How could DEA imagine future fentanyl research (or a vaccine) being useful to their law enforcement efforts, particularly in border patrol and customs enforcement activities?

The Honorable Frank Pallone, Jr.

1. Mr. DeLena, the DEA leads the federal government's enforcement of the Controlled Substances Act and plays a critical role in federal drug cases. How does the Administration's proposal address accountability for violating the law?

2. Approximately what percentage of illicit fentanyl is intercepted by law enforcement?

3. Approximately what percentage of illicit fentanyl is seized at legal ports of entry?

4. Approximately what percentage of illicit fentanyl is seized between legal ports of entry?

5. Approximately what percentage of illicit fentanyl is seized in the mail?

6. Of the amount of illicit fentanyl not seized, what is the most likely method of entry into the United States?

7. Is there any evidence that the majority of illicit fentanyl not seized by law enforcement enters the country on the backs of migrants crossing unlawfully between ports of entry?

March 7, 2023

Additional Questions for the Record

"Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

Kandi Pickard
President and CEO
National Down Syndrome Society

The Honorable Gus Bilirakis

1. **Mrs. Pickard, the QALY methodology seems rather subjective: Could you please elaborate on the arbitrary nature of QALYs?**

   Quality Adjusted Life Years (QALYs) discriminate against people with disabilities in several ways. QALYs use numeric indicators called "utilities" to assign a value to life lived in a particular health state. These utilities are created through broad population surveys in which participants, many of whom do not understand the lived experiences of people with disabilities, must assign a value to health states in which they may have limited knowledge of and likely have not directly experienced. Participants may perceive individuals with disabilities to have a lower quality of life based solely on their diagnosis and thus, assign them a lower utility. This framework is inherently flawed as it allows for the biases of survey participants to undermine the assessment. As a result of QALYs, people with disabilities are often seen as too expensive or not worth treating. As a parent of a child with Down syndrome, I know firsthand that my son's diagnosis does not mean his life is any less valuable than my children without disabilities.

2. **What are the ethical implications of the Institute of Clinical and Economic Review (ICER) model and its utilization of QALYs?**

   The Institute for Clinical and Economic Review (ICER) conducts QALY-based cost-effectiveness assessments, which payers acknowledge relying on for formulary decisions.[1] These assessments have led to restricted and delayed access to treatments. In 2014, ICER evaluated Hepatitis C treatments and found them to be low value to the health care system despite providing high impact to patients. Following this evaluation, patients struggled to receive coverage for these treatments.[2] In 2015, ICER conducted an assessment of PCSK9s, a treatment for heart disease, and found them not to be cost-effective which resulted in denial of coverage at a high rate.[3] Both of these treatments yielded profound benefits for patients yet, based on the flawed and discriminatory assessments provided by ICER, were ultimately restricted. Parents of children with Duchenne Muscular Dystrophy have also reported having ICER's assessment cited to them as a rationale for denying coverage of eteplirsen.[4]

   Most recently, CMS relied upon a report from ICER that used QALYs and similar one-size-fits all metrics in its national coverage determination for Aduhelm, the first treatment approved for Alzheimer's disease. The initial coverage determination excluded individuals with disabilities. This was particularly concerning as individuals with Down syndrome have a heightened lifetime risk – higher than 90 percent – of developing Alzheimer's disease.[5] Access to treatments for this

[1] https://www.xcenda.com/insights/ispor-2022-poster-impact-icer-assessments-payer-decision-making
[2] http://icerorg.wpengine.com/wp-content/uploads/2020/10/CTAF_HCV2_Final_Report_013015.pdf
[3] https://familyheart.org/research-circ-ce-data
[4] https://www.bostonglobe.com/2021/11/22/opinion/how-health-care-systems-do-do-not-support-patients/
[5] McCarron, M., McCallion, P., Reilly, E., Dunne, P., Carroll, R., & Mulryan, N. (2017). A prospective 20-year longitudinal follow-up of dementia in persons with Down syndrome. Journal of intellectual disability research : JIDR, 61(9), 843–852. https://doi.org/10.1111/jir.12390

debilitating disease is paramount to our community, and we will continue to work with Members of Congress and this Committee to ensure individuals with disabilities are not left out of the conversation.

3. **What lessons should the United States learn from the controversial utilization of QALYs in other global health care systems?**

Many countries, including our friends in the UK and Canada heavily rely on QALYs to determine who is worth treating and who is "too expensive" thus determining which medicines or treatments are available to patients. For example, from 2016 to 2019, the UK used QALYs to restrict access to the first ever approved treatment for cystic fibrosis, and there are still severe limitations put on the use of disease modifying drugs for Cystic Fibrosis in countries that rely on QALY-based HTA, including Canada and New Zealand. A 2018 Avalere Health study found that of over 329 health technology assessments of cancer drugs between 2013 and 2017, the National Institute for Health and Care Excellence (NICE) in the U.K recommended access restrictions for nearly 70% of the drugs it assessed and rejected 22%.[6] Unfortunately, as indicated above, these metrics are used here in the United States as well for federal health program coverage determinations.

The Honorable Michael Burgess

1. **How else, besides using QALY measurements, can Congress determine cost-effectiveness for care while also acknowledging the inherent value of every person?**

According to a 2019 report issued by the National Council on Disability, no single alternative exists that serves all the functions of the QALY as a sole metric for determining value.[7] The NCD and entities such as the Disability Rights Education and Defense Fund (DREDF) have recommended that alternative metrics be used jointly, in combination, to understand value from different perspectives, similar to methods like multi-criteria decision analysis (MCDA).[8] I believe more research is needed to further develop and test alternative methods and frameworks for determining the value of health care treatments. We must also ensure that individuals with disabilities are included in decisions regarding the value of their health care. This will better inform policy makers on the nuances missing from the available evidence base and ensure that the voices of the disability community are kept at the center of this issue.

2. **How have QALYs been used previously to restrict access to treatments?**

QALYs are routinely used in cost-effectiveness assessments by the Institute for Clinical and Economic Review (ICER), which payers acknowledge relying on for formulary decisions.[9] This had

[6] https://avalere.com/insights/htas-recommendations-for-oncology-have-grown-more-restrictive-over-time
[7] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[8] https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/
[9] https://www.xcenda.com/insights/ispor-2022-poster-impact-icer-assessments-payer-decision-making

led to restrictions on coverage for treatments for conditions such as Hepatitis C and heart disease, even when the treatments yielded significant benefit to the patient.[10] [11]

Many countries, including our friends in the UK and Canada heavily rely on QALYs to determine who is worth treating and who is "too expensive" thus determining which medicines or treatments are available to patients. For example, from 2016 to 2019, the UK used QALYs to restrict access to the first ever approved treatment for cystic fibrosis.

Here in the United States, QALYs continue to be utilized at the state level in many states. The state of Oregon ranks health care services in a prioritized list form more to least important. The Oregon Health Evidence Review Commission (HERC) uses QALYs in its cost-effectiveness formula to determine where treatments fall on the prioritized list.[12] Only services over a certain line are covered, regardless of individual determinations of medical necessity. Oregon is not the only state to rely on this form of health care rationing and states such as Massachusetts, New York, and Minnesota have all sought to enact legislation that relies on value-based assessments in healthcare.

3. **What has happened as a result?**
As a result of QALYs, access to and coverage of necessary treatments have been routinely restricted for patients who are deemed "too expensive" or "not worth" treating. Most recently, CMS relied upon a report from ICER that used QALYs and similar one-size-fits all metrics in its national coverage determination for Aduhelm, the first treatment approved for Alzheimer's disease. The initial coverage determination excluded individuals with disabilities. This was particularly concerning as individuals with Down syndrome have a heightened lifetime risk – higher than 90 percent – of developing Alzheimer's disease.[13] Access to treatments for this debilitating disease is paramount to our community, and we will continue to work with Members of Congress and this Committee to ensure individuals with disabilities are not left out of the conversation.

All individuals should be valued by our healthcare system and should have access to the treatments that have been prescribed to them by their physicians. My son, and other individuals with disabilities, deserve to access a healthcare system that is free from discrimination and imposed biases.

[10] http://icerorg.wpengine.com/wp-content/uploads/2020/10/CTAF_HCV2_Final_Report_013015.pdf
[11] https://familyheart.org/research-circ-ce-data
[12] https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx
[13] McCarron, M., McCallion, P., Reilly, E., Dunne, P., Carroll, R., & Mulryan, N. (2017). A prospective 20-year longitudinal follow-up of dementia in persons with Down syndrome. Journal of intellectual disability research : JIDR, 61(9), 843–852. https://doi.org/10.1111/jir.12390

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

Responses to Questions for the Record for Frederick Isasi, Executive Director, Families USA

U.S. House of Representatives Committee on Energy and Commerce Health Subcommittee
Wednesday, February 1, 2023
"Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

Questions from the Honorable Gus Bilirakis

Mr. Isasi, the U.S. health care system is one that fosters pharmaceutical innovation and development that is leaps and bounds beyond any other global entity. The cures that come out of America benefit patients the world over. That being noted the use of QALYs has created ethical questions in nations like the UK.

- ***Do you believe it is ethical to ration treatments for patients based on subjective methodologies like the QALY?***

Response:

Nobody should be denied access to a treatment or coverage for health care due to their age, health, or disability status, and we should never assign more value to one life over another in making health care decisions.

But the proposed legislation under discussion, H.R. 485, *The Protecting Health Care for All Patients Act,* would do nothing to prevent rationing of care. The vague and broad federal prohibition of the use of "adjusted life years or a similar measurement" included in this legislation would likely call into question non-discriminatory measures of health care value and exacerbate the terrible waste in other aspects of the U.S. health care system – estimated at an astounding $760 - $935 billion.[1] For example, the proposed legislation likely would create a very serious legal "loophole" that the pharmaceutical industry will use to argue against any efforts to determine the real value of a prescription drug and negotiate a fair price for our nation's families, under new drug negotiation authorities authorized through the *Inflation Reduction Act of 2022* (IRA).[2] For this reason, the legislation could play a significant role in worsening the health care affordability and quality crisis faced by millions upon millions of our nation's families, often most acutely by people with disabilities, and could lead to the *actual* rationing of health care services and treatments due to people being unable to afford the care they need.[3]

- ***Is it reasonable to utilize an elongated QALY based review processes, like the Institute of Clinical and Economic Review (ICER) model or the National institute for Health and Care***

[1] Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. 2019;322(15):1501–1509. doi:10.1001/jama.2019.13978
[2] Public Law No: 117-169.
[3] As recently as late last year, CDC estimated that more than a million Americans with diabetes rationed their insulin annually due to the high costs of the life-saving drug, and that Medicare beneficiaries were disproportionately impacted. For more information, see Insulin: 1.3 million Americans with diabetes rationed their supply in the past year, study finds | CNN

Excellence (NICE) model in the United Kingdom, which have been proven to have negative life shattering implications for patients?

Response:

We do not support utilizing any measure in health care decision-making that discriminates on the basis of disability status, age, or severity of illness, including the quality-adjusted life year (QALY). We are proud to have supported including language in both *the Patient Protection and Affordable Care Act* (ACA)[4] and IRA that explicitly bars the U.S. Department of Health and Human Services from using QALYs in treatment and coverage decisions.

[4] Public Law 111–148.

Stephen Loyd, MD
Responses to Member Questions – "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"
House Committee on Energy and Commerce

Questions Submitted by the Honorable Frank Pallone, Jr.

Why is it important to shift the focus away from criminalization and towards treatment and recovery?

The reason for this is simple: criminalizing drug use will do nothing to change the underlying addiction. If we are serious about addressing the fentanyl crisis and the broader opioid epidemic in this country, we must treat substance use disorder, and evidence has shown that treatment and recovery is the best path for that.

Outside of the medical community, and even in some parts of it, many people believe that those suffering from addiction are doing so as a matter of choice. They believe that the person using drugs is doing so as a choice, not because of an underlying brain disorder driving behavior. Society needs to recognize that drug addiction is a disease and treat it as such, which does not involve strictly punitive measures, but must also include appropriate and evidence-based treatment.

According to data from the Department of Justice, half of state and federal prisoners meet criteria for substance use disorder. However, it largely goes untreated in criminal justice settings. What can be done to improve access to treatment for justice-involved individuals?

In my experience treating justice-involved individuals, the largest barrier to access is knowing who needs treatment. You can't treat substance use disorder without knowing who has it. First, we need to increase screenings for SUD as people enter the system. Next, we need to initiate treatment process at the appropriate level of care for people with SUD, which should be continued throughout the time that someone is incarcerated. Finally, in order to make sure there is no recidivism, the treatment protocol should be incorporated into an individual's release plan, and follow-up should be done consistently during the probation and parole period.

Dr. Loyd, you have been very involved in the state of Tennessee's work to determine how to use opioid settlement dollars. As a person in recovery as well as a clinician, what do you think the best use of these settlement dollars is? And relatedly, how can states effectively allocate these funds?

In my opinion, any effort to abate the impacts of the opioid epidemic must be a multi-faceted campaign that gets to all aspects of the epidemic; for me, those key areas are:

1. Programs to treat people with OUD, including infrastructure and delivery, treatment along the full continuum of care, and provider training and support
2. Programs to reduce harms from opioid use, including Naloxone, HIV/HCV screening

and treatment, remedial pain management, and increased investment in child welfare, foster care, and abatement of adverse childhood events
3. Programs to prevent future opioid misuse, including additional investment in Prescription Drug Monitoring Programs, programs for targeted audiences (school-aged children, college-aged adults, and at-risk communities), and additional training for prescribers
4. Coordination and monitoring of efforts, administration and appropriate stewardship of opioid settlement monies

Any effective allocation of settlement dollars should be done with those four pillars in mind, as they are key to abating the impacts of the opioid epidemic in our communities. Many of these will take years to see the full impact on our communities, which is why careful allocation and stewardship of the funds is so essential.

From a treatment angle, guaranteeing quicker and consistent access to care is the easiest way to see quick results. By specifically targeting at-risk populations, the initial impact will be greater; my recommendation would be to be increased focus on justice-involved individuals and overdose survivors that have been treated in emergency departments.

As a doctor who actively treats people with opioid addiction, how will passage of the MAT Act will affect your practice and your patients?

The passage of the MAT Act will greatly impact my practice, as well as potential patients as it immediately improves access to essential care for those impacted by substance use disorder. If we can get people into the appropriate treatment, there is an immediate impact on not only the lives of that patient, but their friends, family, and broader community. Additionally, it has great potential to increase retention in treatment as it will be easier to access, which will greatly improve long-term outcomes.

Now that the X-waiver has been eliminated and doctors can prescribe buprenorphine to an unlimited number of patients under their care, how do you think this will affect the opioid treatment landscape?

I think this will have a two-part impact on the current opioid treatment landscape. First, it will increase access to care by permitting more prescribers to treat patients, as well as decreases the initial barriers to care for patients seeking treatment. Second, it has the potential to increase awareness among physicians of evidence-based treatment, as more doctors can prescribe this treatment. Additionally, the continued requirement for education on addiction treatment for providers is an important inclusion in the X-waiver as it ensures that prescribers will be providing the best possible care to patients.

Stephen Loyd, MD
Responses to Member Questions – "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities"
House Committee on Energy and Commerce

Can you please dispel any misconceptions about the misuse or diversion of buprenorphine and suboxone?

There is a common and incorrect belief that all people who misuse or divert buprenorphine and suboxone are doing so for illicit purposes – i.e., to inject or snort. However, studies have shown that those who use non-prescribed buprenorphine or suboxone often do so to bridge the gap in treatment services.[1] The diverted buprenorphine and suboxone are used to stop withdrawal symptoms, commonly referred to as dopesickness, or do self-detox. Those that take this path often have other barriers to care, including limited access to a prescribing physician or a lack of health insurance.[2]

The most impactful way to decrease diversion is to increase access to care; studies like the ones I cited above show that many people using diverted buprenorphine and suboxone are not using it illicitly, but rather to manage withdrawal or to ease symptoms during a self-detox period. By increasing access to MAT, these individuals will be able to manage their SUD through a legitimate prescription, rather than diverted drugs.

As a doctor of Internal Medicine, can you tell me what education on addiction you received in medical school? Residency?

Between medical school and residency, I had one hour of training on addiction; it was during my first-year course on Neuroanatomy. From what I understand, this is a bit of an outlier as most physicians that trained around the same time I did received less than that. We were only given this small amount of time because the course was taught by someone who was in recovery.

For additional context, I graduated medical school in 1999, and completed my residency training in 2001.

Do you agree that more physicians, especially new physicians entering the workforce, should have access to continuing education and training to identify and treat substance use disorders?

Yes, I do. At this point, it's inconsistent across states, and this is not only a health equity issue,

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[1] Monico, L. B., Mitchell, S. G., Gryczynski, J., Schwartz, R. P., O'Grady, K. E., Olsen, Y. K., & Jaffe, J. H. (2015). Prior experience with non-prescribed buprenorphine: Role in treatment entry and retention. Journal of Substance Abuse Treatment, 57, 57–62 doi:S0740-5472(15)00109-9.

[2] Allen B, & Harocopos A. Non-Prescribed Buprenorphine in New York City: Motivations for Use, Practices of Diversion, and Experiences of Stigma. Journal of Substance Abuse Treatment. 2016;70:81-86. doi:10.1016/j.jsat.2016.08.002

but it also impacts patients' lives directly if they visit a physician with little-to-no training on what is a pervasive issue.

I believe that the best way to increase training on it is fairly basic – the best way to ensure that training happens is to add questions on substance use disorder to the US MLE, which is the national licensing exam that all aspiring physicians have to take in order to practice medicine in the United States. By adding questions on this, medical schools would then add it to their standard curriculum, and it would provide a sound foundation for additional trainings and continuing medical education courses as people progress in their careers.

The Biden Administration's proposal to address FRS exempts those charged with an FRS offense from quantity-based mandatory minimum penalties, unless the offense results in death or serious bodily injury. Is there any indication that permanent scheduling of FRS, with exemptions for quantity-based mandatory minimums, will lead to an increase in new FRS being created?

I agree with the Biden administration position that mandatory minimums should be limited for those whose offenses do not result in death or serious bodily injury to another person. In my opinion, I do not believe this will lead to more FRS on the market; the illicit drug market is like any other, and it responds to market forces like supply and demand.

If we want to reduce the FRS market, as well as other illicit drug markets, the best course of action is to provide treatment for those with underlying SUD in order to facilitate lower demand; if there are fewer customers, the market will necessarily shrink. By increasing access to safe, evidence-based care and treatment, we can limit the customer base for the FRS market and also prevent the deaths and overdoses associated with this class of drugs.

Attachment 1
Additional Questions for the Record, The Honorable Frank Pallone, Jr.

1. How will passage of the MAT Act affects efforts to treat opioid addiction in the Emergency Room? How important is it to intervene at that point of care?

Intervening in the emergency department (ED) in substance use disorder (SUD) is critical. The quicker you can get someone to start MAT and get them into treatment or closer to treatment, you've kept them alive and away from playing Russian roulette with the fentanyl polluted drug supply. Improving and maximizing access to treatment is critical in treating opioid use disorder, anything that does that should be embraced. SUD intervention needs to happen at any and every point of contact.

However, it is important to note that the MAT Act removes the burden that was put in place in the first place by the federal medical regulatory community (NIDA/HHS/DEA/FDA) on physicians to prescribe buprenorphine. That requirement for a special certification to prescribe buprenorphine had the opposite effect of what the medical regulators intended, instead of increasing knowledge around and increasing the prescribing of buprenorphine, it stigmatized it and put in place a significant regulatory burden that has gone on to cause it to be massively underutilized. This underscores the difficulty in being able to predict the unintended consequences of well intended legislation and regulation.

Buprenorphine especially when given with naloxone in its formulation (as suboxone) is effectively the safest opioid medication that could be prescribed. There is little to no euphoria from it and with naloxone ingested in combination with it, there is almost no chance of overdosing and dying from respiratory suppression.

It never made sense to me that the federal government decided to put heavy restrictions on prescribing the safest opioid while allowing anyone and everyone to prescribe as much oxycodone, oxycontin and almost every other opioid (except methadone) as we cared to. The FDA even changed the indication for opioids from only short acting to ok for long term use without any research to back it up (by a guy that went from his job at the Center for Drug Evaluation and Research at the FDA to a job at Purdu Pharma which then went on to make tens of billions off that simple indication change.)

Starting in 2014, I was the physician architect of the Wisconsin prescription opioid reform strategy and designed. I worked with State government and the medical community to reverse the tide of opioid overprescribing that had started in the 1990's from big Pharma fully endorsed by the federal medical regulatory community (chiefly HHS, the Joint Commission for Hospital Accreditation and the Federation of State Medical Examining Boards) that urged physicians to prescribe as many narcotics as the patients asked for (and at times threatened those who didn't.) They asserted that patients pain was being under treated, pain was the fifth vital sign and patients had a right to have narcotics for their pain - (which all unbelievably were uncovered to have started as Purdu marketing strategem.)

The policies, laws and regulations I put in place in Wisconsin in 2016 gave physicians back the tools and empowered them to go back to prescribing opioids as they saw fit clinically, which has happened. There has been a cultural awakening amongst physicians who are getting back to prescribing opioids judiciously-the way we used to- as little as is humanely possible. Equally or more importantly there has grown an awareness of society in general that opioids are not harmless and potentially very dangerous. Deaths are now driven by illicit fentanyl pouring into the country poisoning our kids, not from overprescribing by physicians.

The problem with centralized federal medical regulation is that it always seems to be a one size fits all answer. It is usually well intentioned, and meant to solve a problem that's real. But there are almost always unintended outcomes, many times that happen to be the opposite of what the original intended outcome was. Medical regulation and oversight needs to happen at the state and local level as it is already set up to be. I hate to say it, but the federal government just needs to get out of the way and not fix what isn't broken.

2. As a doctor of Emergency Medicine, can you tell me what education on addiction you received in medical school? Residency?

The training to become a physician is the most rigorous of any profession in our society, as it should be. I started preschool at age 4 and finished my residency at age 30 with no time off. Physicians have a culture of constant re-education, staying up to date with the most current treatment options and therapies. We are self directed learners, constantly looking at our knowledge gaps and learning what we need to to give the best care to our patients.

My training in medical school included many hours of pre-clinical academic study of psychiatry and addiction medicine, then a month or more of clinical psychiatry with addiction medicine.

Emergency medicine training is full of lectures on substance abuse and addiction, along with the actual work of caring for innumerable hundreds of patients who present to the academic training institutions with diseases that are either directly or indirectly related to substance abuse. I'd make a guess that that number is at least 10% of the patients I saw.

3. Do you agree that more physicians, especially new physicians entering the workforce, should have access to continuing education and training to identify and treat substance use disorders?

But we do, there is a large and growing body of education on SUD. It seems to me the more relevant question to ask is whether the legislature/federal government or it's agencies should mandate more continuing education around such training? Because as I've stated, physicians are amongst the most educated members of society (looking at years of and time spent in preparation of independently practicing medicine) and are in a much better position to know their educational and training shortcomings, and to know the path to rectify any knowledge gaps or deficits than anyone else, especially the government. The opportunity cost for time we spend on mandated education that we really don't need is less time for the education and trading we really need.

My daughter is a med student who just finished her academic pre-clinical work and she's already had significant substance use disorder (SUD) education and training, way more than I had when I was in her shoes 30 years ago. Medical education is set up to adapt quickly to new treatments, best practices, and knowledge deficits.

The government needs to be very cautious when trying to impose it's own idea as a solution to an incredibly complex problem. The main problem that surrounds SUD is tied into the very nature of the disease itself. A significant problem is getting those unfortunate patients who suffer from it to accept the treatment that is available. The old adage of how you can lead a horse to water but not make him drink certainly applies.

To be quite clear, I'm certain that the main issue with SUD treatment is not that physicians haven't been taught or don't have access to continuing education and training to identify and treat SUDs.

The other important factor to consider is the way any federal educational mandates would be rolled out. Again as with any legislatively mandated medical reform, it would almost invariably be a one size fits all solution that would attempt to modify the behavior of a tiny percentage of physicians who do have a lack of knowledge of SUD treatment. The majority of physicians do practice above the minimum level of competence, and if they don't, then the solution best comes from the system that is already in place to provide medical oversight and regulation. This is the state medical boards, specialty licensing boards, and hospital system credentialing and quality boards, not legislators and government agencies.

4. What evidence is there that FRS scheduling has led to a decrease in the appearance of new FRS substances? Please give us specific numbers.

The main evidence and source of information comes from In the 2021 GAO report on FRS page 23 of 98 it says this :

"Our analysis of DEA data on these reports show that encounters with fentanyl analogues that were not individually scheduled by name—which is what class-wide scheduling was intended to target—decreased from 7,058 reports in 2016 and 2017 to 787 reports in 2018 and 2019."

https://www.gao.gov/assets/gao-21-499.pdf

5. In response to a question from Chairman Guthrie at the January 11 roundtable, you mentioned rapid descheduling of substances that are inert and not biologically active. Do you agree that FRS found to have a lower risk or no risk to public health should be rescheduled or descheduled, respectively?

I do agree that the ability to rapidly de-schedule an inert FRS should be included in FRS legislation that moves in Congress. The reason rapid de-scheduling wasn't included initially in the Wisconsin FRS language is that the language was so specifically targeted to include only known bioactive modifications that any trafficked FRS would certainly be bioactive. Which turned out to be true. The data from research done of FRSs in the 5 years since have borne out and validated this. The fact is that there are no inert FRSs. All FRSs encountered to date by DEA are potent opioid stimulators. One of them is 7,000 times more powerful than morphine, making it the 3rd deadliest chemical weapon, behind carfentanil, tetanus toxin, and botulinum toxin.

So the idea that there could be a prosecution, conviction and incarceration for trafficking an inert FRS is purely theoretical and doesn't seem possible, except the theoretically. This theoretical argument is however being used by the major groups opposing FRS scheduling who are in fact mainly criminal justice reform and drug reform legalization based activist organizations.

The power of FRS scheduling and what makes it proactive and preventative is in the fact that it removes the existing incentives for Chinese chemists and translational criminal organizations

from creating new FRSs and stops them from existing in the first place. I've heard it argued that FRSs shouldn't be subject to the same penalties as other schedule 1 substances and this concerns me. That would re-incentivize the chemists and cartels to create and traffic new FRSs because the penalty would be less than for illicit fentanyl and other schedule I controlled substances. The effect would be to significantly degrade the powerful proactive and preventative effects.

Thank you for your questions. I'm happy to discuss further as needed.

Tim Westlake, MD, FFSMB, FACEPP