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FRONT LINES OF THE FENTANYL CRISIS: SUPPORTING COMMUNITIES AND COMBATING ADDICTION THROUGH PREVENTION AND TREATMENT

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

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FRONT LINES OF THE FENTANYL CRISIS: SUPPORTING COMMUNITIES AND COMBATING ADDICTION THROUGH PREVENTION AND TREATMENT

THURSDAY, MAY 23, 2024

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:07 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

Present: Senators Stabenow, Cantwell, Carper, Brown, Bennet, Casey, Whitehouse, Hassan, Cortez Masto, Crapo, Grassley, Cornyn, Cassidy, Daines, Barrasso, Tillis, and Blackburn.

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Marielle Kress, Senior Health Advisor; and Joshua Sheinkman, Staff Director. Republican staff: Kellie McConnell, Health Policy Director; Charlotte Rock, Senior Health Policy Advisor; and Gregg Richard, Staff Director.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The Finance Committee will come to order. Today, we are going to discuss the scourge of the deadly synthetic opioid fentanyl. Fighting fentanyl requires fitting together all the pieces in the puzzle. Already this year, Congress has acted to disrupt the flow of fentanyl from countries like China, thanks to the work of Senator Brown.

Today, what we are going to be digging into is the issue of how the health-care piece fits in. These health-care issues have not had the attention they deserve. My colleague from the Pacific Northwest, Senator Cantwell, has been leading the way in our region. I want to thank her for her attention to this issue, and she has invited a guest who has some really promising ideas for how we could have some real health-care breakthroughs here.

The epidemic has hit communities in the Northwest like a wrecking ball. The health-care puzzle piece is about real people whose lives have been ripped apart by the devastating disease of addiction. I am going to focus my remarks on just a few areas that need immediate attention.

The first is prior authorization. Only one in five Americans receive lifesaving medication treatment for opioid use disorder, despite the evidence that it works. Two months ago, Congress passed

a law that I and others championed requiring State Medicaid programs to cover medication-assisted treatment. This approach, MAT, if we cover it on a permanent basis, could really be the gold standard treatment for opioid use disorder.

One of the reasons that we are digging into this issue this morning is, I am concerned that big health insurers like UnitedHealth and Aetna that contract with the Medicaid program are using prior authorizations at high rates, and that is causing delays and denial of this important treatment.

In the context of the opioid epidemic, private prior authorization can be the difference between life and death. If somebody walks in for treatment for their opioid use disorder and gets stymied by prior authorization, they may just never get back, never return, dying from an overdose before the prior authorization is approved.

Last fall, we launched an investigation looking into how these big insurance companies are ripping off taxpayers and Medicaid—and patients—by using the Medicaid program as a piggybank through tactics like prior authorization. As patients suffer, as these mega-corporations post record profits, they are also dragging their feet as the committee tries to get answers about several of these tactics. These multibillion-dollar companies owe answers to taxpayers about how these Medicaid dollars are being used.

Next, I would like to talk about opioid use disorder for individuals who are coming out of prisons and jails. I have heard repeatedly now from law enforcement officials in rural Oregon that these individuals need to be able to get adequate treatment for the disease during and after their sentence.

Making these reforms is common sense. States are working on their own initiatives to support access to care for people before coming out of incarceration who need uninterrupted care. I especially want to credit State legislators like Pam Marsh from southern Oregon and the sheriffs from across Oregon, who are leading the effort to get this done.

These reforms are a start toward being responsive to what law enforcement officials are asking for: getting people off their addiction before they get out of jail so they do not come back.

I am going to wrap up by talking about prevention and thoughtful approaches to pain management. More needs to be done to head off opioid use in the first place, and encourage more nonopioid pain management to be used in American health care.

There are promising new therapies in development that block pain signals rather than flooding receptors in the brain with opioids that create an addictive feedback loop. Members of this committee are watching the development of these therapies closely. I encourage this, and we are going to look for ways to accelerate their entry into the health-care system. Every single member of this committee understands the health-care anguish and pain that opioids bring to our communities, from one end of the country to another.

We have an excellent panel of witnesses. I will have a special introduction for our friend from Oregon here in a little bit. But I want to thank all our guests. We are talking about ways to break down the remaining barriers to health-care treatment in this cru-

cial area, save lives, and get struggling Americans the help they need.

Senator Crapo?

[The prepared statement of Chairman Wyden appears in the appendix.]

OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

Senator CRAPO. Thank you, Mr. Chairman.

The fentanyl crisis has devastated communities across this country. Far too many families have experienced the pain of losing a loved one from this deadly substance, and the threat it poses to our communities and neighborhoods cannot be overstated.

In Idaho, overdose deaths involving fentanyl increased nearly fourteen-fold between 2017 and 2022, an alarming statistic. It is important to note that this crisis and the uncontrolled flow of fentanyl into our communities has not occurred in a vacuum. In the last 2 decades, we saw an unprecedented increase in the use of prescription opioids, causing overdose deaths to rise dramatically.

Congress took critical steps to authorize programs to reduce the use and supply of prescription opioids, and to expand access to treatment for those who need it. In recent years, as prescription opioids have become harder to obtain, illicit fentanyl, a cheap, widely available, and potent drug entered the drug supply, making overdoses even more unpredictable and deadly.

According to the Administrator of the Drug Enforcement Administration, fentanyl is the deadliest drug threat our Nation has ever faced. While this hearing is focused on prevention and treatment, we cannot ignore fentanyl's alarming supply chain. It is well documented that China is a primary source of fentanyl precursors and analogs. I joined several of my colleagues on both sides of the aisle in pressing China on its role in the fentanyl crisis on a trip to that region late last year.

These precursor chemicals are shipped either directly to the United States or to Mexico-based drug cartels and smuggled across the southern border before they are pressed into counterfeit pills, mixed into other illicit drugs, or manufactured into powder form.

Any conversation about illicit fentanyl must acknowledge the role of this administration's porous border policies, which have given drug cartels easy access to our neighborhoods and communities. Any efforts to bolster health-care services for treatment and prevention cannot fully remedy the fentanyl crisis unless we also eliminate its supply.

This committee has acted on a bipartisan basis to consider a number of policies that expand access to mental health and substance abuse disorder treatment for those who need it. This includes consideration of the BETTER Act, legislation that was passed out of this committee last fall. A number of policies included in the BETTER Act were recently signed into law, including permanent Medicaid coverage for medication-assisted treatment, expanded access to residential substance use disorder treatment, treatment for Medicaid patients, and guidance to States to improve the availability of substance use disorder services for those enrolled in Medicaid and CHIP.

I welcome continued consideration of policies that improve the provision of care, including through the use of telehealth, which has dramatically transformed the availability and provision of mental health care and substance use disorder services for millions of Americans.

This committee has made a lot of progress in expanding access to care, and I look forward to working with my colleagues on targeted policies that can make a difference and address the root causes of the fentanyl crisis.

Thank you to our witnesses for being here today, and for all the work that you do in our communities. I look forward to your testimony.

Thank you, Mr. Chairman.

[The prepared statement of Senator Crapo appears in the appendix.]

The CHAIRMAN. Thank you, Senator Crapo.

And Senator Crapo has highlighted that this crucial issue, this crucial health-care issue, has always been bipartisan here, and on my watch, we are going to continue that.

I am going to introduce several of our guests, and then I am going to yield to my friend from Washington State to introduce Dr. Caleb Banta-Green, who is doing extraordinary work in the Pacific Northwest with what I think is a breakthrough set of opportunities.

Mr. Vezina is the executive director of the 4th Dimension Recovery Center in my hometown of Portland. He is also a person in long-term recovery. Fourth Dimension is a recovery community organization providing a variety of addiction recovery services to adolescents and young adults.

I would also like to tell my colleagues how it is that Mr. Vezina is sitting in that chair with us this morning. A few months ago, I was shopping in our legendary grocery store in the Pacific Northwest called Fred Meyer. I have had the honor of having a chicken in every Fred Meyer in Oregon; there are more than 50.

Senator CANTWELL. How many?

The CHAIRMAN. There are just over 50. I have been to all of them, and we can discuss that later. Mr. Vezina came up to me a little bit stunned that I was standing there with him, and started telling me some of the things that were crucial in terms of health-care treatment in this area.

It was not politics; it was not the Democrats and Republicans. He said, "This is what we need to do." And so, all of us try when we are home to get out and listen. Mr. Vezina is here because he was in Fred Meyer when I was, and I really thank him for coming.

The next guest will be Dr. Abigail Herron. She is vice president and chief behavioral health officer at the Institute for Family Health in New York. She is board-certified in adult psychiatry, addiction psychiatry, and addiction medicine. These are all going to be excellent witnesses.

And let me go to the end of my list and then yield to Senator Cantwell. Dr. Jeanmarie Perrone is an emergency medicine physician and toxicologist, as well as a professor in the Department of Emergency Medicine, and the founding director of the Center for Addiction Medicine and Policy at the University of Pennsylvania.

She leads a very important program that I have learned about, in the treatment of substance use disorders in the emergency department, and she is also using telemedicine in a very creative way, and we appreciate that.

Senator Cantwell, you have a terrific guest here, and why don't you introduce him?

OPENING STATEMENT OF HON. MARIA CANTWELL, A U.S. SENATOR FROM WASHINGTON

Senator CANTWELL. Thank you. Thank you, Mr. Chairman, and to Senator Crapo, for having this important hearing.

I would like to introduce Dr. Banta-Green, a research professor in the School of Medicine at the University of Washington, and adjunct research professor at the University of Washington School of Public Health. He is also director of the Center for Community-Engaged Drug Education, Epidemiology, and Research within the Addictions, Drug, and Alcohol Institute.

In his role, he leads research to generate evidence-based solutions to the opioid crisis. He also serves on local, State, and Federal working groups and committees related to interventions for those who use illicit substances.

In 2012, he served as Senior Science Officer for the Office of National Drug Control Policy in the Executive Office of the President, and I am confident that his experience in developing evidence-based treatment solutions for substance use will generate much-needed insight during our hearing today.

Dr. Banta-Green participated in a roundtable that we had about treatment models, but his research on what are community-based treatment models and health engagement hubs—I kind of say similar to how Senator Stabenow added mental health to the community, on top of our already-existing infrastructure, so it saved dollars.

But his research on these hubs has shown a 68-percent reduction in overdose deaths. So to me, this is something we need to understand; see if we can implement this. In King County, we lost 1,000 people last year from opioid overdose, so I look forward to the discussion today on how we leverage these opportunities for community-based treatment, so we can get something implemented as quickly as possible.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Cantwell. Thank you for taking the lead in our part of the country. We have been so hard-hit. We are really looking for breakthrough answers, and to have Dr. Banta-Green and Mr. Vezina here today from the Pacific Northwest is terrific.

So let us go right to our witnesses. We will make your prepared statements a part of the record. If you all can take 5 minutes or so, we will begin with you, Mr. Vezina. Again, thank you for that day when you came up to me and said, "We ought to do this." Welcome.

STATEMENT OF TONY VEZINA, EXECUTIVE DIRECTOR, 4TH DIMENSION RECOVERY CENTER (4D), PORTLAND, OR

Mr. VEZINA. Yes; maybe we can get chicken after this. [Laughter.]

The CHAIRMAN. You got it.

Mr. VEZINA. Chairman Wyden, Ranking Member Crapo, and members of the Senate Finance Committee, my name is Tony Vezina. I am the executive director of 4D Recovery. I am also the chair of Oregon's Alcohol and Drug Policy Commission, though my remarks today do not represent these organizations.

It has been 11 years, 11 months, and 26 days since the last time I used heroin or any other substance. On July 19th of 2012, I was arrested at a convenience store in Portland, OR for possession of heroin, and I haven't used since.

I had wanted to quit for some time and had attempted treatment several times before that. My motivation to get sober was simple: it was for my daughter. I had made a promise to myself at a young age that if I ever had a kid, they would not know the isolation and despair I felt as a result of my parents' addiction.

I was born in Idaho, but my mom fled when I was young to Camas, WA to get away from the drugs and crime my father was involved with. I partied in high school like other kids, but unlike some of my peers, I had a predisposition to addiction. A combination of genetic circumstances and my own personal choices resulted in a 9-year opioid career which took off in high school when my mother was prescribed an absurd amount of OxyContin.

Everyone is aware of how OxyContin impacted our Nation, and now we are facing a drug that is much more powerful, addictive, and lacks government oversight: fentanyl, or what the kids that I work with call "fetti." According to the CDC, over 20 teenagers die every week from drug overdoses, and fentanyl is the leading cause of death for this age group.

I can hope my testimony today moves this committee to advance our Nation's response to our addiction crisis, because I know people can and do recover when they are given the tools to do so. This committee can address the crisis in many ways, but I will highlight a few that draw from my personal and professional experience.

Foremost, we need to protect our children by preventing them from becoming addicted in the first place, with primary prevention, and then swiftly intervene with school-based interventions and connections to critical treatment recovery services for those who have substance issues.

I believe we could utilize CHIP funds to bolster prevention and school-based interventions. We can increase Medicaid rates and provide startup funds for new treatment programs. According to the Substance Abuse and Mental Health Services Administration, 97 percent of adolescents with a substance abuse disorder in 2022 did not receive care. And according to the National Institutes of Health, the average wait time for an adolescent residential treatment bed is 28 days. This is unacceptable. We must capitalize on the opportunity to provide treatment immediately when people seek it.

When I was addicted, if I had to wait for treatment, there was a good chance I would not make my appointment, and with the

fentanyl risk of fatality, it is more important than ever to create access on demand. We can increase access to peer-delivered services by allowing Medicaid billing in recovery centers, and also pretreatment engagements.

Recovery centers provide sober social hubs for people in recovery to build relationships and access recovery support groups. I still attend recovery meetings today, and they still keep me sober. Pretreatment peer outreach services allow people in recovery like me to go out and encourage people using to seek help.

We can fund recovery residences, also known as "sober livings." After residential treatment, I moved into a sober house and lived there for a few years. Being around other sober people reinforced my commitment to recovery and provided time for me to go to college, pay off debt, and purchase my first home.

Last, we can increase access to medication-assisted treatments. This is probably the quickest way to address the issue. Some people balk at this proposition because they think it's replacing one drug with another, and I used to think that. But I realized that it is more like other replacement therapies.

Take smoking cigarettes, for example. If a person wants to quit smoking and switch to patches, nobody would say anything. I have a large scar on my left forearm from an abscess I got from injecting Vicodin. Apparently, you cannot do that. While I was in the hospital and I was detoxing from heroin, I begged the medical staff to prescribe me medication, which they did not.

They did, however, later on have a priest stop by, which I did appreciate, but I did not think you could exorcise the addiction out of me. So I left the hospital daily to get well on heroin. If that were me today, the likelihood I would have overdosed would be exponential.

We must provide people with medication-assisted treatment, especially those exiting jail. The vast majority of people in jail have an associated addiction with their crimes. I am not advocating for abolishing jail; you know, it saved my life. But I do think we should rehabilitate people so that when they exit, they can reenter society as contributing members.

This week, a classroom full of American teenagers will die from drug overdoses. You know, I have three kids. They are very important to me. The likelihood that they will have addiction is pretty high, given my family. I just really hope and implore you all to take swift action that expands access to care and ultimately saves lives, because our kids depend on it.

Thank you.

[The prepared statement of Mr. Vezina appears in the appendix.]

The CHAIRMAN. Thank you. You make Oregon proud, and especially Portland.

Dr. Herron?

STATEMENT OF ABIGAIL J. HERRON, D.O., VICE PRESIDENT AND CHIEF BEHAVIORAL HEALTH OFFICER, THE INSTITUTE FOR FAMILY HEALTH, NEW YORK, NY

Dr. HERRON. Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you for the opportunity to speak with you today. As a psychiatrist specializing in the treatment of

addiction, I have had the privilege of caring for individuals with mental health and substance use disorders for the past 20 years. I am the chief behavioral health officer at the Institute for Family Health, which is one of the largest Federally Qualified Health Centers in New York State, where we provide outpatient services for people affected by opioid use.

My career has been defined in many ways by the opioid epidemic, and more recently the rise of illicit fentanyl, which has catastrophically worsened this public health crisis. Fentanyl is a synthetic opioid, a member of the class of medications called opioid analgesics, which are used for pain relief.

While opioids do have legitimate medical indications, they carry a high liability for misuse, because they also produce euphoria. Opioids can cause respiratory depression, which suppresses the body's ability to breathe adequately. In an overdose, this can progress to loss of consciousness, coma, and death. Synthetic opioids, primarily fentanyl, are currently the main driver of deaths due to overdose.

Fentanyl is highly potent, about 50 times stronger than heroin and 100 times stronger than morphine. Taking even a small amount of fentanyl can result in a fatal overdose. Illicitly manufactured fentanyl is inexpensive to produce, leading to the sharp increase in its availability.

Fentanyl is found in illicitly obtained opioids including heroin and is also pressed into pills, where it may be marketed and sold illegally as prescription opioids. It is also passed off as nonopioid substances such benzodiazepines, cocaine, or methamphetamine. When an individual has not used opioids and therefore has no tolerance to the effects of them and they are exposed to fentanyl, the risk of overdose is especially great.

Safe and effective treatment for opioid use disorder, such as the prescription medications buprenorphine and methadone are available. However, individuals can face barriers when attempting to access this type of treatment. Addiction treatment needs to be fully integrated into mainstream health care so that we are prepared to welcome patients and to care through multiple entry points.

At the Institute for Family Health, we practice an integrated care model which allows patients to receive primary care, behavioral health care, and addiction treatment in a shared treatment setting. Colocated, integrated care increases patients' acceptance of behavioral health care and reduces stigma in accessing services.

There are challenges to the implementation and expansion of the integrated care model, however. In New York and elsewhere, same-day billing restrictions on medical and behavioral health services prevent a single provider entity, such as a Federally Qualified Health Center, from billing insurance for a medical visit and a behavioral health visit provided to the same patient on the same day. This creates barriers for patients who face transportation and schedule limitations that can be common in low-income populations. In addition, there is a tremendous need for better reimbursement for case management, screening, and preventive mental health services.

All health professionals should receive education and training in substance use disorders and available treatments. At the Institute

for Family Health, we focus on training the next generation of providers, ready and willing to incorporate addiction treatment into community-based services. We have made treatment of substance use disorders a core component of our primary care residency training programs, and we operate an accredited fellowship program in addiction medicine.

HRSA's Teaching Health Center Graduate Medical Education program supports innovative community-based residencies like the Institute for Family Health programs. Continued funding for this program will ensure that medical, dental, and psychiatric residents receive training in outpatient safety-net provider settings.

The rise of telehealth over the past several years has led to a great improvement in access. In addition to combating workforce shortages, telehealth decreases delays in accessing care, provides expanded availability outside of traditional treatment hours, boosts communication between patients and their clinicians, and enhances engagement and care.

During the COVID pandemic, many restrictions on telehealth services were temporarily lifted, and reimbursement rates were on par with in-person services. It is vital that we maintain these flexibilities, including prescribing medications for opioid use disorder via telehealth.

Telehealth payment parity is also a crucial component of the ability to combat the fentanyl crisis. Full payment parity for telehealth services, and not just coverage parity, will require insurers, including Medicare, to pay for telehealth and in-person services at equal rates. Underserved communities and health center patients deserve access to telehealth. Without payment parity, many healthcare providers will be forced to limit or eliminate telehealth services, because they cannot afford to provide care at reduced reimbursement rates.

Thank you for allowing me this opportunity to share my thoughts and experiences from throughout my career. On behalf of the Institute for Family Health, I appreciate this committee's commitment to combating addiction and expanding access to treatment and recovery. I welcome your questions once testimony has concluded.

[The prepared statement of Dr. Herron appears in the appendix.]

The CHAIRMAN. Thank you very much. We will have questions in a moment.

Dr. Banta-Green?

STATEMENT OF CALEB J. BANTA-GREEN, Ph.D., MPH, MSW, RESEARCH PROFESSOR, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE, SEATTLE, WA

Dr. BANTA-GREEN. Good morning, Chairman Wyden, Ranking Member Crapo, and members of the committee. Thank you for the opportunity to speak about this critical topic, and thank you to Senator Cantwell, my Senator, for your consistent and impactful leadership on addiction.

It is heartening to see the leadership of the Pacific Northwest—Idaho, Oregon, and Washington—really demonstrating their leadership by holding this hearing. As a health services and public health researcher, it is an honor to participate.

My name is Caleb Banta-Green, and I have worked to support individuals and communities impacted by opioid use disorder for nearly 30 years. Over this time, the predominant opiate has changed multiple times, and models of care and treatment medications have evolved.

We have made a dent in the treatment gap—that is, the gap between those with active opioid use disorder and those on the medications methadone and buprenorphine. These medications are the most evidence-based treatments for opioid use disorder. They support ongoing recovery, and they reduce mortality by at least 50 percent.

Unfortunately, the treatment gap persists, with approximately three-quarters of those with opioid use disorder not on lifesaving medications. Opioid treatment programs primarily using methadone, and medical office-based treatment using buprenorphine, are excellent models of care.

Yet, despite our decades of effort to expand these models of care, they continue to serve the minority of people with opioid use disorder. Policymakers and health-care systems continue to improve these two models of care and expand access, but it is clear we need a new third model of care as well.

Nonpharmaceutical fentanyl has exacerbated this need for a new model of care. Fentanyl is a very potent and inexpensive drug that presents substantial risk for rapid development of opioid use disorder and high risk for overdose. Fundamentally, we need to make it easier to access treatment medications than it is to access fentanyl.

As part of our ongoing research, we regularly interview people who use drugs and are accessing overdose and infectious disease prevention services. Our published research shows that 80 percent of people who are misusing opioids do want to stop or reduce their use. Seventy percent do want to be on these lifesaving treatment medications, and yet most are not able to access care in the traditional health-care and treatment systems.

Further, three-quarters of these folks want to obtain health care at community-based programs, at a place they know and with people whom they trust. Over the last 10 years, we and others have been developing and testing new models of care based on clients' stated needs, health services and public health data, and research-supported interventions.

We are combining a low-barrier clinical model with community-based access points and a team-based model of care. To support the treatment medication prescriber, we have added nurse care managers, mental health care managers, and care navigators. These folks provide the majority of face time with clients, and they provide vital supports so that people can start and stay engaged in care.

People recovering from opioid use disorder have served in these medical and care navigator roles, and their insights and ability to quickly build trust with clients have been invaluable. This new care model has positively influenced the care continuum that you are seeing up here.

We are finding that jails and emergency departments that were once hesitant to start people on medications, because they did not

think they would show up for a medical appointment in the next week or two, are now starting people on buprenorphine because they know there is a place in the community providing drop-in access to medications and other supports.

These community-based health hubs for people who use drugs are showing positive outcomes, including in our research with six rural and urban communities across Washington State, where we have had significant increases in buprenorphine use and significant declines in deaths. To date, these programs have been funded with one-time funds including grant dollars.

What we need is a bundled care model, an alternative payment model with adequate funding to pay for the complete care team in these community-based settings. Again, we need the flexibility in locating community care, and adequate funding for the entire care team to manage this complex, chronic, relapsing medical condition.

As one of our clients, an older unhoused woman with long-time opioid use disorder in eastern Washington, told one of our community staff, "I've been in and out of treatment throughout my life, and you are the first people to treat me well. So I keep coming back, and I've brought my friends."

Opioid use disorder with fentanyl is tough, but we have a third model of care that can help us dramatically close the treatment gap, support recovery, keep people alive, and help restore the health of individuals and their communities.

Thank you very much for your time, and I look forward to your questions.

[The prepared statement of Dr. Banta-Green appears in the appendix.]

The CHAIRMAN. Well, Dr. Banta-Green, I am trying to recover my jaw, because it has dropped sort of at the description you have given of a promising new treatment plan. And we are just going to probably turn you and Senator Cantwell loose to get this done, because it is very exciting. I appreciate your being here.

Dr. Perrone?

STATEMENT OF JEANMARIE PERRONE, M.D., PROFESSOR, EMERGENCY MEDICINE AND MEDICAL TOXICOLOGY; AND DIRECTOR, CENTER FOR ADDICTION MEDICINE AND POLICY, UNIVERSITY OF PENNSYLVANIA, PHILADELPHIA, PA

Dr. PERRONE. Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you for inviting me to share my experiences as an emergency physician in a busy hospital in Philadelphia. Although the statistics we have heard today are dramatic, nothing is worse than facing a parent whose son or daughter has been brought to our hospital after a fentanyl overdose.

The struggles of a family battling opioid addiction and navigating the health-care pitfalls in this chronic, relapsing disease are heartbreaking. In the chaos of missed appointments, we recognize that the emergency department can be a gateway to same-day treatment, initiating the first dose of lifesaving treatment with suboxone or methadone.

Multiple randomized control studies have built the evidence demonstrating that treatment with these medications can reduce the risk of fatal overdose by 65 percent. Yet only 11 percent of people

with opioid use disorder receive these medications. Appointments, insurance, transportation, and pharmacies stand in the way.

We started a program to provide these medications in our emergency departments in 2018. My colleagues have been trained in prescribing, and our nurses help to identify and support patients to take that step.

Tuesday, overnight in the emergency department this week at 2 in the morning, I saw three patients with opioid use disorder: one who was seeking treatment was started on methadone; one who had been revived from a nonfatal overdose with naloxone; and one young woman, particularly memorable, who received her first dose of suboxone and was discharged with a prescription alleviating her withdrawal symptoms and with followup to our telehealth program, our peer-led model.

I would have liked to have started her on a long-acting injectable medication, but that is not available. This is one aspect of low-barrier treatment, meaning that the patient does not need an insurance card or an ID and does not need to wait weeks for an appointment or be subject to various scrutiny, all of which can derail early attempts at recovery.

Telehealth has now created a critical safety net, more cost effective than the emergency department and more patient-centered than other care settings. Our CareConnect warmline offers free telehealth substance use navigation and same-day clinician appointments to start treatment with suboxone.

We leveraged our peer-led model to staff 9 a.m. to 9 p.m., 7 days a week. We have now treated over 2,000 patients, including 10 percent of our patients who report release from incarceration in the past 30 days. Implementing this important safety net for citizens reentering the community mitigates this high-risk period and is critical to closing the treatment gap that patients face when they leave carceral settings.

We have also expanded other services for this vulnerable population, including assistance navigating insurance applications, phones, and transportation to future appointments. A Ryan White funding model could be used to establish regional networks of telehealth addiction bridge treatment, to prevent gaps in care and continue patients on medication during care transitions.

We have found that two-thirds of our telehealth patients were recently on suboxone, yet were discharged from a care setting without a timely follow-up, or lost insurance, or faced a life event where their care was disrupted. Experiencing opioid cravings without medications drives patients back to the street, only to face the most lethal supply and, potentially, overdose.

Creating low-barrier models such as telehealth bridges enhances retention. Telehealth can also solve long appointment wait times in rural areas due to provider gaps. We must sustain current exceptions to Federal regulations for telehealth and create billing parity for these services.

Telehealth can also address treatment access disparities. In the Philadelphia area, there has been a 30-percent increase in fatal overdoses in communities of color since 2020. Fentanyl adulteration of the stimulant drug supply has yielded a new cohort of patients with opioid exposures.

Qualitative interviews from our community share that they want more privacy in their substance use treatment options. They do not want to wait in lines outside of opioid treatment programs. We need to focus on developing culturally informed treatment, medication education, and harm-reduction tools to address these disparities.

Telehealth can help establish care with privacy, and then transition patients to a primary care integrated model, where patients can receive their addiction care with their hypertension and diabetes medication, all from one trusted provider.

Our patients transition from our ED or telehealth visits to our primary care practices. This integrated model needs to be expanded and reimbursed to sustain discrete treatment options. This requires investment in clinician workforce, including expanding addiction medicine training in graduate medical education, and support for expanding capacity for more trainees for addiction medicine fellowships.

Our programs utilize the wisdom of peers like Mr. Vezina, who build alliances with patients and help them navigate the early treatment journey. Peer training provides a pathway to employment for people in recovery. We must expand these programs by developing billing and reimbursement strategies for these services.

Their journeys destigmatize and provide role models to our community members struggling with addiction and are a source of inspiration. People do recover, and we need to share that narrative.

Thank you again, and I look forward to your questions.

[The prepared statement of Dr. Perrone appears in the appendix.]

The CHAIRMAN. Thank you. This has been a terrific panel.

Let me start with you, Mr. Vezina, and set the table this way, because this committee has a lot of history in this. We felt some time ago—Senator Crapo and I, Senator Stabenow, Senator Cornyn—that one of the key pieces for the treatment gap was schools, that you really had to get these services into the schools.

So, when we dealt with the gun safety legislation here a couple of years ago, Senator Crapo and I basically had black letter law ready to go that we could give to Senator Stabenow and Senator Cornyn. Those two did a terrific job as we molded this gun safety legislation, in particular to pay for more behavioral health services in the schools. That is essentially what we were able to do, working with the leadership, Senator Stabenow, and Senator Cornyn.

So my question to you is, here you are having battled this for quite some time; what supports and services would have been helpful to you in your youth to ward off the addiction? Just put yourself in that kind of role, because your expertise would be terrific. And as we started talking, earlier in the grocery store, I think we really need to learn from our experiences.

Mr. VEZINA. Sure. Chairman Wyden, Ranking Member Crapo, and the other committee members, thanks for the question. I think there are a few different things we could do in school-based settings. You know first and foremost, like I said, we need primary prevention strategies that educate kids and give them the tools around drug use.

Second, I think we need to educate kids about recovery. When I was in high school and I was using a lot of drugs, there was a wrestling coach at my school. He was really good, and I had found out that he was in recovery from addiction, and I had looked down on him for that at that time, because I had no concept of the disease model of recovery. It was not until I got into recovery and I learned about the disease model, that I realized it was not a moral failing. It was a disease that could be put in remission.

And then I think having peers in schools would be good, to talk to kids who exhibit symptoms of substance use disorder.

And then last, for kids who have substance use disorder that is more chronic and severe, recovery high schools have shown to be efficacious, and I helped start one in Oregon. We have been working with those kids regularly.

Thank you.

The CHAIRMAN. Well, we will be following up with you, because this issue is going to have to be tackled again. And I remember my colleague Senator Stabenow with her Hallways to Health, and that really summed it up. And so, this has been part of our committee's kind of focus, to take our area of jurisdiction where we could have an opportunity to make a difference. And thank you for making the trek.

I know a little about most subjects, but I know everything about airline schedules. It is hard to get here except for our one nonstop.

Question for you then, Dr. Banta-Green. I think you could tell from my comments earlier, I am outraged at the level of abuse with this prior authorization. I think it is being used too often by big insurance companies to basically pad their pockets, and they are not doing what is needed for Medicaid and for patients.

And I know from having talked with Senator Cantwell, you have got some thoughts on this. Give us your sense about what impact prior authorization has on access to treatments (A), and then (B), what should we be doing to get more people opportunities through Medicare and Medicaid—our committee's jurisdiction—to get the help they need?

Dr. BANTA-GREEN. Thank you for the question. You have heard what a life-threatening condition we are talking about—in the moment, every day. You know, people are often using fentanyl 10 or 20 times a day, and every time they are using it is a risk for overdose.

So, any delay in accessing care with these medications—methadone, buprenorphine—increases the chance of death. So that is really the fundamental impact of prior authorization: any delay in care can be life-threatening.

A somewhat more subtle point, but also important, has to do with dosing, and which doses are allowed. We started off with how we dosed buprenorphine in particular at fairly low doses, and the research keeps showing that the higher doses you use, the better folks do. The easier it is to get them started on medications, the better they will stay engaged in it.

If we use low doses at the outset, people may have a bad experience and think that buprenorphine does not work, when perhaps the dosage was not working. And so, it has this unintended consequence in that way. Another aspect of prior authorization—which

we know from an insurance perspective—has to do with moral hazard. We think people are somehow going to over-use or misuse that substance.

That does not make sense in this context. It is cost containment. And one of the really important issues that was brought up about all these long-acting, injectable forms of buprenorphine that can last a week or a month is, these are very expensive, and they are very effective.

We are hearing—it is really emerging in the last 6 to 12 months how much providers and patients are really liking these medications, and doing really well on them. So that cost issue in the long-acting injectables is also going to be a factor when it comes to prior authorization.

The CHAIRMAN. Thank you.

Senator Crapo?

Senator CRAPO. Thank you, Mr. Chairman.

And, Dr. Perrone, in recent years we have begun to see an emerging pipeline of nonopioid medications and devices with serious potential for pain management. In 2022, our committee worked to advance access to these options by addressing problematic reimbursement policies through the NOPAIN Act.

As safe and effective alternatives to opioids come to the market, policymakers will need to continue identifying and addressing potential barriers and disincentives. What steps, legislative or otherwise, do you think would help ensure providers and patients can access these nonopioid options as they come to market?

Dr. PERRONE. Thank you, Senator Crapo, for the question. We have spent a lot of effort decreasing opioid prescribing. We have done a lot of clinician education. There have been policies put in place at the State level limiting the numbers of opioids, which have been very effective. So, a typical prescription might be previously for 30 pills and now is limited to 10.

Those really help us divert from opioids to nonopioid pain medications. Depending on the cost, we have a lot of very effective nonopioid pain medications that were underutilized in the opioid era. Medications like acetaminophen—Tylenol—and ibuprofen are incredibly effective.

I can remember, I was a doctor at a summer camp, and there were young women coming to camp with Percocet or oxycodone for menstrual cramps. So we have moved very far away from the overprescribing of opioids, but there have always been very effective analgesics, like I mentioned, that can actually be used.

If we have new, nonopioid, nonaddictive medications, we would want to use them, but we also want them to be compared to current nonaddictive medications that are very effective.

Senator CRAPO. Well, thank you. And while I am visiting with you, I would like to go to xylazine. DEA Administrator Milgram recently stated that xylazine is making the deadliest drug threat our country has ever faced, fentanyl, even deadlier. While this hearing is focused on fentanyl, I am concerned that the parallel rise in the presence of xylazine, and FDA's warning that it is undetectable using routine toxicology screens, is a problem.

How has this cooccurring rise in xylazine complicated your ability to recommend and provide treatment for patients?

Dr. PERRONE. Thank you again; very good question. In Philadelphia, the fentanyl supply has been adulterated with a veterinary tranquilizer called xylazine, sometimes called "tranq," and it has been convincingly impacting our patient population. It has been associated with wounds, really significant wounds like Mr. Vezina mentioned: wounds on his arm.

We are now seeing a different kind of wound, and these wounds on patients who are housing-challenged really fester and progress, so that when they finally come to the emergency department because they have wounds, they actually need to be hospitalized. And then after hospitalization, it is very difficult to send them to rehabilitation facilities because most of the rehabilitation facilities cannot accept patients with wounds.

So, it is a big Catch–22 that is limiting our ability to get the most vulnerable patients who need the help the most into treatment. However, I do not want to misguide, and I think as Ms. Milgram said in her statement, our deadliest drug is fentanyl. Fentanyl stops people from breathing, and all of the xylazine is accompanied by fentanyl.

So, we still have naloxone that reverses the fentanyl component, so patients do get revived with naloxone. They may still be sleepy, but they're breathing. So I want to keep the focus on fentanyl as the most important drug we need to focus on. We have one antidote that works incredibly effectively. We do not need 10 antidotes.

I do not want to be distracted by all these other drugs coming into the drug supply, because they are really mixed with fentanyl, and fentanyl is the deadliest component of all of this.

Thank you.

Senator CRAPO. Thank you, and well said.

My last question, Dr. Banta-Green, will be to you. In 2023, law enforcement seized a record number of counterfeit pills containing fentanyl, more than double the amount in 2022. While there are many people who knowingly consume fentanyl, I am concerned by the number of fentanyl-involved overdose deaths among young people, despite declining drug uses in that same population.

How has the proliferation of fentanyl-laced counterfeit pills impacted the efficacy of overdose prevention and other harm reduction efforts?

Dr. BANTA-GREEN. Thank you for the question. We are seeing really profound differences in substance use disorder with fentanyl for youth. We have just conducted research, and our preliminary results show that the time from use to developing use disorder for heroin averages 4 years. For fentanyl, it is closer to 1 year, and in many cases, it is months. So it is very, very fast.

I think what it really points to is the fact that we need all of these messages simultaneously. We cannot just be doing prevention and hope that works, and then later move into health education and treatment and recovery. We have to have these conversations simultaneously, so that people are aware of what the whole bundle looks like.

So with youth, we are really looking at this rapid development of use disorder. We are looking at substances that are very potent and of unknown potency, so the overdose risk is very high. We absolutely should be doing overdose education and distributing

naloxone. That will always have a small impact; it is an emergency rescue medicine after an overdose has occurred.

So primary prevention, I would argue—really focusing on physical and emotional pain and building resiliency to those things in youth and their environments to reduce the emotional pain—is going to be really important as well.

Senator CRAPO. Thank you.

The CHAIRMAN. Thank you, Senator Crapo.

Senator Stabenow?

Senator STABENOW. Well, thank you. Thank you so much, Mr. Chairman. Thank you to all of you for really providing excellent testimony.

And, Mr. Vezina, speaking about the stigma and so much around addiction, people just say, "Well, just stop; just stop." The reality is that this is physiological. I mean, it is about health, and your brain changes in its patterns, and so on, as you know.

And so, this is something that involves treatment and support for people to be able to make the changes. So, the rise of fentanyl has had a devastating impact, as we have been talking about this morning, and certainly had a devastating impact in Michigan.

In 2023, we had about 3,000 Michiganders who died of a drug overdose, and three out of four of those were related to fentanyl. So, it is pretty scary what is happening right now, and it does not even come close to encapsulating the pain and the tragedy Michigan families have faced, as I know families have faced across the country.

So we know that, among other things, this is an all-hands-on-deck moment for treatment, access to treatment. In addition to what we have done moving forward in schools and the legislation we passed in Safer Communities, we have begun to transform behavioral health care in the community by fully funding Community Behavioral Health Clinics on the exact same model as Federally Qualified Health Clinics.

So, the FQHC model—full Medicaid reimbursement, prospective payment, and so on—we now have 10 States, as hopefully you know, that are fully funded through Medicaid. In a couple of weeks, 2 or 3 weeks or so, the next 10 States will be announced. And then we will keep going and going until we have every State having the opportunity to have fully funded clinics—not just individuals, but the cost of the clinics. It is so important.

So, I do want to just note that, of the clinics that we now have, 82 percent of the behavioral health clinics offer at least one form of medication-assisted treatment for opioid use disorder, compared to 56 percent of other types of clinics. So these are comprehensive clinics. We want to see them all over the country, and I'm anxious to work with all of you to do that.

And so, Dr. Banta-Green, I wondered—you talked about comprehensive community-based care in your testimony. I turned to Senator Cantwell and said, "He is describing CCBHCs, Certified Community Behavioral Health Clinics," because that is what we are talking about: primary care, comprehensive care, addiction and mental health services—whoever walks in the door, regardless of payment method, and so on.

But I wonder if you could speak a little bit more about Community Behavioral Health Clinics, in terms of their role in closing the gap for opioid use disorders.

Dr. BANTA-GREEN. Thank you very much for the question. They are really providing a very important access point for many folks, and I think particularly folks with serious mental illness. I think there is just a huge gap for those folks. It is very difficult for them to access care, and I think in particular, that is such a wonderful access point for them.

So, I think that is a great thing that is happening there. It is a little—it overlaps and it is a little bit adjacent to the model that I am describing, which is a bit different. We are sort of purposely not using a clinic-based model. We are really going into community settings, programs that are serving folks who are unhoused, really getting out into these community-based programs where folks already go, they already have a relationship.

So it is a bit different in that way, and there is also quite a bit of focus on infectious disease testing and treatment, which is very important. And we are working toward hepatitis C elimination and the great medications we have for HIV. So there are definitely some parallels, but there are some distinctions as well.

Senator STABENOW. Well, I think both are necessary. I think it is terrific what you are doing. I would love to see a comprehensive model that involved full funding—the capacity for both—which is what we should be doing.

And I would just say quickly, as my time runs out, that, Mr. Vezina, you talked about access to recovery services for young people. Could you speak any more about school-based support for—we have health clinics in many places, but not necessarily mental health and addiction services. And sort of broadly, what more should we be doing?

Mr. VEZINA. Yes; thank you so much. It is a really good question. I would start off by saying we could educate teachers. Teachers spend a lot of time with our children, and they need to be equipped with the skills to identify and then properly refer kids to where they need to go.

Now, depending on the severity of the disorder, it could be treated, eliminated, inside the school, or they are going to need a referral out to a more specialized service. And so, one thing that we see in Oregon is that there is not the comprehensive care for kids.

And so, they may have some comorbidities with mental health and addiction, but there are not services to serve them, so they end up in places where the providers do not have the tools for it. So we need to bolster kind of the entire system of care and then intervene with kids in schools and get them at the appropriate level that is going to serve them best.

Thank you.

Senator STABENOW. Thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. And thank you for your years of work in this area, Senator Stabenow, and particularly with Senator Cornyn.

Senator Grassley?

Senator GRASSLEY. We hear this figure of 107,000 Americans dying from a drug overdose. We learned just last week that more

than 321,000 children have lost a parent to a drug overdose in the past decade. I am working to tackle the illegal production and distribution of this deadly drug fentanyl from multiple directions: through legislation to close loopholes, putting pressure on the Biden administration to enforce the laws, holding adversaries like China accountable, and securing the southern border.

As cochair of the Senate Caucus on International Narcotics Control, I am fighting to permanently classify fentanyl knockoffs. Throughout much of the opioid epidemic, drug kingpins have laced heroin and other drugs with highly potent fentanyl. We must do more to proactively step up to stop the spread of that.

Now I am going to follow up a question that Senator Crapo asked about xylazine, and I am going to ask Dr. Perrone and Mr. Vezina this question. First of all, I am leading a bipartisan bill that recognizes this lethal threat and provides law enforcement with tools to combat it.

Because it is a sedative and not an opioid, its effects cannot be reversed by naloxone. That is the standard opioid overdose treatment. So, to you two, what effects have you seen in Philadelphia and Oregon on drugs laced with xylazine?

Dr. PERRONE. Thank you for that question. As I think I alluded to, it is a little bit confusing, but fentanyl and xylazine are always going together. So 99 percent of our exposures are fentanyl and xylazine. When a patient is resuscitated from that kind of overdose with naloxone, they will wake up, they will restore breathing, and they will be revived.

They may be sleepy for a couple of extra hours, and so the time to bring them to an emergency department to support them, to have a peer like Mr. Vezina talk to them when they wake up, is really valuable. There has been a lot of talk about antidotes for xylazine. I do not think that that is necessary.

To make an analogy, there are medications like valium and Xanax, which are benzodiazepines. They are not opioids. They make patients sleepy, but they do not stop people from breathing. We have an antidote for that, but we do not use it because it would immediately cause withdrawal, which might be life-threatening.

So, we have other antidotes for medications that cause sleep, but we do not use them. So really, I want to focus back on naloxone and fentanyl. Those are the deadly drivers of this epidemic. Fentanyl is the cause of people stopping breathing and dying.

That is the 107,000 number, the 80,000 number—we need naloxone, and we need to focus on fentanyl. Xylazine has been a problem, but I think it has been a little bit overestimated relative to the huge impact that fentanyl continues to make.

Senator GRASSLEY. Can you add anything to that, Mr. Vezina?

Mr. VEZINA. Yes; thank you so much. What I would say from engaging people in the recovery process, most people that we work with are not targeting xylazine as their drug of choice. Like the doctor said, it is just included in the fentanyl, and what I have heard is, the strategy is to extend the legs of fentanyl. What that means is to extend the effect.

You know, fentanyl wears off really quickly. When I was using heroin, it would last me about 6 to 8 hours before I would start to go through withdrawals. With fentanyl, people are having to use

every hour, and so I think it is a method, to put xylazine in there, to extend the effect.

And so, I think we need to focus on what can we do to help people discontinue fentanyl use. And again, medication-assisted treatment is probably one of the quickest and most efficacious ways to give people a chance to recover.

Thank you.

Senator GRASSLEY. To the same two of you, this: a few years ago—I suppose about 5 years ago, when I was chair here—I held a hearing that included a discussion on distinguishing between good treatment providers from bad treatment providers.

Since then, the Federal Government has published best practices and guidelines for recovery providers. Five years later, have we gotten better at weeding out good treatment providers from the bad ones, and if not, why are ineffective efforts and unaccountable treatment providers still in business, and what should be done about it?

Dr. PERRONE. The terms "good" and "bad" are difficult, but I would say that it is easy, if any of us had a child who was suffering from addiction, to think that you want to send them somewhere and get them off of everything. That is kind of a detox abstinence model. You may have friends or relatives who have gone through treatment for alcohol. That is an abstinence-based treatment model, and that is very effective for alcohol. For opioid use disorder, we desperately need these medications. Patients may succeed in becoming detoxed off of their opioids, but within days to weeks they will have cravings, and they will get back to that drug.

The death rates after treatment in rehab facilities that do not offer medications are incredibly high. We know that the evidence basis supports methadone and buprenorphine. So we can incentivize only reimbursing places that offer these medications.

In addition, these places might offer the medications, but the patient alone may say, "I do not want that. I do not want to substitute one drug for another." So we need to reeducate both treatment providers and patients in our communities, because there is such a push to abstinence that people just do not understand the evidence.

And that is on us, clinicians, to continue to educate everyone. It is an immediate instinct to think you do not want someone on any medication because you want them detoxed. But that is really just ineffective, and our evidence really suggests we desperately need medications.

The long-acting injectable medications that persons would get once a month, would decrease their need to take a medication every day, and that really is supported as well.

The CHAIRMAN. The time of my colleague has expired.

I do want to brag a little bit about Senator Grassley. He mentioned when he was chairman, some tall guy from Oregon—kind of obscure—was his ranking minority member.

Senator Grassley put together a very important report that looked into the whole question of tax-exempt entities helping to drive up opioid sales, while downplaying the risk of opioid addiction.

In all seriousness, I was pleased to be able to join you as the ranking minority member, and I ask unanimous consent to put Senator Grassley's important report into the record at this time. Without objection, so ordered.

Senator GRASSLEY. Thank you.

[The report appears in the appendix beginning on p. 70.]

The CHAIRMAN. Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman, and thank you again to the witnesses.

Dr. Banta-Green, from 2022 to 2023, Washington State saw a 34-percent increase in drug overdose deaths, which is the single highest increase in the United States. Overdose is now the leading cause of accidental death in our State, outnumbering firearms and car crashes.

Out of a report, "Drug Overdose Deaths in 2022," 70 percent involved synthetic opioids like fentanyl. So I definitely appreciated your opening statement about this model that Washington State did as a demonstration program. It became impressive with the number of results that I think you say are—well, it implies that if King County had those hubs in operation last year, the hubs could have saved over 600 lives.

But you are saying there has been a 68-percent reduction. I think, almost to Dr. Perrone's point she just made, if you are not into the treatment, then you are not into a solution basically, because it is such an addictive product.

So, one of the things that you discussed in your testimony was that low-barrier, community-based models and bundled care basically solved two problems. One, they got people into immediate treatment, and they got everybody else in the system, including the jails, to start this process with you. So basically, from the time of interaction with an individual, we now have them on a path to treatment.

And then second, that bundling of care with those care navigators also provided a support for the system. My guess is though, we do not have all the numbers from your results.

We do have the information about how many lives are being saved, but my guess is that this also is cost-saving. While it might sound like a bundled care payment is similar to what Senator Stabenow has done on community-based care, you are literally saving dollars, because now you are not seeing the same people over and over again.

You are definitely not seeing them in the emergency room. You are definitely not housing them in our jails. Could you speak to why this prospective payment model—I want to thank Senator Cassidy though before you comment, because he has agreed to help us demonstrate this also at the Federal level. He has done great work on methadone oversight and trying to make sure that our clinics expand on those issues. But could you talk about why this prospective payment system is so important?

Dr. BANTA-GREEN. Yes. As you are hearing, we really need to allow people to access care rapidly and stay engaged. The process of recovery for alcohol and cannabis generally takes about a year, per research from John Kelly. For opioids and stimulants, it is about 3 years.

And during that process of recovery, people are often returning to use, and they continue to use substances. So we need a place where people can start today and come back tomorrow no matter what. Just like the woman I was describing in our program earlier, she kept coming back because she was treated well.

We had another client tell us, "In previous treatment programs, when I relapsed, I did not go back to treatment, because I knew they were going to kick me out. But this time when I relapsed, I came back to care, because I knew you were not. I knew you were going to keep caring for me."

So this model of care, this easy access no matter what, this open door while people work on building their recovery over years, is really vital. And that takes the people and the place, and it takes the model of care. It is all of those things together.

That stat to me is particularly exciting, because we hear these statistics—around a 50-percent or a two-thirds reduction in mortality. This was a population that was largely unhoused. This is a very vulnerable population. And these statistics—the way we did our analysis is actually compared to other people who were in standard models of care and also got medications.

So this reduction in mortality is really around high-risk populations getting this complete model of care, and that is what is really exciting, and why we need to package those things together.

Senator CANTWELL. And we are basically though tying into existing infrastructure, which is also the cost savings of the model.

Dr. BANTA-GREEN. Right, and if you think about the cost savings, we are building on existing infrastructure. We are adding in things like nurse care managers and care navigators, which can be very difficult to bill for. There can be ways to bill for them in certain settings for certain types of conditions. But here, they need to be sort of universally folded into this bundle of services that are getting paid, because they are the glue. They are the ones who are doing all of this face time.

There have been multiple research studies that have shown prescribers will see a lot more patients. They will start seeing any patients, and they will see a lot more patients if they have these care supports, because it makes their job easier, and their patients do better.

Senator CANTWELL. So, it is also—you are just saying it is more streamlined. The whole system is streamlined.

Dr. BANTA-GREEN. So, it is more streamlined. We haven't even talked about the savings when you are actually able to intervene, test, and treat someone's infectious diseases. I mean, there are a lot of things that we are doing here. It is not just treating the opioid use disorder. Opioid use disorder almost never occurs in a vacuum. You know, it is also the reason that we are able to bring people in who have mental health issues, who have infectious disease issues.

We are going to realize those cost savings. They no longer need to be stealing in order to obtain their substances. So there are lots of different ways that we obtain those cost savings.

Senator CANTWELL. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

I want to make sure everybody understands that the package that we produced in terms of what to do for kids and for treatment and prevention did not happen by osmosis in 2022. Senator Cornyn was particularly valuable as it related to schools, and I remember you and I talking about telemedicine provisions in terms of helping these kids, which largely came from Senator Carper.

So, Senator Cornyn, you are on, and we thank you for your past effort to make sure that the Republican leadership was a key part of getting this done. It was a real breakthrough.

Senator CORNYN. Well, thank you for that testimonial, Mr. Chairman.

The CHAIRMAN. I hope it does not hurt you. [Laughter.]

Senator CORNYN. Thank you all for being here and for your contribution to our understanding of what is an extraordinarily complex problem. I remember H.L. Mencken was quoted as saying, "For every problem, there is a solution that is simple, neat, and wrong." And so, I think we need to look at the whole problem and not just parts of it, and we have tried to deal with the mental health aspects of it.

Obviously, we are talking today about treatment issues. It is important, I think, that we treat the people who are suffering from these addictions with compassion. And, Mr. Vezina, I just want to congratulate you personally, not only for your personal recovery, but your example to show other people that it is possible, and that ought to be a source of hope and inspiration to others.

But there is something called the law of supply and demand, and every time I go to Mexico City or somewhere like that and complain to the Mexican Government about the drugs that come across the border, they say, "Well, if there wasn't a demand in the United States, then there wouldn't be a supply."

What can we do to address demand? Nancy Reagan had an answer: "Just say no." But that, I do not think, turned out all that well. So, what could we do to address demand? Any of you.

Dr. PERRONE. Thank you for that question. I thought a lot about this in thinking through an answer. I think that, you know, we have two problems. Right now, we have an abundant supply based on the price. The drug is incredibly cheap, and so it is everywhere, and that is actually driving some demand because they are putting fentanyl in other drugs including stimulants and cocaine.

Many of the patients that we see who are now becoming addicted are becoming addicted because, unintentionally, they were exposed to these substances. So a big supply problem. I think demand can be mediated primarily by medications for opioid use disorder for patients who already have fentanyl dependence, as well as, I think, primary prevention, which is very complicated.

You know, Mrs. Reagan's "just say no" program was not effective. I think we need to trust adolescents to understand within their own communities how they want to take this on. You know, for adolescent drug overdoses, if you look at who is overdosing, a third of the patients have a substance use disorder. A third of them have a mental health condition and are just self-medicating with what they think might be Xanax, and it contains fentanyl. And then a third are actually just overdoses that are part of the inadvertent supply.

So we need to take those patients, those adolescents, and learn from them and empower them to educate their own communities with, obviously, more guidance about primary prevention. So we need to listen to our teens and figure that out.

Senator CORNYN. Well, in my much more limited experience talking to parents who are grieving the loss of their children, public awareness, both of the individual who consumes the drug unwittingly—maybe they think they are taking something else, only to have it contaminated with fentanyl—but also parents and schools educating their students; that is, as the DEA's slogan goes, "one pill can kill."

But it strikes me that we cannot just look at the treatment side. We have to also look at the supply side, and unfortunately, we have seen a tsunami of human beings coming across the southern border, which is actually part of the business model of the cartels. They get rich for every person they can smuggle across the border, and then, when the Border Patrol are occupied with processing migrants, maybe unaccompanied children and the like, then here come the drugs that killed 108,000 Americans last year alone.

I was just looking at the statistics, and in the last 3 years, about 200,000 Americans have lost their lives due to fentanyl poisoning, and it seems to me we have been extraordinarily naive and unsuccessful in dealing with the supply side, primarily because our border is not controlled.

And if you go to places like Colombia, for example, typically the source of cocaine or the heroin that comes from Mexico and elsewhere, they say that their market share of those drugs is actually going down for the very reason that you mentioned, Doctor. It is because fentanyl is so cheap. You do not have to grow a plant. You do not have to process it. You just mix up the precursors in your sink or wherever, make it look like a Xanax or Percocet, and there you go.

So, I think we have to look at the supply, which also includes interdiction of those drugs coming across. I am not suggesting that is the only answer. Obviously, it is a very complex set of circumstances. But to just look at the treatment without the supply, I think does not address the whole problem.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Cornyn.

Senator Carper?

Senator CARPER. Thanks, Mr. Chairman and Mr. Crapo; thanks to you and our ranking member for pulling this together, for this important hearing.

Sometimes when witnesses come before us, they actually bring a member of their family, and they sometimes will actually ask to introduce members of their family.

But I am not going to do that today. It is pretty easy, Dr. Perrone, to find the one who—because she looks just like you, and she is sitting right behind you. So, we are watching to see if her lips move when you speak. We will see who is calling the shots here. [Laughter.] But welcome to any other family members who might be here today. Welcome.

The substance use commonly, as we know, usually, oftentimes begins during adolescence and compromises the well-being, com-

promises the safety and the development of our young people. When it comes to health care, I have long believed that we have to meet the people where they are, and for our youth that is in schools in many cases.

During the time I was privileged to serve as Governor for 8 years before I came here 22 years ago, I was proud to put a school nurse in every Delaware public school, and a wellness center in just about every high school in Delaware.

Mr. Vezina, you stated in your testimony that people with substance use disorders can recover when they are provided the tools to do so. I think that is what you said, and I would just ask, Mr. Vezina, could you please speak further to the importance of school-based supports in providing adolescents the tools they need for the prevention and treatment of opioid use disorder?

Mr. VEZINA. Yes; thank you so much. You know, I would just reiterate again that we need to prevent it from happening in the first place. And from my limited understanding—I do not run any prevention programs, but I do work with a bunch of prevention advocates in Oregon, and they always make sure I say "primary prevention," not preventing overdoses.

They do not have necessarily a reimbursable service model like treatment does, and so it is hard for them to get their services up and running. And so, I would ask this committee to figure out a way to fund primary prevention for organizations to go out and educate our kids and build resilience in our kids.

There is one private organization that I work with that I am on the board of called "A Song for Charlie." It is led by two parents who lost their son to fentanyl. They have done incredible work with educating kids around the dangers of fentanyl.

I recall a study before around the naivete of children with fentanyl, where they thought cigarettes were more hazardous than fentanyl, and that is a big problem. So we need to educate our kids and give them the tools not to use. And again, when they do develop the symptoms of a substance use disorder, we have to be able to intervene and then get them to the services that are going to best fit them.

And right now, at least in Oregon—and I assume it is like this across the rest of the Nation—there is not an infrastructure for adolescent care. From my understanding on the Medicaid side, it is two parts: one is regulatory and administrative burdens, and the other part is low reimbursement rates for care. Those two things disincentivize individuals like myself who have run treatment programs from opening up care for kids.

Thank you.

Senator CARPER. Okay; thank you.

I am going to follow up my question I just gave you with a question for the record, and I would appreciate your comments there.

A question on workforce readiness. In recent months, not only has our health-care system in Delaware seen a greater number of patients being treated for suspected overdoses, but there has always been a significant increase in the severity of the effects of overdoses. This severity is reflected in a greater percentage of overdose patients needing a higher level of care, including intubation, and requiring admissions to intensive care units.

Dr. Perrone, my question is, can you speak to why we are seeing such an increase in the severity of the effects of overdoses? How can we work together to ensure that our first responders are best equipped to address this growing crisis?

Dr. PERRONE. Thank you for that question. The question was, why are we seeing an increase in serious consequences of overdose, and I think that goes back to these mixed substances.

So, a patient who overdoses on a typical bag of what somebody thinks is fentanyl now contains three or four other drugs, including xylazine, especially in Delaware where, you know, the radius of xylazine concentration certainly extends to the Delaware area.

So, patients may be quite sleepy after an overdose, despite the fact that they got some naloxone. Their respirations or their breathing might have been adequately restored, but in the setting of continued sleepiness or somnolence as we call it, they may undergo intubation. And once they have intubation, meaning that they are on life support, then they end up in the ICU because that is the only place in the hospital where we can manage people on a ventilator.

They might be able to not be intubated and be managed in an emergency department, but frankly, we have such boarding issues in the emergency department. We are filled to the gills, 100 people in the waiting room. So sometimes moving a patient who might be critical for the emergency department to manage back to the ICU because they are intubated, is a good strategy because the emergency department needs to manage new patients coming in.

And so, I think for EMS, we need to continue to advise them to use naloxone. They have the airway management skills. And when a patient comes to the hospital, we could probably manage some of them very closely without intubation and allow them to wake up on their own.

Once you are on a ventilator, we actually often need to give you additional sleepy medications to keep you on a ventilator. So, it is a little counterintuitive. But we need new research looking at these mixed substance overdoses and the best way to manage them.

Senator CARPER. Thank you very much.

The CHAIRMAN. I thank my colleague.

Mr. Vezina, very important point about getting the architecture right for getting information to kids in schools and the like. We are beginning to build it. I have been getting out and talking about the benefits of the 2022 law in terms of Medicaid.

But since you are here and you are doing so well, we are going to get you involved in building out that architecture too, because I think you said it very well.

Senator Cassidy?

Senator CASSIDY. Dr. Perrone, in my medical practice—I am a doctor too. In my medical practice, I worked in a hospital for the uninsured and the poorly insured, which is a euphemism for Medicaid.

I am recognizing that Medicaid, although it is coverage, oftentimes pays so little that, frankly, people do not take it. So, knowing that Medicaid is financing a lot of these treatment programs, but as a poor payer, your business model somehow has to accommodate for that. It might be a community health center, et cetera.

If you look across our 51 jurisdictions, what is the kind of uptake? Relate to me on some sort of a graph, if this is Medicaid and this is the number of treatment programs relative to population, how good is Medicaid doing in terms of encouraging people to provide these programs?

Dr. PERRONE. Thank you for that question. You know, we work in a model where we are primarily—all of our patients are Medicaid or no insurance, so we rapidly get them on Medicaid. And fortunately, in Pennsylvania, we do have pretty rapid access to Medicaid.

Whether or not that reimbursement is sufficient, it certainly is not. You know, I work in an academic medical center where the mission pays for——

Senator CASSIDY. So you have less—you have some sort of subsidy for good human work?

Dr. PERRONE. Yes; yes.

Senator CASSIDY. Now that said, then my question is not on the particular, but rather on the statistical. If I were to look at the average among States on a per capita basis—and the capita is the number of people who need treatment. And knowing that many of these are Medicaid patients, how well is Medicaid doing in terms of financing this care?

Dr. PERRONE. That is a difficult question for me to answer. I can say Medicaid is the largest purchaser of addiction services in the country. But I do not know what the gap is in terms of people who are not getting appropriate addiction care.

Senator CASSIDY. Can you just speak in general then about what is the—well, okay. Let me just kind of drop that.

Mr. Vezina, again in my medical practice, I used to treat patients in jails. I used to go to the prisons, so I am aware of all this.

I am aware that somebody who is currently booked into jail loses Medicaid benefits before being adjudicated. And so, they may not have been guilty, but they still lost their Medicaid, and they have to go through the whole rigamarole to get back on Medicaid.

Now, something that we are working on in this committee, Senator Wyden and I—two bills. One, the DUE PROCESS Act, which would allow 7 days of coverage or 14 days, depending on the version, for somebody with substance abuse to continue on Medicaid once put into a jail. And then the Reentry Act, which would allow the enrollment in Medicaid 30 days prior to discharge from a prison.

So, any comments from your, kind of like, living the experience, how might this help somebody either initiate or continue therapy once on the outside, to aid that transition, or never lose Medicaid so they never lose the coverage that they would like to have?

Mr. VEZINA. Yes, thank you so much. In the most general terms I would say, you know, jail serves as a rehabilitation place.

Senator CASSIDY. It serves as a rehabilitation place?

Mr. VEZINA. Right, and so we would want the services in the jail, however we pay for them. That would give people rehabilitative services. And knowing that the majority of people in jail have a substance use issue and a lot of times that drove their other criminal behavior, we would want to address that first and foremost. And so, in the county jail systems, a person loses Medicaid, and

then the jail has to pay for the services. I am not an expert on the criminal justice budget, but I feel like they do not have the money to pay for adequate services.

And so, leveraging Medicaid match for those behavioral health services would be ideal from a cost savings perspective. And then in prisons—I have been working with some guys in prison. From what I understand, adults in custody are not eligible for treatment until 6 months before they leave.

That does not make a lot of sense to me, because you'd think you would want to treat them and get them support right when they got there, so that they could——

Senator CASSIDY. Hang on. But if somebody is in a prison, therefore they are at least incarcerated for a year or more.

Mr. VEZINA. Right.

Senator CASSIDY. Theoretically, although we know there is lots of contraband, they would not have access. Granted, as Dr. Perrone says, that does not mean that they will not go back, but in prison they will have less opportunity to go back.

Mr. VEZINA. Yes, you would think that, but that is just not the case. And so, what I would say is that we would want them to have access to treatment right away.

Senator CASSIDY. Do we know from data the degree of fentanyl overdose within prisons?

Mr. VEZINA. I am not able to answer that question today, but I will say that it has been a problem in Multnomah County that I am aware of, to the point where there is a passing of the torch of who is going to help people who are addicted. So jails may be less hesitant to take people if they have a risk of overdose.

Senator CASSIDY. I am out of time.

Dr. Herron, I had a question for you, but instead I have kind of a critique. One of my favorite employees is sitting right behind you—you stole him from me. I'll forgive you for that, only because I want him to have a great opportunity. But again, thank you for your good work, and, Mandar, great to see you, man.

I yield.

The CHAIRMAN. Thank you, Senator Cassidy. Our work is going to continue in this area relating to prisons, and particularly because we have some exceptional sheriffs and law enforcement officials in southern Oregon working with their State Representative, Pam Marsh, on exactly the questions that you are raising about this whole kind of proposition.

Because of the nuts and bolts of this—we are getting the Medicaid match and all these related issues—you are going to be a busy guy, Mr. Vezina, because this committee is going to keep you, as an Oregonian, active on these issues, and I look forward to it.

Senator Bennet?

Senator BENNET. Thank you, Mr. Chairman, and thank you to you and the ranking member for having the hearing. Thank you all for being here today and taking time out of your schedule to be here.

Let's see. Dr. Banta-Green, I am not going to pick on you, but I have a question for you. The opioid crisis continues to devastate Colorado communities, especially our kids. Last year, Colorado tied New Mexico for the second-highest number of fentanyl pill seizures

in the country, and Colorado has the second-highest youth overdose rate, more than double the national average for kids between 14 and 18.

Today in Colorado, and I would say across the country, students are petitioning their school boards to allow school nurses to provide naloxone in their office because without it, their friends might die before an ambulance arrives.

I once was the Superintendent of Schools in Denver. It was not that long ago, and that is not what kids had to spend their time doing. But it is what they are spending their time doing today.

When I heard a student had died back then—and it would happen from time to time when I was Superintendent—I used to ask whether that child had been in a car accident or whether she was dying of cancer. But now when I hear a child has died, the question that I ask myself is, did they die from guns, did they die from suicide, or was it a fentanyl overdose?

Like tree rings, you can see—you know, at least I can—that there was something very different about the world when I was running the Denver public schools 15 years ago versus today, and especially for our kids.

Historically, treatment for substance use disorder wasn't focused on kids. It is clear to me that we need to do more to address teen substance abuse. So, Dr. Banta-Green, could you identify gaps in treatment or services for young users in this country, and how do we recalibrate our approach, particularly under the Medicaid program, to account for the rise in youth substance use disorder?

Dr. BANTA-GREEN. Thank you for the complex question. A few things I will note on that. So, in terms of schools, I understand why we want to work in schools. We know where many youths are, and that is an important place to do this work. We need to do this work in schools and support them.

We of course need to look at the social determinants of health upstream of that, out in the community. How do we support those families so they can have their own resiliencies, so they can identify and address physical and emotional pain?

There is this idea in schools—and I have done many trainings with school nurses about naloxone. Naloxone is great. Naloxone is the floor of what we should be doing. Naloxone is the gateway drug to talking about opioid use and opioid use disorder. Those same school nurses have to know that this is a treatable medical condition, and that buprenorphine will reduce mortality by over 50 percent.

It is appropriate and authorized for adolescents, so it absolutely should be used. We run a learning collaborative once a month for adolescent medicine providers around treating opioid use disorder. We have about 30 to 40 prescribers showing up from across our State. So that is very important.

And then I just cannot say enough about what Dr. Perrone said. If you think about these different time horizons—okay, they have opioid use disorder. We know what to do. But why are they using opioids? So, in the moment, they are often using in the context of peer pressure. But what we find often is really in the context of the same reason that adults are using medications, which is pain, anxiety, and sleep problems.

Identifying those, and having those resources in schools, is going to be very, very important, and then there are the upstream factors as well. But those are just a couple of things to think about with adolescents. We have to again be thinking about what are all of the different opportunities to intervene.

Senator BENNET. I would like to talk about, what I think, is a crisis that we are facing as a country. Teen suicide is at an all-time high. Children's emergency room visits for mental health have increased by 140 percent over the last 5 years. In 2021, 40 percent of Colorado's high school students reported persistent sadness or hopelessness.

To Dr. Banta-Green's point, Dr. Perrone's point, Colorado psychiatrists tell me in all their years of practice, nothing has affected kids the way that social media has affected kids. Parents and teachers tell me they feel absolutely hopeless to address it. And I do not think that we can lay this all at their feet, but when people ask me what is different about schools today than when I was there, the answer is mental health, mental health, mental health.

You can chart it back to when everybody ended up with one of these phones in their hand, and social media is—one of the leading law enforcement officials in America told me recently that social media is the last mile for every fentanyl and meth death in America.

Dr. Herron, could you elaborate on the intersection between the mental health crisis and increasing substance use among our youth, as Dr. Banta-Green was talking about? I am going to stop there because I am out of time. So, if you could just take a second, and then I will turn it back over to the chairman.

Dr. HERRON. Thank you for the question, Senator. We see the intersection between mental health and substance use disorders as the primary focus of someone like me as an addiction psychiatrist. The majority of individuals in either treatment setting are contending with the other type of disorder as well.

So, if you look among mental health treatments, we see a large group of people with substance use disorders and vice-versa.

But primary prevention—where we teach people to recognize that the feelings that they are experiencing, the anxiety, the pain, are an illness, and there are treatments available—is essential. And also, pushing those services into school-based mental health treatment models, into pediatrician offices, into family medicine offices, so that there is a recognition and an ability to treat those things before they get into adulthood, before they have more exposure to substance use, is really essential to helping to impact the crisis.

Senator BENNET. Thank you.

Mr. Chairman, thank you. I apologize for going over.

The CHAIRMAN. Well, I want to apologize to our colleagues, because we are doing some juggling here. If we could, let's go with Senator Barrasso and Senator Brown. Nothing is going to get in the way of that order.

Senator Barrasso?

Senator BARRASSO. Thanks so much, Mr. Chairman. This is a critically important hearing. I am so glad you are calling this.

I just heard from Dr. Cassidy, a physician as well as a member of the committee. I am a physician as well as a member of the committee. Both of us are concerned, as we all are, about the health and safety of our Nation—truly alarmed by the fentanyl crisis facing our Nation. Clearly, nothing like that existed when I was practicing medicine. It is everywhere. No community is spared. A lethal dose is equivalent to just a few grains of salt.

You know, across the country, the number of deaths has been skyrocketing. In my home State of Wyoming, you would not think there would be a problem there. We have had 81 opioid-related overdose deaths this past year. It is double the number from 5 years ago—completely unacceptable. It is touching every community across our Nation. You've got mothers, fathers, brothers, sisters, all losing family members. I hear about it all around the State.

Since President Biden took office, nearly 10 million illegal immigrants have flooded into our Nation—Senator Grassley touched on this a little earlier today—77,000 pounds of fentanyl confiscated at the border over that time. You do not know how much got through, but you can imagine, just based on the statistics and the deaths, the number is high.

Whether it is from China or Mexico, the transnational criminal networks that are producing, transporting, and marketing these drugs are poisoning our country. Our Border Patrol agents, who are supposed to be our first line of defense in apprehending the drug smugglers, they cannot get their job done to the level that it needs to be done. They are being forced, I believe by this administration, to deal with unaccompanied minors, asylum-seekers who are surging across the border, which is making an increased opportunity for the criminal cartels to get more drugs across.

Mr. Vezina, I read your story, heard what you had to say. I really appreciate your ability to be here to speak on substance use disorder care, because that is what we are looking for. Care is needed now more than ever. Today, you have spoken about the challenges that folks in recovery face when they do not receive a full continuum of services.

It is not like there is one silver bullet on this. You need the whole thing. Your experience as someone in recovery, someone providing collaborative care, says that you need a network: mental health counseling, substance use counseling, peer support, case management, medication-assisted treatment—all of those things.

So, given the frontier nature of my home State of Wyoming, people are spread out. You do not have all of those services available everywhere. There are only two towns with a population that can support this level that you have described in the specialty care. There is even less availability for youth-focused programs like yours.

Are there existing programs, either State or Federal, that you are aware of, that can help in rural communities where you do not have that full continuum, even though we know that is the best treatment?

Mr. VEZINA. Yes; thank you so much. From what I can tell you in Oregon, telehealth services have been able to meet some of the gap. So, figuring out ways to fund telehealth services—there are

also some restrictions in kind of geographic capacity that providers run up against when they are not reimbursed for that. Sometimes there are standard reimbursement rates for care that are really designed for when people walk into the office, and they do not take into consideration some of the other costs. Like some of the things that we do in Clackamas County are, we have to drive all over the place, because it is part urban and part rural.

And so, we have to either fundraise money or get additional grant costs and stuff like that to cover our mileage, for people to drive out and meet people where they are at. So that is a couple of things I could think of.

Senator BARRASSO. Dr. Perrone, a quick question. You know, in February this year, the DEA reported on regions of the U.S. being targeted by the Mexican drug cartels. I live in one of those regions in Wyoming. They found that the cartels are targeting States further away from the border. Highest areas of focus are Native American reservations, they talk about in those States.

Certainly, that is the situation in Wyoming. Our Eastern Shoshone and Northern Arapaho, they live on the Wind River Reservation: it is larger than the State of Connecticut. I mean, we are talking about a big geographic area with low population. It continues to experience one of the highest rates of drug overdose deaths in the State.

I am deeply concerned about the cartels that are targeting our Native American populations. A lot of that has to do with the fact that the size of the geography and the smaller number of people make it an area where they can really focus.

You know, can the Federal Government do things? How can we best respond, from the Federal Government level, to counter the efforts by the cartels?

Dr. PERRONE. Thank you, Senator Barrasso, for that question. I mean, in terms of supporting patient populations in rural areas, I think telehealth can give more rapid access to treatment. I think you are going to need some onsite care in the Indian Health Service in order to provide support for this population.

In terms of around the country, other groups have targeted vulnerable populations. The drug companies that precipitated a lot of this have also targeted populations in Appalachia and other places that started the demand for opioids.

So we have a lot of work to do to unwind a lot of these things. But I think resources and reimbursement for services onsite would be really important, and perhaps expanding the Native American health services with a focus on integrated care models there would be helpful.

Senator BARRASSO. Thank you.

It just seems to me—this is my last statement, Mr. Chairman—that until we secure the border and protect Americans, we are not going to be able to get to the bottom of the root of the fentanyl problem.

The CHAIRMAN. The time of my colleague has expired.

Today, we are focusing on the bipartisan efforts on the health aspects of fentanyl. Several of my colleagues have mentioned the whole supply issue. If we are talking about supply and fighting the cartels, that gentleman over there, Senator Brown of Ohio, has

written the FEND OFF Fentanyl bill, the FEND Act, that is going to make a big difference on supply.

Senator Brown?

Senator BROWN. Thank you, Mr. Chairman. Thanks for mentioning that at the beginning of the hearing too.

Four hundred people die every month in my State, a relatively large State. The problem is serious, of course. I was in Toledo not too long ago talking to the former husband of a woman who was an auto worker at the Jeep Cherokee assembly plant in Toledo. And she had a workplace injury, and she started taking opioids, and she developed an addiction. She died of some kind of fentanyl poisoning, not sure where it came from.

We know that those are human stories, not just statistics, obviously, as, Mr. Vezina, you certainly know. And as the chairman said, after fighting for a year, Congress passed my bipartisan FEND Off Fentanyl Act, which focuses on targeting and sanctioning the precursor chemical makers in China and the manufacturers, the cartels in Mexico that put this stuff together.

Cracking down, obviously on the supply, and at that level going after where the big money is, is really important. But of course, as the chairman said, it is an all-of-the-above approach.

Let me start with this, Mr. Vezina. You discuss in your testimony the importance of prioritizing interventions for youth and young adults to prevent and treat substance use disorders, and peer support workers or people who have a lived experience with a substance use disorder or mental health condition and work with people in recovery.

These services have been shown to be effective in helping people recover. Mr. Vezina, as communities work to implement various peer support models for addiction, what are the biggest barriers in their doing that?

Mr. VEZINA. Yes; thank you so much for the question. Certification can be a barrier. Sometimes State license certifications or licensed behavioral health providers have really stringent background checks, and a lot of people like myself in recovery have criminal histories. So that is a barrier that we have faced.

Additionally, reimbursement rate models that are commensurate with the actual activities that peers do, you could look at that; for example, pretreatment engagement. So this would be before somebody got an assessment and a prescription for care. Allowing peers like myself to go out and engage people and motivate them to seek recovery—that is something that you could look at.

And then, I do not think it is within the jurisdiction of this committee, but from my limited understanding, there are issues with reimbursing peers on the commercial market as well.

Senator BROWN. Okay. And Medicaid clearly has been a lifeline. I was in Cincinnati at Talbot House, an iconic treatment program and center for 60 years now, and I was sitting with a man and his probably 30-year-old daughter, and he put his hand on her arm and said she is alive today because of Talbot House, which we are in because of Medicaid—and we all know that.

How important is Medicaid in your mind when it comes to patients accessing treatment services?

Mr. VEZINA. Oh, it is incredibly important. You know, just for myself, before the expansion of Medicaid, there was a lottery system, and I was trying to get into treatment, but I did not get selected for the lottery. And so, I had to wait, and they had to prioritize other populations aside from me.

But after Medicaid expansion, I was able to get into treatment immediately, any time I sought it for the most part, in Oregon.

Senator BROWN. And there is obviously the question of prior authorization, which occurs in far too many cases. So, the overuse of prior authorization is a burdensome process that requires an insurance plan to approve services before a patient can receive them.

For Dr. Perrone, how important is it for a patient who is ready to get started with treatment to be able to access it immediately? And in the face of the problems we have with prior authorization, talk about that, if you would for a moment.

Dr. PERRONE. Yes; thank you. Our care model has been built on same-day treatment. So, when a patient comes for care, we want to start them on medications immediately. Because I work in the emergency department, prior authorization is not necessary for me to give that medication. But for me to prescribe it and for the patient ultimately to get it filled, that was a big barrier.

In Pennsylvania, they did get rid of prior authorizations for the initiation of buprenorphine a few years ago. They recently also allowed us to write for higher doses, which have been necessary in the fentanyl era, and which also required prior authorizations until recently.

Senator BROWN. Talk about that, why you write for higher doses.

Dr. PERRONE. So, because, as Mr. Vezina explained, the use of heroin was often about four times a day, because it lasted 4 or 5 hours. Fentanyl lasts a couple of hours, so people are using 8 and 10 times a day.

The degree of opioid dependence that people have developed from fentanyl rivals anything I have ever seen, and there is a tremendous need for medications at much higher doses to combat that, both methadone and suboxone or buprenorphine.

So now we need to prescribe higher doses. The higher doses were restricted to prior authorizations, but now that process has actually been changed in Pennsylvania, but probably not in a lot of other States. So we can prescribe 24 milligrams instead of 16 milligrams a day, because that is what our patients need.

Senator BROWN. Thank you for the work you are doing in Senator Casey's State. Thanks.

The CHAIRMAN. Thank you, Senator Brown.

Here is where we are. First, with respect to the comments Senator Brown has made, I think this kind of highlights where we are in this debate. We are going to have to tackle the supply issue, and that is why Senator Brown's approach under the FEND Act is going after the cartels.

I strongly support that effort, and we have got to come back and deal with the medication issue, which is why he talked about the prior authorization. Those two pieces are critical as we sort out this puzzle, and I thank my colleague for doing it.

Here is where we are. I am going to have to run and vote. Senator Crapo will run this until I get back. I think next in the queue

is Senator Whitehouse. But Senator Crapo will run this, and we are getting close, colleagues, to wrapping this up. I have an additional question, Senator Crapo may, but we are getting close.

So, if the word can go out that we are almost there, we are getting ready to finish——

Senator Crapo, we'll just call Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Mr. Chairman.

The CHAIRMAN. Thanks.

Senator WHITEHOUSE. I heard my colleagues' comments about the need for added border protection against fentanyl, and it is timely to hear that, because we all have the chance today to vote on a bipartisan border measure that would add unprecedented levels of detection and enforcement at the border. So it will be interesting to cross-reference the comments and the votes.

Just a word on Rhode Island. I am pretty proud of what we have done in this space. We were early leaders on getting medication-assisted treatment into our correctional institutions. That reduced opioid fatalities by over 60 percent, just that one measure.

And it has expanded beyond that. I am really proud of our police chiefs in multiple police departments who have peer recovery specialists, recovery coaches, recovery follow-up after the night sheets come in, social workers engaging with the police departments. It has really been pretty outstanding.

Some of our fire departments turn up after treatment, will get you into treatment sites. Some States have difficulty making that work. We made it work. We've got the 988 program operating with a group called Behavioral Health, BH Link, so that if you call, you are immediately on the phone to get the resources you need, which can include vans that go to you.

So there is a lot going on. I want to really applaud the Rhode Island treatment and recovery community, which has stepped up to this in wonderful ways. And the behavioral health centers that Senator Stabenow talked about are very often being set up in Rhode Island in conjunction with the treatment and recovery facilities that are already there.

So we even have a safe injection site that is doing full wrap-around services to try to get people off of their addiction as quickly as possible. So there is a lot going on.

I think, as all the witnesses know, this is an ecosystem that is being built piece by piece, and we need to build it out more robustly and improve the coordination. But I have been really impressed with what I have heard from all of you today. I am very, very grateful for your work and your focus.

Dr. Perrone, one of the things that we are going to have to face up to is that at the end of the year, the COVID telehealth authorization for opioid treatment expires. I have a bill that I hope will prevent that from happening. We have to get it passed. In plain words, is there any upside to letting that telehealth authorization expire?

Dr. PERRONE. Thank you for that question. I also would applaud the Rhode Island Department of Health and their many innovations.

As COVID started, I was actually on the phone with my colleague at the Rhode Island Department of Health, as we rapidly

pivoted to a telehealth strategy. And I would say, "no." We definitely want the telehealth reimbursement parity, the telehealth options that we have that were rapidly innovated.

I would like to applaud all the people involved in allowing us to provide telehealth during COVID as swiftly as it was made, and we need to sustain that regulation, because it is critical. We have treated 2,000 patients. I am sure Rhode Island has treated a large proportion of people via telehealth. Various other programs have popped up around the country.

But we could create a telehealth network that would be less expensive than a lot of other onsite care, just for care retention and gaps and people leaving carceral settings. So, telehealth could be widely used more than it is, and save a lot of lives.

Thank you.

Senator WHITEHOUSE. In my last 30 seconds, I will add one additional observation that I have heard repeatedly out of the recovery and treatment community in Rhode Island—which we had a witness here in the Finance Committee the other day also volunteer—which is that the professionals who are dealing with people in recovery not only saw telehealth as an important functional advantage in terms of people being able to meet their appointments and have the communications that they needed to have, but that the actual substantive content of the engagement improved, because people felt more comfortable being able to engage telehealth from home, not have to drive across town, not have to wait in the waiting room, not have to fill out the stupid clipboard, not have to go into somebody's office, but actually be able to engage from a place where they felt considerable personal comfort.

So, I offer that closing thought, and thank you very much.

Senator CRAPO [presiding]. Thank you.

Senator Hassan?

Senator HASSAN. Thank you, Senator Crapo, and thanks to you and the chair for holding this hearing. To all of our witnesses, thank you not only for being here, but for the work that you do.

I just wanted to start, Senator Crapo, commenting—because we were both part of the bipartisan congressional delegation that traveled to China, and I know you talked about that a bit. We really pushed Chinese President Xi to stop illegal fentanyl precursors from flowing out of China. China has said it would work with the United States, and that was a really good first step. But we need to see stronger actions from the Chinese Government to disrupt drug trafficking that empowers international cartels.

And while we continue to work to stem the flow of fentanyl into our own country—and I would echo Senator Whitehouse—we are voting on a bill this afternoon that would provide extremely strong protections at the border, strengthen our border, including strengthening the way we combat fentanyl at the border. I hope my colleagues will join us in voting for that bipartisan bill.

But we also need to continue to seek progress on treating opioid addiction. So I wanted to ask all of you, because there has been a line of questions about medication-assisted treatment and the importance of Medicaid coverage to help people get that treatment. Senator Brown and Senator Wyden both talked about it.

Dr. Perrone, you talked about some of the barriers to getting people access to medication-assisted treatment when they need it, at the place they need it. Can we just—is there anything that has not been mentioned that is a barrier, whether it is through Medicaid or elsewhere, to getting that kind of medication-assisted treatment? And I will start with Dr. Perrone, and we will just go right down.

Dr. PERRONE. I think we subtly mentioned stigma. People are embarrassed. They are terrified. They have been treated poorly in health-care settings. So back to telehealth. That is one of the reasons why people feel more comfortable initiating care over the phone, meeting a provider over the phone, and then knowing that in a peer-led model they would see someone else as a familiar face when they go into treatment. So I will just stop there and let my other colleagues respond.

Senator HASSAN. Yes, that would be helpful; thank you, because time is limited.

Dr. BANTA-GREEN. I will just mention a couple of quick things on the same theme of stigma. We know that approximately half of physicians still think of medications for opioid use disorder as a replacement, in a negative way, for addiction. So that is a very important factor that we need to be thinking about.

And we really need to educate the general public that opioid use disorder is a treatable medication condition, and medications are the most evidence-based interventions we have. And very importantly, they do not just reduce mortality, but they actually support recovery.

I have had people who are on suboxone and cycled on and off it because they thought while they were still on it, they were still an addict. And the idea that you can be in recovery and be on medications is important for everybody to know, because if the family is not supportive, those folks may not start or stay on medications.

Senator HASSAN. Thank you.

Dr. HERRON. Thank you for the question. You know, I will just underscore again the importance of low-barrier access to treatment: people working in integrated care settings having the ability to receive patients at the moment that they are ready to enter care.

Addiction is inarguably a disease. There is also a behavioral component to this illness, and we need to be able to catch and welcome patients into care at the time that they are ready to do it, and have no wrong door, so that, if you are with your primary care provider, your dentist, your psychiatrist, anyone is able to do that.

I will also add, the fentanyl crisis in particular has increased the need for higher doses of medication. That also means that not everyone can adequately be treated with buprenorphine. Buprenorphine was a revolution in providing care by prescription so people did not have to travel to opioid treatment programs.

I know, Senator, you are well aware and have a similar position about expanding access to methadone. But that is a serious geographic concern, where there are entire States, hours of travel necessary for people to be able to engage in methadone under the current treatment structure.

Senator HASSAN. Just to follow up on that, would it be safe to expand methadone treatment beyond certified methadone clinics? I

think we have now evidence because of the pandemic that says that it is.

Dr. HERRON. Absolutely. It should not be more difficult to access treatment for a substance use disorder than it is to get prescriptions for opioids.

Senator HASSAN. Right; thank you.

Mr. VEZINA. Yes, and I would just say it should be easier to get medications that treat opioid use disorder than to purchase drugs on the street. That seems like a no-brainer.

One thing that we run up against is, there is a need for education around MAT for adolescents. Some people believe that you cannot prescribe adolescents MAT, and then when we do have those providers, there is lack of demand because people are not educated in the fact that, hey, I have an addiction or my kid has an addiction, or, hey, this is treatable and here is an intervention than can work.

And then something that I fought really hard for when I was student body president at Portland Community College was to educate allied health professionals, and health professionals in general, around substance use disorder and recovery. And so we need to do a better job of educating our health-care system.

Senator HASSAN. I appreciate that.

One last thing, Mr. Chair. First of all, Senator Markey and I do have a bipartisan bill on modernizing opioid treatment that would expand access to methadone outside of methadone clinics. And also, we need to do a lot more to understand and encourage doctors to do appropriate MAT for pregnant women who are suffering from addiction as well. Thank you.

Thank you all for your testimony.

Senator CRAPO. Thank you, Senator Hassan. I appreciate your mentioning the fact that we were able to meet with President Xi in person in China, and talk about this issue. You are leading on that, so I congratulate you on that.

Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you, Mr. Chair, and thank you to the panelists. I know it has been a long morning. You are probably getting asked the same questions over and over and over again. But I thank you, because the advocacy and your experience, it matters to help us address here, at least at the Federal level, what we can do to continue to address the fentanyl crisis that we see in this country.

Can I ask this? There has been a lot of conversation about integrating addiction treatment with mainstream health care. I think that is where we need to go, for so many reasons. It is so important for us to do it, and at the Federal level we are working to try to incentivize that movement.

I will say, and I appreciate—Senator Cornyn and I, we introduced the COMPLETE Care Act, which actually increased Medicare payments to primary care doctors who incorporate behavioral health into their practices, the first step of incentivizing it. I thank my colleagues for helping us advance this out of the committee.

But more needs to be done. The continuum of care, there are gaps in it. We all know that, and my focus is how do we address

those gaps, because everybody plays a role, a key role here, at the end of the day.

And so, Dr. Herron, can I start with you, because FQHCs—there are some in my State as well, and despite being well suited for integrated care models, the implementation, however, is challenging for FQHCs. Can you talk a little bit about that, what those challenges are and what we need to be aware of so that we can help overcome those challenges for those clinics?

Dr. HERRON. Thank you for the question. There are a variety of challenges. Some come at the reimbursement level, where there is difficulty for primary care providers, for example, billing behavioral health codes and not being able to get reimbursement for a depression visit versus a diabetes visit.

There are also challenges in education of the workforce, and so putting training into primary care residency programs—and I am an addiction doctor and an addiction medicine specialist, so that is a lot of people who started in other fields and then received additional training in addiction. But really putting that type of education into medical school curriculum and into residency programs, so that people are able to have a base foundation of how to approach mental health, is critical.

There is always going to be a need for specialty treatment. Some people will need inpatient treatment. Some people will need higher levels of care. Some people will need residential sober living and things like that. But not everyone does, and so being able to start at the level of outpatient practice and to help the people who are able to be served in those settings actually also helps to reduce stigma and reduce health-care costs. People do not necessarily need to see a specialist for everything, just like we can do basic hypertension care or basic high cholesterol treatment, and only some people need to see a cardiologist.

Really focusing those efforts on expanding the primary care workforce and recognition help a lot. FQHCs, you know, vary, and I am fortunate to be in New York, where we do have a lot of flexibilities and encouragement around this. But there are also a lot of regulatory hurdles. I am in a State that has multiple different regulatory agencies for addiction versus mental health versus primary care services.

And so, also integrating those and figuring out the reimbursement, the licensure, the regulatory oversight of all the different streams of services, I think have been daunting for some communities and difficult for some health centers to implement.

Senator CORTEZ MASTO. So it is not—you said the Federal, but it is the State and local. The State is a key partner here when we are trying to build out this continuum of care.

Dr. HERRON. Absolutely.

Senator CORTEZ MASTO. And there are barriers to some extent there. Maybe not intentional, but they do exist.

Dr. HERRON. Yes, absolutely. And I mentioned earlier also the same-day billing restrictions, that are again a State decision. My understanding is that they are permissible under Federal law, but it is up to the States to decide to do that or not.

I am in a State that has same-day billing restrictions, and so we have, despite having colocated care—I am fortunate as an FQHC

to be able to provide care even if I cannot be reimbursed for it. We receive funding from other sources to help support that.

But not everyone can afford to do that, and so people can be in centers that offer both types of things, but not actually be able to access different services in a day, and then have to come back, which is going to just decrease the likelihood of being in care.

Senator CORTEZ MASTO. And I only have 20 seconds left, but I am curious, just for the panel: anything you want us to hear that we have not talked about today, that just strikes you as important that you want us to take away from this conversation? Or we have covered everything?

Mr. VEZINA. Yes. The last thing I would just like to say is that there are over 20 million people in America who are in recovery. And in my early recovery, people would say stuff to me like I am unique or one of a kind. But you know, not everybody is vocal about their recovery like me, and so I just want the public to know that if we fund services, people can and will recover from substance use disorder.

Thank you.

Senator CORTEZ MASTO. Thank you.

Senator CRAPO. Thank you.

Senator Blackburn?

Senator BLACKBURN. Thank you, Mr. Chairman.

And last year in Tennessee, we had over 3,800 overdose deaths, and these were primarily fentanyl. It was involved in 75 percent of those cases. Now, one of the things that I hear from our healthcare professionals and our law enforcement is they cannot get their arms around this until the southern border is secured.

And they talk about the uptick in using Narcan. They talk about the need to address these smugglers. I have the Stop Fentanyl Border Crossings Act, which would add drug smuggling as a basis for title 42 immigration enforcement.

I know my colleagues have said there is a vote on the floor later this afternoon to address the border. It is an immigration bill. It is not a border security bill. And what people want to see is for all of this trafficking to stop, and stop pushing these drugs into our communities. And I appreciate you all being here, and as you have heard, we have done a lot of bipartisan work on medication-assisted treatment.

Senator Hassan and I have worked on some provisions. Senator Thune and I are working on allowing States to waive the IMD exclusion for substance use disorder treatment. And I fully feel that any treatment that we have has to include prevention as well as the treatment. And then also enforcement, and making certain that people have access to that continuum of care.

Recovery is not—as you have said in your testimony, this is a long road, and not everyone is willing to talk about that. But we have the Telehealth Response for E-prescribing Addiction Therapy Services Act, the TREATS Act, and Senator Whitehouse and I and others on the committee have worked on this, because it would address some of those barriers that a lot of individuals face as they are trying to get the care they need.

And it would give that critical support—Dr. Herron, you just talked about this—in underserved and rural areas, and getting that help to people. It would leverage telehealth services.

So I want to come to you, Dr. Herron. When we talk about the TREATS Act and how it would enhance that accessibility and efficacy of these services and e-prescribing, talk a little bit about how it would fill in those gaps in service, and why we need to do this.

Dr. HERRON. Thank you for your question, Senator. Telehealth has been one of the greatest innovations to ever come to behavioral health, and it is one of the good things that came out of the terrible tragedy of the COVID pandemic. We have seen incredible improvements in access, in engagement, and quality of care through telehealth. As I mentioned earlier, geographic restrictions——

Senator BLACKBURN. Yes. What about compliance?

Dr. HERRON. People are much more likely to engage and remain in treatment when they have multiple options to access care.

Senator BLACKBURN. Okay.

Dr. HERRON. So, hybrid treatment options are really wonderful, where you do have the ability to still see a treatment provider in person and are able to do certain things that benefit from those face-to-face interactions, and the combination of doing that with the ability to access remote care.

People no longer have to arrange for child care, take off time from work, figure out transportation, how to get there. What could be a 30-minute—you know, really the whole time face-to-face with a therapist was a 2-hour, 3-hour event to be able to leave, travel, wait in the waiting room, do all of those things.

So people are able to still get the same quality of care in a much more efficient way. One of the things that is essential about the TREATS legislation is the provision about audio-only telehealth. I do want to stress—and it is hard for us all sitting here on our smartphones to remember—many, many Americans do not have access to high-speed Internet, to devices with cameras, to phones with data plans that they can use to access video.

And so, the addition of audio-only services as part of the treatment landscape is really essential to maintaining access for people.

Senator BLACKBURN. Thank you. I am almost out of time.

Dr. Perrone, I will send a question to you. I want to talk about prescription opioids and those who are dealing with pain, and as we look at the overuse in the prescription area, how that affects the use of heroin and fentanyl. But I will do that in writing.

Thank you, Mr. Chairman.

The CHAIRMAN. The time of the gentlelady has expired. I am also interested, Senator Blackburn, in that question about the prescriptions, so we will work with you on it.

Senator Casey?

Senator CASEY. Thank you, Mr. Chairman. Thanks for the hearing. Thank you and the ranking member for providing an opportunity to have us be a part of it. I want to thank the panel for your testimony, and your willingness to serve in the trenches on these issues. Really important and difficult work that you do.

Thursday is often a very busy hearing morning, so that is why a number of us are in and out. But I want to direct maybe just two

questions to Dr. Perrone, because I know we are at the end of the hearing.

Doctor, the first one is about barriers to treatment. In your testimony, you mentioned that 11 percent of people with opioid use disorder receive medication. That is due to several factors including cost. I introduced a bill called the MORE Savings legislation, which would eliminate cost for opioid treatment and recovery support services for people with private insurance plans, as well as people enrolled in a new Medicare pilot program—so, those two groups of individuals. The bill will also increase Federal funding for Medicaid treatment programs.

Doctor, can you expand on some of the barriers to treatment and explain how decreasing barriers and costs could result in more patients getting access to needed care?

Dr. PERRONE. Thank you, Senator Casey. So, just for example, I mentioned a patient that I saw a couple of days ago in the emergency department. We started her on buprenorphine. That patient, when she goes to a pharmacy to fill that prescription—she was a little bit far from our area. She was previously from the Lehigh Valley.

So, at the pharmacy, they may say, "You are not on my list. You have never filled a prescription here; you are out of this area. We are not going to fill it." So, the pharmacy barriers we really haven't touched on today, but there is tremendous stigma and other issues.

And then pharmacists are also driven by their fear of regulatory compromise. So you know, it is a double-edged sword on their end. But they are very reluctant to be as collaborative as they could be, because they are really worried about what happened in the opioid crisis with overprescribing of opioids. So we need to mitigate that barrier.

I think incentivizing treatment is a great investment. Some insurance companies have come to me and said, "We are going to pay additional reimbursement, because if you start a patient on medications for opioid use disorder, that decreases our costs as an insurance company." So, the ROI on medications is tremendous, not to mention the lifesaving and other productive components of the success of medications.

Senator CASEY. Thank you, Doctor, for that.

The rate of substance use disorder among older adults over the age of 65 has increased in recent years, with nearly 4 million older adults reporting a substance use disorder just in 2022. The number of older adults needing SUD treatment has tripled from 2000 to 2020.

Unfortunately, older adults are often overlooked when developing screening, prevention, and treatment strategies. Compounding these challenges are the limitations of Medicare coverage for substance use treatment and the dearth of data available to promote understanding of how best to care for older adults with substance use disorders.

What are some of the gaps in Medicare coverage that would make it difficult for older adults to access care for substance use disorders?

Dr. PERRONE. That is a great question; thank you. You know, most of my patients are covered by Medicaid, so most of what I can

speak about is access to filling prescriptions via Medicaid, where it is generally covered in Pennsylvania, whereas Medicare might not be covered, and the patients may not have additional plans. So, including medications in some component of a Medicare plan would be really important.

And a lot of older adults have resulted in opioid use disorder primarily because they have been exposed to medications in their journey of having more medical consequences and being treated with these medications. And then the medications are no longer prescribed, and then they literally—we see patients quite commonly in that age group who just go and buy something on the street because it is widely available to treat their pain.

Senator CASEY. Doctor, thanks very much.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey. I look forward to seeing your important legislation and having more discussions about it.

Senator Daines will be our last member.

Senator DAINES. All right. Mr. Chairman, thank you; Ranking Member Crapo as well.

Just before I get into my line of questioning and my comments, I think—I guess Senator Blackburn brought up the point about what is going on with this vote this afternoon regarding the border.

I think it is safe to say I have personally been to the southern border more times than any member of this committee on the other side of the dais, than the Democrats. I have spent a lot of time on the southern border; I sometimes go on the night shift from 10 p.m. to 6 a.m., watching what is happening.

This vote this afternoon is a political stunt. If we are serious about solving the crisis on the southern border, the Democrats should go down to the Commander-in-Chief, the Oval Office, and ask President Biden for the reversal of the policies that he put in place, the executive action after President Trump left office.

It really is not that complicated, and so this is—this has now become a political crisis for the Democrats. The border crisis is a crisis, but now that it is a political crisis, Leader Schumer has decided he is going to put this bill on the floor so they can cut some commercials here to try to save some of the Senators who have tough races back home, because the American people see the disaster and the tragedy of this invasion that is going on on the southern border.

And linked to that, because the Border Patrol agents do not have enough resources—it is a zero-sum situation. They are apprehending nearly 9 million illegals that come across the border since President Trump left office, and that allows the Chinese to ship the fentanyl precursors to the cartels. They manufacture them and then ship them into the United States.

In fact, by the time it leaves the Rio Grande until it gets to Montana is about 48 hours now, with the efficiencies of the Mexican cartels. What is going to happen this afternoon, frankly, will be seen by the American people as a political stunt in trying to save an election.

Last month, I cohosted a discussion with Senator Cardin in the Finance Health Care Subcommittee on the opioid epidemic in our

country. I am glad the full committee decided to spotlight this issue as well. Driven by the man-made crisis at our southern border, fentanyl manufactured by Mexican cartels, using the precursor chemicals from China, has flooded across the border. And they have been in every community in Montana and sadly across the Nation.

We are a northern border State, but we also have now a southern border crisis. In fact, in Montana alone, the State crime lab has preliminarily reported 80 overdose deaths involving fentanyl in 2023, an increase of 1,900 percent from 2017 when there were just four.

Although we have therapies and FDA-approved medicines for treating substance use disorder, accessing this care has long been outside the traditional health-care continuum, resulting in a fragmented system and a challenge for patients to navigate.

In the subcommittee's work last month, it was apparent to me that the care provider for substance use disorder across the country is often a reflection of each individual community, its specific needs, and the community partners available to help create local continuums of care.

Dr. Herron, could you share with the committee this hyper-local aspect of providing substance use care, and the importance of community partnerships as well as coordination to treat patients?

Dr. HERRON. Thank you for the question. Yes, I think I have an interesting perspective, in that I work in a Federally Qualified Health Center in New York that includes urban sites, rural sites, and suburban sites, and the needs of each community are both different and the same.

I think the access to evidence-based, high-quality, low-barrier treatment is shared among all people with addiction. But building those community partnerships in order to build trust, to build connections with additional resources, with schools, with recovery-oriented communities, organizations that can help to do a lot of the preventive services you have heard about today, are really essential.

And so, understanding the needs of those different communities, whether that be the variable access to technology, to transportation barriers, differences in income levels and insurance demographics, each of those communities really do require a nuanced approach to the services they are providing in that local environment.

Senator DAINES. Dr. Herron, thank you.

I have one more question, a final question for Mr. Vezina. When Senator Stabenow and I led the Finance Committee's efforts on the Mental Health Workforce Working Group, one of the proposals I worked on was increasing Medicare participation for peer support for individuals with mental health or substance use conditions.

Mr. Vezina, your organization provides a number of resources to individuals struggling with substance use and addiction, including peer support, as well as mentorship. Could you speak briefly about the role of peer support in the substance use disorder care continuum, especially for our youth and our young adults?

Mr. VEZINA. Yes. Thank you so much for the question. You know, for hundreds of years, people in recovery have helped other people

recover, and it has been largely voluntary. The first drug and alcohol counselors were a lot of people in recovery.

A lot of the evolution of how we treat addiction has been pushed by people in recovery. So, this peer support occupation gives people in recovery a specific occupation to go out and motivate people to change. That is what peers can do: they can help motivate people. You know, people who have addiction are oftentimes ambivalent. They want to quit and they want to use at the same time, and that is a natural human kind of condition. "I want to stop eating candy, and I want to eat a bunch of candy at the same time." I think everyone can share that duality. And so, peers really can help motivate people to change. And so at 4D, we have about 100 staff, and we have five recovery centers, and that is all we do is go out and motivate youth and young adults to get into recovery and to sustain their recovery.

And so, you can put peers in pretty much any setting and help people to get motivated to participate in the recovery process.

The CHAIRMAN. The time of the gentleman has expired.

I want to thank all our witnesses. We have spent 2½ hours here today trying to learn about the enormous health-care challenges. I underline "health-care challenges," because we are the committee with jurisdiction over health care, over Medicare and Medicaid and these essential health-care programs.

And what I like the most about what we have done for 2½ hours is, overwhelmingly most of our time has been devoted to looking at issues like best practices, state-of-the-art treatment, prior authorization—which I think is a huge rip-off led by insurance companies. All four of you have made a big, big difference in terms of getting the focus on these health-care issues, which frankly have not gotten the attention that is warranted.

And without Mr. Vezina coming up on that day at Fred Meyer in Oregon and saying, "We have got to dig into these health-care issues," all the headlines would be about something else. So I really appreciate what you have done today in getting the focus back on the fact that so many people are addicted.

We heard Senator Bennet talk about when he hears about a death, he looks at it completely differently. My wife and I are older parents, and I am going to close with this. We have twins who are 16. Whenever they go out, I say, "Come back here, William and Ava. Come back here for a minute." And they go, "Oh, God. Dad's going to give us the fentanyl lecture again."

I say, "Yes, I am going to give it to you, because this is something you cannot play Russian roulette with. You cannot just say, 'Well, I am going to take a sample.' You cannot have stuff at parties." You cannot do any of these kinds of things that you all and specialists are warning us about.

So, you have helped us with getting the state of the art with respect to health care, what this committee does. This committee—to its credit, by the way—has focused in a bipartisan way on these health-care issues. A lot of people did not think it could be done, in terms of the gun safety bill.

They did not think we would be able to get these important provisions that relate to the school issue. And, Mr. Vezina, you are very, very thoughtful in terms of assessing how it might have been

different for you if we were moving in healthier directions when you were a kid.

So, Godspeed. I may see you on the plane in a few hours, Mr. Vezina, if we try to make the trek back. But thank you for a particularly good hearing that zeroes in on the issues before the committee.

With that, we are adjourned.

[Whereupon, at 12:24 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF CALEB J. BANTA-GREEN, PH.D., MPH, MSW,
RESEARCH PROFESSOR, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

Good morning, Chairman Wyden and Ranking Member Crapo. Thank you for the opportunity to speak to you about this critical topic. Thank you to Senator Cantwell, my Senator, for your consistent and impactful leadership on addiction. It is heartening to see the leadership from the Pacific Northwest, Oregon, Idaho, and Washington, demonstrate their leadership on the fentanyl crisis by holding this important hearing. As a health services and public health researcher, it is an honor to participate.

My name is Caleb Banta-Green, and I have worked to support individuals and communities impacted by opioid use disorder for nearly 30 years. Over this time the predominate opioid has changed multiple times and the models of care and treatment medications have evolved. We have made a dent in the treatment gap, the gap between those with active opioid use disorder and those on the medications methadone and buprenorphine.[1] These medications are the most evidence-based treatments for opioid use disorder—they support ongoing recovery and reduce mortality by at least 50 percent.[2,3] Unfortunately, the treatment gap persists, with approximately three-quarters of those with opioid use disorder not on medications.

Opioid treatment programs, primarily using methadone, and medical office based opioid treatment using buprenorphine are excellent models of care.[4] Yet despite our work for decades, they continue to serve a minority of people with opioid use disorder. Policymakers and health-care systems continue to improve these two models of care and expand access, but it is clear we also need a new third model of care as well.

Nonpharmaceutical fentanyl has exacerbated this need for a new model of care.[5] Fentanyl is a very potent and inexpensive drug that presents substantial risk for rapid development of opioid use disorder and fatal overdose. Fundamentally, we need to make it easier to access treatment medications other than nonpharmaceutical fentanyl.

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[1] Krawczyk N, Rivera BD, Jent V, Keyes KM, Jones CM, Cerdá M. "Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019." Int J Drug Policy. 2022 Dec;110:103786. doi: 10.1016/j.drugpo.2022.103786. Epub 2022 Aug 4. PMID: 35934583; PMCID: PMC10976290.

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As part of our ongoing research, we regularly interview people who use drugs and are accessing overdose and infectious disease prevention services. Our published research shows that 80 percent of people with opioid use disorder *do* want to stop or reduce their use, the majority *do* want to be on medications, yet most are *not* able to access the traditional health-care system.[6] Further, three-quarters want to obtain health care at the community-based services program, at a place they know and with people they trust.[7]

Over the last 10 years we and others have been developing and testing new models of care based on clients stated needs, health services and public health data, and research supported interventions.[8, 9, 10] We are combining a low barrier clinical model, with community-based access points, and a team-based model of care. To support the treatment medication prescriber, we have added vital staff including nurse care managers, mental health-care managers, and care navigators. These care team members provide the majority of face time with clients and provide vital care and supports so that people start and stay engaged. We have been fortunate to have people in recovery from opioid use disorder in these medical and care navigator roles and their insights and ability to quickly build trust with clients have been invaluable. This new care model has positively influenced the care continuum; we are finding that jails and emergency departments that were once hesitant to start people on medications because they thought patients would never be able to navigate the health-care system for follow-up care, are now starting people on buprenorphine because they know there is a place in the community providing drop in access to medications and other supports.

Community-based health hubs for people who use drugs are showing positive outcomes, including in our research with six rural and urban communities across Washington State where we found significant increases in buprenorphine use and significant declines in deaths.[11] To date these programs have been funded with one time funds including grant dollars. What we need is a bundled care model with adequate funding to pay for the complete care team in these community-based settings. While there has been some movement that allows for paying for nurse care managers and care navigators or peers in certain circumstances, we need a comprehensive approach inclusive of the low barrier community-based health hub treatment care model, flexibility in community care settings, and adequate funding for the entire care team to manage this complex, chronic, relapsing medical condition.

As one of our clients, an older unhoused woman with long-time opioid use disorder, told our community staff: "I've been in and out of treatment throughout my life, and you are the first people to treat me well. So, I keep coming back, and I've brought my friends."

Opioid use disorder with fentanyl is tough. But we have a third model of care that can help us dramatically close the treatment gap, support recovery, keep people alive, and help restore the health of individuals and communities.

Thank you very much for your time. Please contact me with any questions.

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[11] Banta-Green CJ, Owens MD, Williams JR, Sears JM, Floyd AS, Williams-Gilbert W, Kingston S. "Community Based Medications First for Opioid Use Disorder—Care Utilization and Mortality Outcomes." Poster presented at the College on Problems of Drug Dependence (CPDD) annual meeting, Denver, CO, June 2023. *https://adai.uw.edu/wordpress/wp-content/uploads/community-based-meds-poster-2023.pdf.*

PREPARED STATEMENT OF HON. MIKE CRAPO,
A U.S. SENATOR FROM IDAHO

The fentanyl crisis has devastated communities across the country. Far too many families have experienced the pain of losing a loved one from this deadly substance, and the threat it poses to our communities and neighborhoods cannot be overstated.

In Idaho, overdose deaths involving fentanyl increased nearly fourteen-fold between 2017 and 2022, an alarming statistic. It is important to note that this crisis, and the uncontrolled flow of fentanyl into our communities, has not occurred in a vacuum. In the last 2 decades, we saw an unprecedented increase in the use of prescription opioids, causing overdose deaths to rise dramatically.

Congress took critical steps to authorize programs to reduce the use and supply of prescription opioids, and to expand access to treatment for those who need it. In recent years, as prescription opioids have become harder to obtain, illicit fentanyl, a cheap, widely available and potent drug, entered the drug supply, making overdoses even more unpredictable and deadly. According to the Administrator of the Drug Enforcement Administration, fentanyl is the deadliest drug threat our Nation has ever faced.

While this hearing is focused on the prevention and treatment, we cannot ignore fentanyl's alarming supply chain. It is well documented that China is a primary source of fentanyl precursors and analogues, and I joined several of my colleagues on both sides of the aisle in pressing China on its role in the fentanyl crisis on a trip to the region late last year.

These precursor chemicals are shipped either directly to the United States or to Mexico-based drug cartels and smuggled across the southern border before they are pressed into counterfeit pills, mixed into other illicit drugs, or manufactured into powder form.

Any conversation about illicit fentanyl must acknowledge the role of this administration's porous border policies, which have given drug cartels easy access to our neighborhoods and communities. Any efforts to bolster health-care services for treatment and prevention cannot fully remedy the fentanyl crisis unless we also eliminate its supply.

This committee has acted on a bipartisan basis to consider a number of policies that expand access to mental health and substance use disorder treatment for those who need it. This includes consideration of the Better Act, legislation that was passed out of committee last Fall.

A number of the policies included in the BETTER Act were recently signed into law, including permanent Medicaid coverage for medication-assisted treatment, expanded access to residential substance use disorder treatment for Medicaid patients, and guidance to States to improve the availability of substance use disorder services for those enrolled in Medicaid and CHIP.

I welcome continued consideration of policies that improve the provision of care, including through the use of telehealth, which has dramatically transformed the availability and provision of mental health care and substance use disorder services for millions of Americans.

This committee has made a lot of progress in expanding access to care, and I look forward to working with my colleagues on targeted policies that can make a difference and address the root causes of the fentanyl crisis.

Thank you to our witnesses for being here today, and for all of the work that you do in your communities. I look forward to your testimony.

PREPARED STATEMENT OF ABIGAIL J. HERRON, D.O., VICE PRESIDENT AND
CHIEF BEHAVIORAL HEALTH OFFICER, THE INSTITUTE FOR FAMILY HEALTH

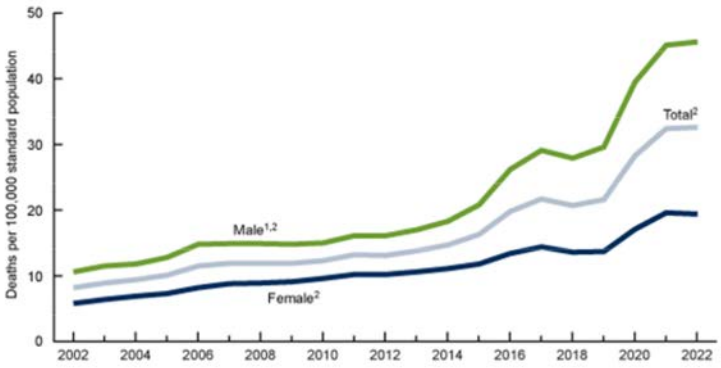
Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you for the opportunity to speak with you today.

INTRODUCTION

As a psychiatrist specializing in the treatment of addiction, I have had the privilege of caring for individuals with mental health and substance use disorders for the past 20 years. I am the chief behavioral health officer at the Institute for Family Health, one of the largest Federally Qualified Health Centers in New York State,

where we provide outpatient services for people affected by opioid use, as well as train clinicians to make this care more widely available. My career as a psychiatrist and health-care administrator has been defined in many ways by the opioid epidemic, and more recently the rise of illicit fentanyl, which has catastrophically worsened this public health crisis. The CDC estimates that 107,000 U.S. residents died of a drug overdose in 2023.[1]

AGE-ADJUSTED RATE OF DRUG OVERDOSE RATES BY SEX: UNITED STATES 2002–2022 [2]



THE FENTANYL EPIDEMIC

Fentanyl is a synthetic opioid—a member of the class of medications called opioid analgesics, which are used for pain relief. While opioids have legitimate medical indications, they also carry a high liability for misuse because they not only relieve pain, but can also produce euphoria. Opioids can be misused when individuals use them without a prescription, ingest them in ways other than prescribed (such as taking excessive quantities, taking doses too frequently, or consuming via other routes such as injection), and/or use them in combination with other substances.

In addition to the desired effect of pain relief, opioids can also produce respiratory depression, suppressing the body's ability to breathe adequately. In an overdose, this can progress to loss of consciousness, coma, and death.

Individuals who use opioids regularly will develop tolerance, meaning they need to take greater or more frequent amounts over time in order to get the desired effects and avoid symptoms of withdrawal. Because tolerance varies among individuals, the amount of opioid that will cause an overdose is also highly variable.

Synthetic opioids, primarily fentanyl, are currently the primary driver of deaths due to overdose, with synthetic opioids involved in over 74,000 opioid deaths in 2023.[3]

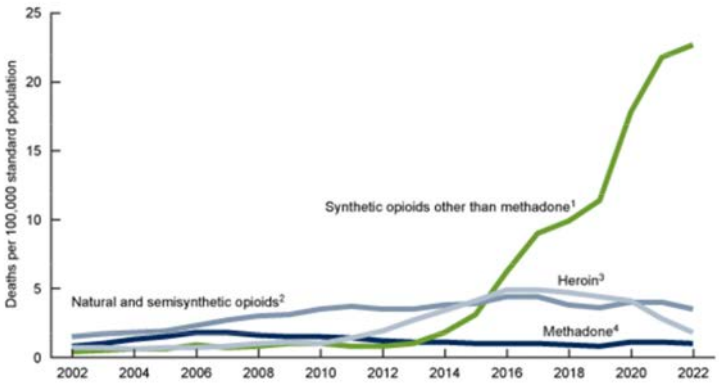
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[1] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2024.

[2] Spencer MR, Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2002–2022. NCHS Data Brief, no 491. Hyattsville, MD: National Center for Health Statistics. 2024. DOI: *https://dx.doi.org/10.15620/cdc:135849.*

[3] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2024.

AGE-ADJUSTED RATE OF DRUG OVERDOSE DEATHS INVOLVING OPIOIDS, BY TYPE OF OPIOID: UNITED STATES, 2002–2022 [4]



[1] Stable trend from 2002 to 2013, then increasing trend from 2013 to 2022, with different rates of change over time, $p < 0.05$.
[2] Significant increasing trend from 2002 to 2016, then stable trend from 2016 to 2022, with different rates of change over time, $p < 0.05$.
[3] Significant increasing trend from 2002 to 2016 with different rates of change over time, stable trend from 2016 to 2020, then significant decreasing trend from 2020 to 2022, $p < 0.05$.
[4] Significant increasing trend from 2002 to 2006, decreasing trend from 2006 to 2018, then stable trend from 2018 to 2022, $p < 0.05$.

Illicitly manufactured fentanyl has become prevalent in the street drug supply throughout the U.S., and is extremely dangerous. Fentanyl is highly potent—about 50 times stronger than heroin and 100 times stronger than morphine. Taking even a small amount of fentanyl can result in overdose, respiratory depression, and death. Because the illicit manufacturing is unregulated, the dosing of fentanyl is extremely variable and unpredictable.

Fentanyl is inexpensive to produce, which has led to the sharp increase in its availability. Fentanyl is frequently found as a contaminant in illicitly obtained opioids, including heroin. It is also pressed into pills where it may be marketed and sold illegally as a prescription opioid, or it may also be passed off as a nonopioid substance such as a benzodiazepine, cocaine, MDMA, or methamphetamine. When an individual who has not used opioids, and therefore has no tolerance to the effects of opioids, is exposed to fentanyl, the risk of overdose is especially great.

IMPORTANCE OF TREATMENT AND PREVENTION

Treatment and prevention are both essential components of addressing this crisis. No one is immune to the risks posed by fentanyl and other substances of abuse.

Medical treatment for opioid dependence is available and is known to save lives. Prescription medications for opioid use disorder (MOUD), such as buprenorphine (also known as Suboxone) and methadone, are safe and effective. However, accessing this type of treatment can be difficult. Individuals attempting to engage in care face stigma, lack of available treatment providers, and inadequate insurance coverage.

In addition, health care and other human service providers have several tools to help individuals at risk for overdose who are not yet engaged in treatment. Education about the risks of opioids, as well as the risk of contamination of nonopioid substances with fentanyl, prepares individuals for the possibility of fentanyl exposure. Naloxone is a lifesaving medication that can reverse opioid overdose. We need to educate people to recognize the signs of opioid overdose, and provide access and training in administering naloxone.

At the Institute for Family Health, we are able to utilize our electronic health record to identify patients who may be at increased risk due to a variety of factors such as current opioid prescriptions, illicit substance use, or past history of over-

[4] Spencer MR, Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2002–2022. NCHS Data Brief, no 491. Hyattsville, MD: National Center for Health Statistics. 2024. DOI. *https://www.cdc.gov/nchs/data/databriefs/db491.pdf.*

dose. We then provide education regarding overdose prevention and dispense naloxone, which can be used to reverse an opioid overdose. Last year, a student at a high school where we operate a school-based health center experienced an overdose while at school. Our onsite primary care provider was able to administer naloxone and provide other medical attention, thus saving the student's life. Partially in response to this incident, the New York City Department of Education now requires all public-school buildings to stock naloxone.[5]

INVESTING IN THE BEHAVIORAL HEALTH WORKFORCE

In addition to expanding the workforce of addiction specialists, all health professionals should receive education and training in substance use disorders and available treatments. At the Institute for Family Health, we focus on training the next generation of providers ready and willing to incorporate addiction treatment into community-based services. We have made treatment of substance use disorders a core component of our primary-care residency training programs, and operate an accredited fellowship program in addiction medicine.

HRSA's Teaching Health Center Graduate Medical Education (THCGME) program supports innovative community-based residencies like the Institute for Family Health's programs. Despite the proven success of this innovative model, the THCGME program receives less than 1 percent of the funding of traditional hospital-based residencies. As the committee considers how to invest Medicaid and Medicare funding in graduate medical education, I urge you to consider the advantages of training medical, dental, and psychiatry residents in outpatient, safety net provider settings:

- Compared to traditional residencies, Teaching Health Center graduates are more likely to practice in a rural location and provide medications for opioid use disorder or behavioral health care;[6]
- Teaching Health Centers attract residents from rural and/or other underrepresented backgrounds;[7]
- Teaching Health Center graduates are also more likely to continue to work in safety net clinics than residents who did not train in those centers.[8]

EXPANDING ACCESS TO INTEGRATED, WHOLE PERSON CARE

Addiction treatment needs to be fully integrated into mainstream health care so that we are prepared to welcome patients into care through multiple entry points. At the Institute for Family Health, we practice an integrated care model which allows patients to receive primary care, behavioral health care, and addiction treatment in a shared treatment setting. Integrated treatment allows individuals to access care for substance use disorders from the same treatment teams they already work with for their physical and mental health. Co-located, integrated care increases patients' acceptance of behavioral health care, and reduces stigma in accessing services.

There are challenges to the implementation and expansion of an integrated care model. In New York and elsewhere, same-day billing restrictions on medical and behavioral health services prevent a single provider entity, such as a Federally Qualified Health Center (FQHC), from billing insurance for a medical visit and a behavioral health visit provided to the same patient on the same day. This creates barriers for patients who face transportation and scheduling limitations common in low-income populations. In addition, there is a tremendous need for better reimbursement for case management, screening, and preventive mental health services.

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[5] A local law to amend the administrative code of the city of New York, in relation to requiring the Department of Education to stock opioid antagonists in all school buildings. (New York City Council.) Accessed May 21, 2024. *https://legistar.council.nyc.gov/LegislationDetail.aspx?ID=5555536&GUID=F7A649E0-7DD7-4C5B-9B3F-19A79ACA97F8&Options=Advanced&Search=.*

[6] Davis, et al. Evaluating the Teaching Health Center Graduate Medical Education Model at 10 Years: Practice-Based Outcomes and Opportunities, Journal of Graduate Medical Education (2022) 14(5):599–605.

[7] Talib, Z, Jewers, MM, Strasser, JH, Popiel, DK, Goldberg, DG, Chen, C, Kepley, H, Mullan, Regenstein, M. Primary Care Residents in Teaching Health Centers: Their Intentions to Practice in Underserved Settings After Residency Training. Academic Medicine. 2018; 93(1): 98–103.

[8] Bazemore A, Wingrove P, Petterson S, Peterson L, Raffoul M, Phillips RL Jr. Graduates of Teaching Health Centers Are More Likely to Enter Practice in the Primary Care Safety Net. Am Fam Physician. 2015;92(10):868.

IMPORTANCE OF TELEHEALTH FLEXIBILITIES

The rise of telehealth over the past several years has led to a great improvement in access for patients with substance use disorders. There is strong support for telehealth from both patients and health-care providers, and its value as an integral component of the health-care system has been clearly demonstrated. In addition to combating workforce shortages, telehealth decreases delays in accessing care, provides expanded availability outside of traditional hours, boosts communication between patients and their clinicians, and enhances engagement in care. During the COVID pandemic, many regulatory agencies and insurers removed restrictions on telehealth services and provided for reimbursement rates that were on par with in person services. It is vital that we maintain the flexibilities allowed during the public health emergency for providing substance use treatment, including prescribing medications for opioid use disorder via telehealth.

Telehealth payment parity is also a crucial component of the ability to combat the fentanyl crisis. Full payment parity for telehealth services, and not just coverage parity, will require insurers—including Medicare—to pay for telehealth and in-person services at equal rates.

Underserved communities and health center patients deserve access to telehealth. Without payment parity, many health-care providers will be forced to limit or eliminate telehealth services because they cannot afford to provide care at reduced reimbursement rates.

CONCLUSION

Chairman Wyden and Ranking Member Crapo, thank you for allowing me this opportunity to share my thoughts and experiences from throughout my career. On behalf of the Institute for Family Health, I appreciate this committee's commitment to combating addiction and expanding access to treatment and recovery. I welcome your questions once witness testimony has concluded.

QUESTIONS SUBMITTED FOR THE RECORD TO ABIGAIL J. HERRON, D.O.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Iowa's Maternal Health Death Review Committee has found that a co-occurring condition in 36 percent of maternal health deaths is substance use disorder. This is similar to data we see nationwide. We know even basic interventions make a big difference. This includes training providers on how to talk to patients with substance use disorder and making sure patients know where treatment services are located.

Can you share best practices for reaching out to pregnant moms with substance use disorder?

Answer. Pregnancy provides a unique opportunity to provide medical care for women, including treatment for addiction. Pregnancy is a time of incredible behavioral change, and motivating factors for addiction treatment during this time may include concerns about the baby's health, readiness to stop substance use, concerns about custody of the child, and a desire to have a more stable environment for the future child. However, pregnant women can be very reluctant to acknowledge or seek treatment for substance use disorder, fearing disapproval and potential loss of parental rights.[1] Pregnant women may also lack information, or have misconceptions, about treatment during pregnancy despite the availability of safe and effective options.

Education among health-care providers about how to approach conversations about substance use during pregnancy is an important step towards helping to improve connections to care. Some key points include the use of first-person language, allowing individuals to choose the terms they use to describe themselves, and to focus on behaviors and outcomes in recovery rather than just adherence to treatment. NIDA (National Institute on Drug Abuse) offers education for clinicians about

[1] Frazer Z, McConnell K, Jansson LM. Treatment for substance use disorders in pregnant women: Motivators and barriers. Drug Alcohol Depend. 2019 Dec 1;205:107652. doi: 10.1016/j.drugalcdep.2019.107652.

stigma and the role of language in more effective communication with women, families, and communities impacted by substance use disorder.[2]

Question. The 988 Lifeline responds 24/7 to calls or texts from anyone who needs support for suicidal, mental health, and/or substance use crisis, and connects those in need with trained crisis counselors. Other online tools, such as *Find Treatment.gov,* have been launched to help those needing treatment and their families find quality addiction treatment.

Have these tools and resources improved access to addiction treatment? How do we measure that?

What information barriers still exist today preventing addicts from getting treatment?

Answer. Significant gaps remain in the provision of substance use disorder services for individuals in need. The 2022 National Survey on Drug Use and Health found that among people aged 12 or older in 2022 who were classified as needing substance use treatment in the past year, only about 1 in 4 (24.0 percent or 13.1 million people) received substance use treatment during that period.[3] There are a number of barriers that prevent or delay treatment for addiction. Medical treatment for opioid dependence is available and is known to save lives. Prescription medications for opioid use disorder (MOUD), such as buprenorphine and methadone, are safe and effective. However, accessing this type of treatment can be difficult. Individuals attempting to engage in care face stigma, lack of available treatment providers, and inadequate insurance coverage. Stigma continues to impact individuals with substance use disorder, resulting in patients who need care being fearful of seeking it. Patients may conceal or minimize their substance use due to fear of bias or mistreatment. Education among the public and the health-care community regarding the disease model of addiction can help towards normalizing the treatment of addiction as a chronic illness.

Patients may also face barriers when attempting access to care because of cooccurring mental illness. While rates of cooccurring substance use and mental illness are high, only a minority of substance use treatment organizations have the capacity to treatment patients with cooccurring mental illness.[4] Addiction treatment needs to be fully integrated into mainstream health care so that we are prepared to welcome patients into care through multiple entry points. Integrated care models allow patients to receive primary care, behavioral health care, and addiction treatment in a shared treatment setting. Integrated treatment allows individuals to access care for substance use disorders from the same treatment teams they already work with for their physical and mental health. Colocated, integrated care increases patients' acceptance of behavioral health care, and reduces stigma in accessing services.

The rise of telehealth over the past several years has led to a great improvement in access for patients with substance use disorders.[5] There is strong support for telehealth from both patients and health-care providers, and its value as an integral component of the health-care system has been clearly demonstrated. In addition to combating workforce shortages, telehealth decreases delays in accessing care, provides expanded availability outside of traditional hours, boosts communication between patients and their clinicians, and enhances engagement in care. During the COVID pandemic, many regulatory agencies and insurers removed restrictions on telehealth services and provided for reimbursement rates that were on par with in person services. It is vital that we maintain the flexibilities allowed during the public health emergency for providing substance use treatment, including prescribing medications for opioid use disorder via telehealth.

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[2] *https://nida.nih.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-language-showing-compassion-care-women-infants-families-communities-impacted-substance-use-disorder.*

[3] McGovern MP, Lambert-Harris C, Gotham HJ, Claus RE, Xie H. Dual diagnosis capability in mental health and addiction treatment services: An assessment of programs across multiple State systems. Adm Policy Ment Health. 2014;41(2):205–214. doi:10.1007/s10488–012–0449–1.

[4] Center for Behavioral Health Statistics and Quality. (2023). 2022 National Survey on Drug Use and Health Final Analytic File Codebook, Substance Abuse and Mental Health Services Administration, Rockville, MD.

[5] Palzes VA, Chi FW, Metz VE, Sterling S, Asyyed A, Ridout KK, and Campbell CI. (2023). Overall and Telehealth Addiction Treatment Utilization by Age, Race, Ethnicity, and Socioeconomic Status in California After COVID–19 Policy Changes. JAMA Health Forum, 4(5), e231018. doi: 10.1001/jamahealthforum.2023.1018.

QUESTION SUBMITTED BY HON. ELIZABETH WARREN

Question. The manufacturing of fentanyl involves a global network that often requires the purchase of precursors—the chemical substances used in the illegal manufacture of drugs—that typically originate outside of the United States.

Would a bill that closes loopholes in our anti-money laundering rules and cuts off international drug suppliers and cartels from using crypto to fuel their illegal businesses be helpful in stemming fentanyl trafficking?

Are digital currencies making it harder to shut down fentanyl trafficking?

Answer. I am unable to respond to these questions, as they are outside the scope of my expertise.

PREPARED STATEMENT OF JEANMARIE PERRONE, M.D., PROFESSOR, EMERGENCY MEDICINE AND MEDICAL TOXICOLOGY; AND DIRECTOR, CENTER FOR ADDICTION MEDICINE AND POLICY, UNIVERSITY OF PENNSYLVANIA

Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you inviting me to share my experiences as an emergency physician in a busy emergency department in Philadelphia, a city with the highest overdose death rate of any city in the country. Although statistics are dramatic, nothing is worse than facing a parent whose son or daughter has been brought to our hospital after a fentanyl overdose.

The struggles and anguish of a patient or parent battling opioid addiction and navigating the morass of lethal pitfalls in this chronic relapsing disease is heartbreaking. In the chaos of missed appointments, we recognized that the emergency department can be a gateway to same day treatment: initiating the first dose of lifesaving treatment with suboxone or methadone while still in the emergency department. Multiple randomized control studies have built the evidence demonstrating that treatment with these medications can reduce the risk of fatal overdose by 65 percent.[1] Yet, only 11 percent of people with opioid use disorder (OUD) receive these medications due to provider and patient level barriers to treatment.[2] Appointments, insurance, transportation, and pharmacies stand in the way of a first dose of this life saving medication.

We started a program to provide these medications in our emergency departments in 2018 and have treated thousands of patients. My colleagues have been trained in prescribing these medications and our nurses and staff help to identify and support patients to take that step. We have a grant funded peer led model that allows for someone with lived experience to guide the patient while they consider treatment options, and that peer can align with their next steps in getting the patient to the pharmacy, transitioning to a primary care doctor for continued medication, follow-up appointments, transportation, reminders and insurance reinstatement. This is one component of low barrier treatment, meaning that the patient doesn't need an insurance card, or identification or a primary care doctor. He/she doesn't need to wait weeks for an appointment or be subject to various scrutiny, all of which can derail early attempts at recovery.

In 2020, both COVID–19 and fentanyl combined to make the drug epidemic more lethal. Patients feared coming to our emergency departments for treatment while social isolation compounded the risk of fatal overdose. Fentanyl was replacing heroin in the illicit opioid supply so typical dosing was suddenly resulting in overdoses and as fentanyl was more potent but shorter acting, patients were using more frequently, resulting in more infections and hospitalizations. However, swift changes in regulations allowed for temporizing treatment access with telehealth which allowed us to shift some of our resources to a virtual platform.

Telehealth has created a critical safety net more cost effective than the emergency department and more patient centered than typical care settings. Through funding from Philadelphia Department of Public Health, our CareConnect warmline offers free telehealth substance use navigation and same day clinician appointments to start treatment with buprenorphine. We leveraged our peer led model to staff 9

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[1] National Academies of Sciences, Engineering, and Medicine. 2019. Medications for Opioid Use Disorder Save Lives. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25310.*

[2] *https://ldi.upenn.edu/our-work/research-updates/lowering-the-barriers-to-medication-treatment-for-people-with-opioid-use-disorder/.*

a.m.–9 p.m. 7 days/week. We have now treated over 1,500 patients via telehealth, including 10 percent of our patients who report release from incarceration in the past 30 days. Creating this important medication safety net for citizens reentering the community mitigates this high-risk period and is critical to closing the treatment gap that patients face when they leave carceral settings. We have also expanded other services for this vulnerable population including assistance with food, clothing, navigating insurance applications, phones and transportation to future appointments.

A Ryan White funding model could be used to establish regional networks of telehealth "addiction bridge" treatment to prevent gaps in care and continue patients on medication during care transitions such as hospitalization to outpatient, incarceration through release and pregnancy to parenting. We have found that two-thirds of our telehealth patients were recently on buprenorphine and were discharged from a rehabilitation facility without a timely follow-up prescription or lost insurance or faced a life event where their care was disrupted. Experiencing opioid cravings without medications can drive patients back to the street only to face the most lethal supply and potentially overdose. Creating low barrier models such as telehealth bridges enhance retention in buprenorphine treatment. Telehealth can also solve long appointment wait times in rural areas due to provider gaps. We must sustain current exceptions to Federal regulations for telehealth and create billing parity for services provided via telehealth comparable to in person.

Telehealth can also address important treatment access disparities. In the Philadelphia area, there has been a 30 percent increase in fatal overdoses in communities of color since 2020. Fentanyl adulteration of the stimulant drug supply has yielded a new cohort of patients with opioid exposures. Qualitative interviews from our community advisory board share that they want more privacy in their substance use treatment options—they don't want treatment in public addiction clinics or opioid treatment programs. We need to focus on developing culturally informed treatment options, medication preferences and harm reduction tools to address these disparities. Telehealth can help establish care with more privacy and then transition patients to a primary care integrated model where patients can have their addiction medication with their hypertension and diabetes medication all from one trusted provider.

Our patients transition from our ED or telehealth bridge to our primary care colleagues that have integrated addiction care into their treatment expertise. This integrated primary care model needs to be expanded and reimbursed to sustain discrete treatment options. This will require investment in clinician workforce including expanding addiction medicine training in graduate medical education as well as support for expanding training programs and trainees for addiction medicine fellowships.

FEDERAL STRATEGIES FOR CONSIDERATION

As Congress considers next steps to addressing this issue, my colleagues from Penn Leonard Davis Institute and I offer several points for consideration:

1. *Integration of Care and Lowering Barriers:* Patients who use substances present for care at a variety of touchpoints, including hospitals and emergency departments, primary care offices, harm reduction organizations, jails and prisons, and many settings outside of traditional substance use treatment settings. Patents may also have complex medical, behavioral health and social needs that are not well addressed in the current relatively siloed treatment system.
    a. Increased funding, including higher levels of reimbursement, for more integrated services at all of these locations.
    b. Requirements for specific settings such as post-acute care and skilled nursing facilities to provide needed medical and substance use care (*e.g.,* medications for opioid use disorder like buprenorphine and methadone).
    c. Welcoming, patient-centered care for people with substance use disorders at whatever locations they happen to seek care, which may involve funding for evidence-based stigma reduction continuing education programs for staff.
    d. Requirements for criminal legal system to provide treatment for substance use disorders, including buprenorphine and methadone, in their facilities.
2. *Methadone Access:* This is a dynamic area of policy with recent changes in SAMHSA guidance and pending legislation about expanding access for meth-

adone. Although we remain hopeful that legislative action will further expand access to methadone and integrate it within the care continuum, there are many opportunities within current regulatory standards to increase methadone access and retention and to better integrate methadone within the broader care continuum.[3]

   a. Improvement of existing methadone clinics requires stronger mechanisms for quality assessment in line with the most up-to-date scientific evidence, including mandates that require clinics to adopt rapid access protocols.
   b. Consider policy changes allowing for methadone access at primary care clinics and pharmacies, which would significantly improve access and lessen the burden on patients.

3. *Billing:* Current billing mechanisms that don't provide reimbursement for registered nurses and certified recovery specialists seriously limit robust, evidence-based interdisciplinary approaches to substance use disorder treatment.
   a. Create billing mechanisms for reimbursement of nursing and certified recovery specialist services.[4]
   b. Provide equal or higher reimbursement rates for mobile or street-based substance use disorder care. These settings reach patients where they are and deliver essential care.

4. *Harm Reduction:* Harm reduction services such as syringe access, overdose prevention,[5] and drug checking are evidence-based interventions in the substance use disorder treatment continuum. These programs are vastly underfunded.
   a. Allow for Federal funding for every aspect of syringe access programs, including safer use supplies such as syringes and pipes.
   b. Increase the availability of low-barrier small grant programs that allow community organizations without complex grant infrastructure to apply for funding.
   c. Expand drug checking and surveillance programs to ensure that experts across the country can keep abreast of changes to their local drug supplies.

In closing, I want to underscore the importance of funding interventions that work at scale, through Medicaid, Medicare and private insurance, and to focus on the importance of peer recovery services. Our programs utilize the wisdom and experience of peer recovery specialists, people in recovery from opioid use, who build alliances with patients and help them navigate the early treatment journey. Peer training programs provide a pathway to employment for people in recovery. We must expand this workforce by developing billing and reimbursement strategies for these services that can be initiated in ED visits, primary care and inpatient hospitalizations so we can grow opportunities for people with lived experience. Their journeys destigmatize and provide role models to our community members and patients struggling with addiction and are a source of inspiration—people do recover and we need to share that narrative.

Thank you again for the opportunity to share this with you today, and I look forward to your questions.

QUESTIONS SUBMITTED FOR THE RECORD TO JEANMARIE PERRONE, M.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. In 2019, the Health Resources and Services Administration began a concerted effort to train more peer support workers who have experience with substance use. Peer support services can be effective in bridging patients to treatment, especially in an emergency room setting.

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[3] Samet, J.H., Botticelli, M. and Bharel, M. (2018). Methadone in primary care—one small step for Congress, one giant leap for addiction treatment. *N Engl J Med* 2018; 379:7–8 DOI: 10.1056/NEJMp1803982.

[4] Kaur, M., and Melville, R.H. (2021). Emergency department peer support specialist program. *Psychiatr Serv,* 72(2), 230–230.

[5] Walley, A.Y., Xuan, Z., Hackman, H.H., et al. (2013). Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ,* 346.

Where do we stand in the number of trained peer support workers today, especially in the emergency department setting?

Has the Federal Government done all it can to remove barriers to peer support services?

Answer. Peer support workers in the United States number at least 30,000, however the specific number of peers working as recovery specialists for patients with substance use disorders in the emergency department (ED), while growing, are not available. Estimates suggest that there are several thousand peers employed in various health-care settings including the ED. Studies have demonstrated positive outcomes from the utilization of peer support workers in the ED. These benefits include:

- Reduced repeat visits to the ER.
- Lower health-care costs.
- Improved patient engagement in follow-up care.
- Enhanced overall patient satisfaction.

Despite the progress, several barriers still hinder the full integration of peer support workers into the ED setting:

- **Inconsistent Funding:** Many peer programs rely on grants, limiting the sustainability and career growth of these positions.
- **Justice Involvement*:** Individuals in the peer recovery community often have prior justice involvement, which can limit their job opportunities due to background checks.
- **Reimbursement*:** Expanding peer support services is limited by challenges in billing and reimbursement, essential for employment pathways and job sustainability.
- **Varying State Regulations:** The lack of standardized regulations across States creates challenges in training and certifying peer support workers.
- **Cultural Shifts:** Integration into existing ED teams requires cultural changes and buy-in from medical staff, which can be a slow and challenging process.

Question. Iowa's Maternal Health Death Review Committee has found that a co-occurring condition in 36 percent of maternal health deaths is substance use disorder. This is similar to data we see nationwide. We know even basic interventions make a big difference. This includes training providers on how to talk to patients with substance use disorder and making sure patients know where treatment services are located.

Can you share best practices for reaching out to pregnant moms with substance use disorder?

Answer. Pregnant individuals who use substances face substantial obstacles to health-care access, ranging from lack of transportation to fear of legal consequences, which may delay care. Black patients are more likely to be tested for drug use during pregnancy and referred to child protective services than their non-Black counterparts despite equivalent rates of positive drug tests between the 2 groups. Caring for pregnant individuals with substance use disorder (SUD) requires a compassionate, equitable, and nonjudgmental approach.

Best practices:

Offer comprehensive care through a multidisciplinary team including obstetricians, addiction medicine specialists, mental health providers, social workers, and peer support.

Facilitate access to opioid agonist treatment (*e.g.,* buprenorphine, methadone) for opioid use disorder, which improves outcomes.

Connect patients to wraparound services including counseling, case management, housing, and transportation assistance.

Avoid punitive actions such as criminal sanctions or automatic reporting, as this deters prenatal care seeking. Build trust by protecting confidentiality as allowed by law.

Provide education on harm reduction principles, which demonstrate respect and focus on reducing negative consequences of substance use during pregnancy.

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*Barriers that could be addressed by the Federal Government.

Partner with community organizations, peer support groups, and social services to identify and engage pregnant individuals with SUD who may not be accessing prenatal care.

QUESTION SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. I've been working on legislation that would improve implementation of plans of safe care, for infants and families affected by substance use, to better provide substance use disorder treatment and other services that support parents in their recovery and prevent adverse experiences for children.

Can you speak to the need in your communities to ensure infants affected by parental substance use disorder and their families receive treatment and other support services that allow them to thrive while also preventing the need for foster care?

Answer. Ensuring infants affected by parental substance use disorder (SUD) and their families receive appropriate treatment and support services to thrive while preventing foster care placement requires a comprehensive, intersectoral approach. Here are some key strategies:

EARLY SCREENING AND INTERVENTION

Implement universal screening for prenatal substance exposure and SUD during pregnancy and at birth to identify infants and families in need of services early.

Provide immediate referrals to evidence-based interventions like Plans of Safe Care and home visiting programs that support maternal recovery and promote positive parent-child bonding. Expand access to family-centered SUD treatment that allows the birthing parent to receive medication for opioid use disorder (MOUD) treatment while keeping infants with them.

Provide wraparound services like parenting support, counseling, and care coordination to address families' complex needs. Utilizing peers with experience as birthing parents to lead these services is advantageous.

Ensure accessible care and resources for caretakers who are not the birthing parent.

INTERSECTORAL COLLABORATION

Foster collaboration between child welfare, health care, substance use treatment, and other sectors to provide coordinated, comprehensive services.

Cross-train providers across sectors on SUD, neonatal abstinence syndrome, trauma-informed care, and family preservation.

SUPPORTIVE POLICIES AND FUNDING

Implement policies and funding streams that prioritize keeping families together and providing community-based services over foster care placement when safe.

Increase funding for SUD treatment, early intervention, home visiting, and other family support services.

QUESTIONS SUBMITTED BY HON. ELIZABETH WARREN

Question. A 2021 Government Accountability Office (GAO) study found that crypto has "been central to the rise of drug sales in the U.S.," specifically fentanyl and other synthetic opioids.

Are digital currencies making it harder to shut down fentanyl trafficking?

What is your assessment of the role of cryptocurrency in facilitating fentanyl trafficking?

Answer. My scope of work does not include any aspects of interdiction. I cannot share expertise in this domain.

Question. Scheduling drugs can limit researchers' abilities to study these chemical compounds, limiting the potential for discovering new therapeutic indications or treatment options.

In the course of your work treating opioid addiction and mitigating the risks of overdoses, have you identified a need for additional research on fentanyl, fentanyl-related substances, or xylazine? If so, what research is needed, including research into effective medicines for reducing or reversing the effects of those substances?

Answer. There have been extensive investments to date in describing the epidemiology of substance exposures in the forensic population including fentanyl, xylazine, cocaine, methamphetamine and other substances which may contribute to fatal overdose. However, less resources and data are available about substances involved in nonfatal overdose. Many hospitals are yet to include fentanyl testing in their drug screening panels, which has slowed the assessment of the impact of fentanyl on nonfatal overdose. Similarly, we know that xylazine has been present in the drug supply since at least 2012 in some Eastern states, however, it was clinically "silent" until recently as the quantity and ratio of xylazine to fentanyl has increased. However, without the ability to measure either of these substances in real time, identification and management of substance use withdrawal, overdose and other complications proceeds empirically and diagnostic and treatment opportunities are missed.

Research is needed in:

Identifying drugs, patterns of use, phenotypes of people who use drugs and their response to evidence-based medications including methadone, buprenorphine, and naltrexone would help extend treatment to greater populations with enhanced retention in treatment.

The role of naloxone in reversing the fentanyl (or any opioid) component of any overdose is highly effective and lifesaving. The role of higher dose or longer acting opioid reversal agents are not needed.

The role of xylazine reversal agents are also a lesser priority because naloxone sufficiently reverses the fentanyl component of these mixed substance overdoses restoring breathing; persistent sedation due to xylazine or other sedatives can be managed supportively.

Exploring effective modalities to provide low barrier treatment options such as care initiated in emergency departments, via telehealth or via mobile vans to engage more patients into evidence based treatment with methadone or buprenorphine.

Passing the MOTAA legislation *(https://www.congress.gov/bill/118th-congress/senate-bill/644)* to liberalize methadone prescribing in primary care by addiction medicine specialists; future research efforts should assess the safety, efficacy and any unintended consequences as new methadone access is implemented.

Scheduling of xylazine is being considered by multiple States. Although this may help with tracking and accounting of xylazine products by DEA and other law enforcement, concomitant increases in criminal justice interventions for possession or use of these substances should not be the goal or unintended consequence of these efforts.

An additional reference for the xylazine fentanyl research priorities authored by my colleagues and I:

Haroz, Rachel, M.D.; Huntley, Kristen, Ph.D.; Perrone, Jeanmarie, M.D. Research Priorities to Improve Treatment of Patients Exposed to Xylazine-fentanyl: Rapid Communication from a National Institute on Drug Abuse Center for the Clinical Trials Network Meeting. *Journal of Addiction Medicine* 18(1):p 1–3, ½ 2024. DOI: 10.1097/ADM.0000000000001235. *https://journals.lww.com/journaladdictionmedicine/abstract/2024/01000/research_priorities_to_improve_treatment_of.1.aspx.*

PREPARED STATEMENT OF TONY VEZINA, EXECUTIVE DIRECTOR, 4TH DIMENSION RECOVERY CENTER (4D)

Chairman Wyden, Ranking Member Crapo, and U.S. Senate Committee on Finance members, my name is Tony Vezina, and I am a person in long-term recovery, which for me means I have not used any alcohol or drugs since July 20, 2012. I serve as the executive director of 4D Recovery and participate in various roles on boards and commissions, including Oregon's Alcohol and Drug Policy Commission. My remarks do not represent my titles; they are based solely on my personal and professional experience. I hope to provide this committee with testimony combining personal experiences, academic knowledge, and professional insights that move you to take pragmatic steps to curb addiction in America.

Combating the fentanyl epidemic is a paramount priority in the United States, and I am humbled to support the Senate Committee on Finance in exploring solutions that will ultimately increase general welfare in America and spare innumerable deaths from unintentional overdose. The fight for recovery isn't new. Americans started advocacy for treating alcoholism as a health issue in the 1840s with America's first large-scale peer recovery movement known as the Washingtonians. They knew then what I know now: people with substance use disorders can recover when they are provided the tools to do so. According to the National Institutes of Health, a survey of recovering people concluded that "tens of millions of Americans (9.1 percent of Americans) had successfully resolved an AOD (alcohol or other drug problem) using a variety of traditional and nontraditional means." This demonstrates that people can and do recover, and treatment services work.

RECOMMENDATIONS

Improvements to the substance use service sector are vast and complex, requiring regulatory changes and substantial financial investments. The recommendations below align with Medicaid and target Fentanyl and other opioid use disorders. Prioritizing youth interventions, access to medication for opioid use disorder, expansion of recovery supports, treatment services, and workforce development can take critical steps in addressing the Fentanyl and addiction crises. My passion is for youth and young adults; these recommendations reflect that.

PRIORITIZE YOUTH INTERVENTIONS

Adolescents and young adults in America who use substances are underserved despite the incredible benefit to them and our society, investments in substance use services would yield. Emerging research from universities and multiple government and private entities significantly demonstrate that investments in primary prevention and substance use disorder treatment produce substantial economic returns, reducing government burden spending in other sectors, *e.g.,* the criminal justice system, health-care costs, child welfare, etc. U.S. lack of capacity creates vulnerabilities for our youth and our future. The following data illuminate problems American teens face.

- The percentage of people aged 12 or older with an SUD in the past year was highest among young adults aged 18 to 25 (27.8 percent or 9.7 million people), followed by adults aged 26 or older (16.6 percent or 36.8 million people), then by adolescents aged 12 to 17 (8.7 percent or 2.2 million people). (NSDUH, 2023)
- Among the 1.8 million adolescents aged 12 to 17 in 2022 who had an SUD in the past year and did not receive substance use treatment in the past year, 97.5 percent (or 1.7 million people) did not seek treatment or think they should get it (NSDUH, 2024 and MHA, 2024). An estimated 0.5 percent of adolescents with an SUD (or 8,000 people) sought treatment, and 2.0 percent of adolescents with an SUD (or 34,000 people) did not seek treatment but thought they should get it. (NSDUH, 2024)
- New reports from the CDC show that 22 U.S. teens die every week from drug overdose. That is the equivalent of an entire high school classroom dying every week. *Fentanyl has become the leading cause of death among American teens.*

The finance committee can take steps to curb the crisis our youth are experiencing, specifically:

PREVENT AND INTERVENE

Use CHIP and Medicaid funds to increase primary prevention, screening, referral tools, and school-based support investments. Despite the evidence of primary prevention, few public resources are allocated, likely because of the lack of tangible outcomes.

EXPAND ACCESS TO EVIDENCE-BASED TREATMENT AND INTERVENTIONS

Expand access to residential treatment, outpatient, and peer recovery services by increasing reimbursement rates, providing one-time capacity-building funds, and allowing peer-based services that do not require assessments. In the United States today, 23 States do not offer adolescents whose families are receiving Medicaid services to access treatment.

According to a National Institutes of Health-supported analysis, teen residential capacity is lacking, and services are expensive. The report found that 46 percent of facilities contacted had a wait list, with the average time being 28 days. The study found that between nonprofit and for-profit agencies, for-profit was more likely to have a bed open immediately (77 percent versus 39 percent) but at roughly triple the daily cost ($1,211 versus $395). Nonprofits were four times more likely than for-profits to accept Medicaid.

Outpatient treatment is generally less costly and is used by more individuals than residential treatment. Outpatients can provide various levels of care, from simple education to rigorous interventions based on the individuals' substance use severity. Additionally, outpatient services are an adjunct to residential care as a level of care titration that supports continued skill development and a reduction of relapse tendencies, much like physical therapy is an adjunct to an acute muscle injury.

Increasing peer support services such as Recovery Drop-In Centers for teens provide them with critical social support that reinforces and normalizes a life without the use of drugs or alcohol. Youth with substance use disorders need positive peer reinforcement to maximize success. Peer support services use the lived experience of people in recovery and provide hope and guidance to those seeking recovery. Peer support can increase a person's motivation to change behavior and improve treatment outcomes.

Lastly, it is a necessity that medications for opioid use disorders are widely available for youth, given the unprecedented increase in deaths from overdoses. Increased education for prescribers will make sure that they know these medications are successfully treating opioid use disorders, and that access to these lifesaving drugs is available.

The Finance Committee can take other significant steps for adults in America, such as the following.

EXPAND RECOVERY SUPPORT SERVICES

Create access to recovery centers and recovery residences (sober living) by creating specific funding models that facilitate service durations aligned with chronic disease conditions and reimburse peer support for pre-treatment and outreach engagement activities. According to Facing Addiction in America, a report by the U.S. Surgeon General, it can take more than 5 years of remission before the risk of relapse drops below 15 percent. This demonstrates the need for services that provide ongoing support post-treatment or incarceration.

Recovery Centers provide people in recovery with free daily access to essential community-based and peer support services. This service is extremely cost effective and leverages grassroots recovery supports like 12-step Meetings. This service modality is currently being studied closely by the Recovery Research Institute, a nonprofit organization of Massachusetts General Hospital, an affiliate of Harvard Medical School, dedicated to advancing addiction treatment and recovery. A Recovery Center is typically open daily, offers 12-step and other recovery meetings, organizes events for recovering people, and offers skill-building workshops and one-on-one peer support services. Medicaid could potentially fund or partially fund Recovery Centers on a per-member basis.

Peer support services provide hope and encouragement to people during recovery, and extensive research demonstrates other positive outcomes, including reduced recidivism, lowered health-care costs, and increased employment. Expanding Medicaid-covered for pre-treatment outreach activities can increase treatment enrollment, especially for those addicted to fentanyl.

INVEST IN RECOVERY RESIDENCES

In decades past, recovery housing was considered a "Treatment First" model, antithetical to the body of research supporting the "Housing First" model. Today, this is not the case. Recovery housing now operates pre-treatment, post-detox, concurrent with treatment, post-treatment, concurrent with medication-assisted treatment, and in harm reduction practices with "Stabilization Houses" and "Aid and Assist Recovery Housing" as a part of community restoration services.

Recovery housing now operates on a continuum and is supported by over 100 research studies demonstrating its efficacy in supporting recovery and enhancing treatment outcomes. Currently, NSTARR (the National Study of Treatment and Addiction Recovery Residences) is implementing the U.S.'s most extensive scale series of studies on the efficacy of the Recovery Residence model through the ARG re-

search group. ARG has previously completed over 50 studies demonstrating the efficacy of recovery housing.

SAMHSA's best practices manual summarizes that recovery housing produces "decreased substance use, reduced likelihood of return to use, lower incarceration rates, higher income, increased employment, and improved family relationships."

Recovery housing is now endorsed by:

- HUD (Recovery Housing Policy Brief, 2015);
- White House ONDCP and LAPPA (Model Recovery Residence Certification Act, 2021);
- NCMW (Building Recovery: State Policy Guide for Supporting Recovery Housing, 2018); and
- SAMHSA (Best Practices for Recovery Housing, 2023).

NARR, the National Alliance of Recovery Residences, is the largest accreditor of recovery housing in the U.S., active in 37 States. Like CARF and JCAHO, NARR accreditation implements a credentialing process with 105 research-based standards that recovery housing providers must meet to obtain accreditation.

Increased funding to Recovery Residences will ensure individuals addicted to fentanyl have supportive housing environments free from the temptation of drugs. Medicaid can provide funding to NARR Accredited or State-Licenced Recovery Residences to ensure low-income individuals have access.

INCREASE ACCESS TO MEDICATION FOR OPIOID USE DISORDERS

Increasing access to Medication for Opioid Use Disorders is an expedient option that can create an immediate impact on the fentanyl crisis. The efficacy of this intervention is well researched, but accessibility is limited, creating significant barriers to care. Providing access in jail settings, through mobile clinics, in emergency rooms, and via telehealth would drastically reduce overdose rates while increasing engagement and retention in the recovery process.

EXPAND SUBSTANCE USE DISORDER TREATMENT

According to the National Survey on Drug Use and Health, people were classified as needing substance use treatment in the past year if they had an SUD or received substance use treatment in the past year. Among people aged 12 or older in 2022 who were classified as needing substance use treatment in the past year, about 1 in 4 (24.0 percent or 13.1 million people) received substance use treatment in the past year.

Limited access to treatment creates system flow issues where the linkage between complementary care is severed, leaving individuals at high risk for relapse. For example, an individual exiting detoxification services cannot enter residential treatment due to wait-lists, so they return to their previous environment and risk using again. This scenario is common, depending on individual States, and perilous for fentanyl users.

Increasing reimbursement rates is a necessary and critical strategy to expand access. Reimbursement rates that do not cover the costs of detoxification and residential treatment disincentivize organizations to establish or expand operations and create workforce barriers due to low wages.

WORKFORCE DEVELOPMENT

A summary of research from the National Conference of State Legislatures reveals that burnout rates among behavioral health professionals are higher than among other types of workers.

The U.S. mental health crisis, fueled and synergized by newer synthetic forms of methamphetamine, fentanyl, xylazine, and nitazenes, is leading to extreme and profound psychiatric effects that have also exacerbated the growing Aid and Assist population in the U.S. Court system. These clients are challenging to work with due to growing comorbid psychoses and are leading to increased rates of burnout among staff.

In 2023, the Health Resources and Services Administration (HRSA) reported that the shortage of addiction counselors is projected to last until 2036. NSDUH estimated that 44 million people had SUDs in the past year. According to HRSA, there

are 86,794 addiction counselors in the U.S., and we need 125,010 additional addiction counselors to fill the need.

Reimbursement rates remain low, and wages remain very low for workers who are being asked to work with individuals with severe addiction and mental health conditions.

Expanding peer support services can help ameliorate the workforce shortage.

Moreover, the Obama White House Report on Occupational Licensing warned of the consequences of over-licensing in the United States and called for voluntary certification instead. Licensing is often coupled with irrelevant requirements, rules, and extreme background checks not supported by research. The over-licensing of America has led to extreme difficulties for military families to move from State to State due to the inability to acquire reciprocity for their occupational license in other States and discrimination that leads to workers of color. For example, in Oregon, about 89 percent of licensed behavioral health professionals are non-Hispanic White, compared to only 68 percent of certified behavioral health workers.

The U.S. should support voluntary peer-run certification of peer behavioral health workers with basic or adjustable background check procedures that maximize the workforce while maintaining the safety of those served.

ADDICTION RECOVERY AUTOBIOGRAPHY



Addiction is a reality that I, along with my family, am intimately familiar with. Though I hail from Pocatello, ID, my formative years were spent in Camas, WA. Eventually, I found myself tethered to Portland, OR. My numerous relocations were not the result of family military assignments, parental job obligations, or personal academic aspirations. Rather, I moved around a lot because of drugs and alcohol.

My family's history with addiction stretches back as far as I can trace, but I'll begin with my parents. My mother was just 16 when she had me. She left Idaho soon after, seeking to escape the drugs, violence, and poverty that marked her life. She hoped to give me a chance at a better life. Despite the odds, she succeeded, even though her own life was tragically cut short due to her opioid addiction.

Growing up in the affluent town of Camas presented challenges for me. We were not well-off financially, and my stepfather was an alcoholic. Despite these hardships, I enjoyed playing soccer, football, and basketball. I also loved fishing and bike riding. However, around the age of 12, I began experimenting with alcohol and tobacco. Within a few years, this experimentation escalated into regular partying, leading to frequent run-ins with the law. My drug addiction strengthened in High School, and I eventually dropped out. Around this time (roughly 2002), my mother was diagnosed with fibromyalgia and received a large prescription for Oxycotin, and I started using them. I want to be frank: this was wrong, and I take full responsibility.

I soon became addicted to OxyContin, which I realized when I ran out of the pills and thought I had the flu, but my friend told me it was withdrawal. I knew at the time that I was in a tough spot because I was unable to function for weeks without using a pill to "get well." Opioid withdrawal for me was like getting bashed with a baseball bat wrapped in barbwire, and I spent years trying to quit.

A couple of years into the OxyContin rush, my mother's prescriber was shut down due to overprescribing. I later found that this office was referred to as a "pill farm," a location where people could receive large amounts of various addictive medications. When the pill farm shut down, the heroin dealers ramped up, leveraging an opportune moment to capitalize on an emerging consumer base. **Something strikingly similar to the current fentanyl crisis, which will be addressed later.**

With a vacuum in the Oxycotin market, many people I knew turned to heroin to avoid the sickness. For many of us, it started with snorting a liquid mixture, something shared by different types of "users." Heroin soon became a viable option for various individuals, including those dependent on pain management and young people like me, who were naive to the supreme addictive nature of pain medication. We became snared in a vicious cycle, and many did not make it out.

At some point, using drugs became a necessity: I've heard it described by recovering addicts as being reduced to almost an animal level, and I felt that way at times. I moved back to Idaho to live with my grandma a few times; this is known as a geographic in the recovery community, but every time, my addiction followed me. In January of 2007, my addiction took a turn for the worse after my mother died in a fatal car accident, something I had long feared as she would regularly fall asleep while driving because of her medication and heroin use. I am not alone in this; a new report from SAMSHA states that 321,566 children in the United States lost a parent to drug overdose from 2011 to 2021, according to a study published in *JAMA Psychiatry*.

After my mom died, I completely caved to despair and began using drugs intravenously. This was a pivotal moment in my drug use and the beginning of the last chapter. Arriving back in Portland shortly after my mom's death, my girlfriend became pregnant, and I began the long and arduous journey to sobriety. Research estimates that it takes an average of seven attempts to quit using substances, which seems reasonable if you compare how humans struggle with sugar and fatty foods.

My treatment attempts were mostly voluntary, though the one that stuck was via a criminal justice intervention. The last time I used any drugs or alcohol was July 19, 2012, when I was arrested due to my erratic behavior within a convenience store related to my meth and heroin use. In jail, I was held with early release to treatment. I left jail and went to the Volunteers of America Men's Residential Treatment Center, where I stayed for nearly 6 months.

While I partially attribute the criminal justice system intervention to saving my life at age 27, I am not advocating for this as a singular solution to the complex issue of addiction and fentanyl. There were many missed intervention opportunities for me that I will highlight for the committee before discussing my post-use recovery journey. I will not dwell on circumstances that have since been rectified but focus on gaps I see persist today.

HEALTH-CARE INTERVENTIONS

I found myself in various health-care settings and was not effectively engaged despite my obvious addiction symptoms, and I will highlight two. First, I was removed by security guards several times when seeking help, primarily for using heroin in the facility. I think this could have been an opportunity for engagement and rapid medication for opioid use disorder induction or referral to treatment. Second, I was hospitalized for an abscess on my left forearm caused by my attempt to inject Vicodin (apparently, you cannot do that). During my stay at the ER, I begged and pleaded for a prescription of methadone but was denied, although a priest did visit a couple of times. I was in terrible withdrawal and kept leaving the hospital against medical advice to get well.

YOUTH-BASED CARE

I now know that I have several vulnerabilities for addiction—genetics, socioeconomic, and family use patterns—but was never taught this in school. I knew that drugs were illegal, but I also loved them the first time I tried them. I didn't know about addiction either, at least not as a health-care disorder; I knew there were drug addicts but thought they were inept people. Primary prevention strategies may

have been effective in helping me. Additionally, school-based substance use interventions and recovery services may have intervened on me earlier and helped me avoid a lot of problems.

CRIMINAL JUSTICE INTERVENTIONS

I started going to jail at 15 years old, all related to my substance use. I do not believe I was ever offered treatment while in prison as an adolescent. I cycled in and out of county jail in multiple States throughout my addiction but was never provided treatment while in jail, including medication for opioid use disorders. The criminal justice system is saturated with substance users who don't have much . . . except for time. Investing in treatment and recovery services in carceral settings would undoubtedly facilitate the rehabilitation process.

Back to my story. I am 27 years old, exiting county jail to a residential addiction program with no driver's license, no education, no money, and no shoes, but I did have about 65 percent of my teeth left and warrants in two States (Idaho and Washington). As I sat in the lobby of the treatment center, I had a moment of clarity: instead of leaving and going to get high one more time, I would stay long enough to get as healthy as the men I saw eating in the chow hall.

While in treatment, I was required to do several things I was reluctant towards. One was to attend GED classes on Tuesdays and Thursdays at the Londer Learning Center, a program the criminal justice system funded to help those on probation improve their education. This ultimately led to me receiving my GED and being awarded a scholarship to Portland Community College for 12 credits. I attended daily therapy groups led by alcohol and drug counselors and met one-on-one with my counselor every other week. Many of the counselors stated they were in recovery, which eased my suspicions and cracked the door for learning. Lastly, I was required to go to recovery meetings and build a support group. While the cognitive therapy was impactful, the integration into the recovery community was essential.

I enrolled in Portland Community College and started my educational journey during my treatment stay. In my first semester, I attended a recovery support group hosted in the women's resource center that gave me one free credit. The allure of saving money kept me engaged, and I met a faculty member who suggested that I start a recovery club. The Recovery 101 Club's mission was to destigmatize addiction by organizing community service events led by recovering students. Club organizing introduced me to student government, where I became the president of the Phi Theta Kappa Honors Society and later the student body president. During my tenure at PCC, I also cofounded a nonprofit organization called The 4th Dimension Recovery Center. I am still the executive director today (I included our most recent annual report). My leadership development at PCC was profound, and I am incredibly grateful to the faculty and staff who shaped my aspirations.

I graduated from PCC and moved to Concordia University for the social work program, discontinuing student government to pursue my dreams at 4th Dimension Recovery Center, now 4D Recovery. 4D Recovery is a nonprofit recovery community organization providing a variety of treatment, peer-based recovery, and housing services for adolescents and young adults with substance use disorders. As I attempted to grow 4D Recovery, I realized there needed to be more funding opportunities. I began organizing, engaging in local and State politics, and participating in service opportunities on boards, committees, and commissions.

In 2017, I cofounded Oregon Recovers, a statewide advocacy group charged with increasing services for substance use disorder. After researching the actual gap in services for people who need them, I was astonished by the contradiction that addiction is a treatable disease, but services are lacking. I decided then that I would do everything I could to change that in Oregon. Over the last 7 years, I have participated in many great things in advancing recovery, which my resume illustrates in the appendix.

As I grew professionally, I lived in recovery-supportive housing for several years. This housing was inexpensive and right down the street from my treatment center. Living with other sober people provided a sanctuary from the onslaught of addictive substances lingering outside the house and provided accountability and the opportunity to develop financial skills. I exited recovery housing, lived with recovery friends, and then rented a room until I bought my first home.

FENTANYL CONSIDERATIONS

Quitting heroin was nearly impossible for me, but I cannot imagine the difficulties associated with fentanyl, which is changing the illicit drug market and related attempts to tackle it. Heroin and fentanyl are similar to cocaine and crack in many ways. First, crack was cheap and readily available, and the high peaked quickly and evaporated just as fast. This means a person has to use it frequently to maintain the desired effect. Fentanyl is similar in cost, availability, and effect duration, but the fatality risk is much higher, and it is consumed by a broader user market.

Where I once needed to use heroin every 6–8 hours to stay well, it is being reported to me that people need to use it every hour. Because of the fatality risk, this results in the frequency of potential overdose increasing exponentially. The consumption frequency also reduces the "window of opportunity" for intervention. Most people I know in recovery describe stories of fleeting ambition to quit and even sustained use despite knowing they need to quit. To be successful in treating fentanyl addiction, we need rapid access to effective tools—and one of the most effective tools is medication for opioid use disorder.

We cannot treat people who die from overdose, and medications for opioid use disorder curb the necessity to use and provide opportunities to engage in service interventions. Access to MOUDs should be widely available and accessible in multiple settings, including jails, hospitals, and via telehealth.

Tackling the fentanyl crisis requires investments in prevention and education, treatment, and recovery support services—the U.S. Senate Finance Committee has the opportunity to expand critical access via Medicaid and CHIP authority.

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QUESTIONS SUBMITTED FOR THE RECORD TO TONY VEZINA

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. In 2019, the Health Resources and Services Administration began a concerted effort to train more peer support workers who have experience with substance use. Peer support services can be effective in bridging patients to treatment, especially in an emergency room setting.

Where do we stand in the number of trained peer support workers today, especially in the emergency room setting?

Answer. I am a board member of Oregon's non-governmental peer certification board, the Mental Health and Addiction Certification Board of Oregon (MHACBO), who worked closely with SAMHSA on the National Model document. In consultation with its executive director, we have drafted the following response to peer support.

This is a difficult question to answer as there isn't, to the best of my knowledge, a national database for peer support workers. Additionally, States vary on practice standards and certification requirements. Recently, the Substance Abuse and Mental Health Services Administration published National Model Standards for Peer Certification which will help standardize peer support practices (certification and service delivery). This report, and effort, will bring clarity to national peer capacity.

According to a National Institutes of Health article, it is estimated over 30,000 peers are in America. We project that this number has grown in recent years with the total number being closer to 50,000. Estimating the number of peers working in emergency rooms is unattainable, yet the concept is gaining popularity, but significant barriers exist to expansion, mostly related to background checks and reimbursement issues.

Question. Has the Federal Government done all it can to remove barriers to peer support services?

Answer. Indeed, by permitting States to employ private peer-run credentialing boards, the process has shifted from onerous background checks to more streamlined ones. More States should move away from State driven licensing/certification of peers to voluntary certification as is recommended by the Obama White House Report on Occupational Licensing. Moreover, by permitting Medicaid to reimburse for peer services, the Federal Government has allowed the expansion of peer services to lower-income American's, but from my understanding the private insurance market lacks requirements for peer support benefits.

Question. In 2022, Congress passed my bipartisan Rural Opioid Abuse Prevention Act. The law supports rural communities with a high level of opioid overdoses in their efforts to improve prevention, treatment, and recovery efforts.

What do successful rural efforts need to reduce overdoses and deaths?

Answer. There are several efforts to address rural overdoses, including:

- Expanding access to medication-assisted treatment via mobile clinics and longer prescription periods.
- Increasing funding for outreach and engagement from peers.
- Increasing funds to addiction recovery centers.
- Expanding access to telehealth services.
- Providing reimbursement rate models that support transportation.
- Provide workforce recruitment and retainment strategies, including relocation costs and loan forgiveness for rural-based work.

Question. The 988 Lifeline responds 24/7 to calls or texts from anyone who needs support for suicidal, mental health, and/or substance use crisis, and connects those in need with trained crisis counselors. Other online tools, such as *Find Treatment.gov,* have been launched to help those needing treatment and their families find quality addiction treatment.

Have these tools and resources improved access to addiction treatment? How do we measure that?

Answer. I have not read reports on the efficacy of these tools and resources, but I am aware that finding treatment and navigating the complex treatment service market is a significant barrier to care. I suspect these tools will be helpful.

Question. What information barriers still exist today preventing addicts from getting treatment?

Answer. One barrier is the lack of public understanding of substance use disorder and the disease concept of recovery. Some professionals in the substance use field reference "stigma attached to drug use," but I believe it is the stigma of the behaviors associated with substance use disorders (especially severe addiction) that drive negative attitudes and beliefs of "addicts." It wasn't until I understood that my addiction was a disease, one that was treatable, and that I was responsible for, that I began to take steps to be a functional member of society by quitting drugs and changing my life. By increasing the publics awareness of addiction, the treatment of it, and the result of recovery, we can get more people to participate, maybe even earlier in their using careers.

In this process, we should be cautious of "harm reduction" philosophies that are rooted in beliefs that drugs are a human right, and subsequently seek to normalize drugs use, establishing passive approaches to addiction treatment engagement and even, at the extreme, pursue illicit drug commercialization. Recovery should be normalized, not addiction, and public funded efforts to help those addicted to drugs, especially peers, should have clear expectations of increased health and well-being.

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PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

This morning the Finance Committee gathers to discuss the scourge of the deadly synthetic opioid fentanyl. Fighting fentanyl requires fitting all of the pieces of the puzzle together. Already this year, Congress has acted to disrupt the flow of fentanyl from other countries like China, thanks to the work of Senator Brown.

Today, the committee is looking at how the health-care piece fits in. These health-care issues have not had the attention they deserve. Senator Cantwell has been leading the way in our region, and I want to thank her for her attention to this issue. This epidemic has hit communities like a wrecking ball, especially in the Northwest in recent years. The health-care puzzle piece is about people—real people—whose lives have been ripped apart by the devastating disease of addiction.

I'm going to focus on a few areas that need attention. First is prior authorization.

Only one in five Americans receive lifesaving medication treatment for opioid use disorder—despite evidence that it works. Two months ago, Congress passed a law that I championed requiring State Medicaid programs to cover "medication-assisted treatment" or MAT on a permanent basis, which is the gold standard treatment for opioid use disorder. I'm very concerned that big health insurers like UnitedHealth and Aetna that contract with Medicaid are using "prior authorization" at high rates, and that is causing delays and denial of this treatment.

In the context of the opioid epidemic, prior authorization can be the difference between life and death. If someone walks in for treatment for their opioid use disorder, and gets stymied by prior authorization, they may never return, dying from an overdose before the prior authorization is approved.

Last fall, I launched an investigation looking into how these insurance companies are ripping off patients and taxpayers in Medicaid by using the program as a piggy bank through tactics like prior authorization. As patients suffer and these mega-corporations post record profits, they are also dragging their feet providing the committees with answers about these tactics. These multibillion-dollar companies owe answers to taxpayers about how these Medicaid dollars are being used.

Now I'd like to talk about opioid use disorder treatment for individuals who are coming out of prisons and jails. I have heard from law enforcement officials in rural Oregon time and time again that these individuals need to be able to receive adequate treatment for this disease during and after their sentence.

Making these reforms is common sense. States are working on their own initiatives to support access to care for people before coming out of incarceration who need uninterrupted care, including my State. I'm working with State legislators like Pam Marsh from southern Oregon and sheriffs across the State to get this done. These reforms are a start towards being responsive to what law enforcement officials are asking for: getting people help for their addiction before they get out of jail so they don't come back.

Let's wrap up by talking about prevention and thoughtful approaches to pain management. More needs to be done to head off opioid use in the first place and encourage more nonopioid pain management to be used in American health care. There are promising new therapies in development that block pain signals rather than flooding receptors in the brain with opioids that create an addictive feedback loop. Members of this committee will be watching the development of these therapies closely and looking for ways to accelerate their entry into the health-care system if they prove to be safe and effective.

Every single member of this committee knows the anguish and pain that opioids bring to our communities from coast to coast. I look forward to hearing from our witnesses and members of this committee about how to tear down the remaining barriers to treatment, save lives, and get struggling Americans the help they need.

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510–6200

To: Members of the Senate Finance Committee
From: Senator Chuck Grassley, Chairman of the Senate Finance Committee
Senator Ron Wyden, Ranking Member of the Senate Finance Committee
Date: December 16, 2020
Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and Other Tax-Exempt Entities

Dear Colleagues:

As the nation continues to respond to the COVID–19 pandemic, we want to bring your attention back to another concerning public health matter: our nation's opioid epidemic. Opioid overdoses claimed more than 450,000 lives in the United States from 1999 to 2019, and preliminary data from the Centers for Disease Control and Prevention (CDC) suggests drug overdose deaths, including those attributed to opioids, have accelerated since the pandemic began.[1] Indeed, COVID–19 has increased risk factors associated with substance-use disorders (SUDs) and opioid-use disorders (OUDs) like feelings of anxiety, depression, loneliness, and an ongoing sense of uncertainty.[2] For individuals suffering from these diseases, COVID–19 has even presented additional barriers to treatment and social support services as people are urged to stay-at-home and social distance.[3] We are concerned that this will only worsen as our country continues to battle COVID–19 and as social isolation and lack of access to SUD and OUD treatment persists.

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[1] Opioid Overdose, Data Analysis and Resources, Ctrs. for Disease Control and Prevention, *https://www.cdc.gov/drugoverdose/data/analysis.html* (last viewed Dec. 10, 2020).

[2] Alex Edelman, Overdose deaths appear to rise amid coronavirus pandemic in U.S., NBC News (Oct. 20, 2020), *https://www.nbcnews.com/health/health-news/overdose-deaths-appear-rise-amid-coronavirus-pandemic-u-s-n1244024;* Jon Kamp and Arian Campo-Flores, The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic, *Wall St. J.* (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401.*

[3] Jon Kamp and Arian Campo-Flores, The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic, *Wall St. J.* (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401. See also* Dep't of Health and Human Servs., Off. of Inspector Gen., Opioid Treatment Programs Reported Challenges Encountered During the COVID–19 Pandemic and Actions Taken to Address Them (Nov, 2020), *https://oig.hhs.gov/oas/reports/region9/92001001.asp?utm_source=web&utm_medium=web&utm_campaign=covid-A-09-20-01001.*

As the opioid epidemic and its impact on programs within the Finance Committee's jurisdiction shows no signs of abating, we write to provide you with an update on the Committee's ongoing investigation into the financial relationships between opioid manufacturers and tax-exempt organizations. To date, the Committee has identified approximately $65 million in payments that opioid manufacturers and related companies have made to tax-exempt entities, which suggest that manufacturers view these organizations as helpful extensions of their sales and marketing efforts.

The Committee's Long-Standing Interest in the Opioid Epidemic

The opioid epidemic has directly impacted Federal health care programs under the Committee's jurisdiction, and has been a long-standing interest of its members.[4] The increased use of opioid drugs for long-term chronic non-cancer pain in the 1990s dramatically increased the number of Medicare and Medicaid patients admitted to hospitals for "opioid overuse."[5] By 2017, Medicare and Medicaid covered approximately 73% of 974,000 opioid-related inpatient hospital stays.[6] Furthermore, earlier this year, and before the COVID–19 pandemic, the Office of Inspector General at the Department of Health and Human Services (HHS OIG) reported that 267,000 Medicare Part D beneficiaries received high amounts of opioids in 2019, and 209,000 beneficiaries received medically assisted treatment.[7] And, while the HHS OIG found that opioid use in Medicare Part D had decreased in 2019 (when compared to the past 3 years) due to the efforts of the Department of Health and Human Services (HHS) and others, it stressed the critical need to remain diligent, especially during the COVID–19 pandemic.[8]

Over the past eight years, we have used our leadership positions to seek greater transparency into the financial relationships between opioid manufacturers and tax-exempt organizations. Our work reveals that opioid manufacturers have maintained extensive financial relationships with tax-exempt organizations, including pain advocacy groups, professional provider groups, and medical associations. In turn, these groups have sought to influence opioid prescribing practices and related Federal policy connected to opioid use and pain care that directly affects Medicare and Medicaid. Given these ongoing concerns, on June 28, 2019, we sent letters to 10 tax-exempt organizations and requested information about their financial relationships with opioid manufacturers.[9] These groups included:

1. American Chronic Pain Association
2. American Pain Society
3. American Society for Pain Management Nursing
4. American Society of Pain Educators
5. Center for Practical Bioethics
6. Federation of State Medical Boards
7. The Joint Commission
8. American Academy of Physical Medicine and Rehabilitation
9. Alliance for Patient Access
10. International Association for the Study of Pain

We requested complete Internal Revenue Service (IRS) Form 990s filed for each year between 2012 and 2019, as well as a detailed accounting of all payments and transfers including, but not limited to, contributions, grants, advertising, program

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[4] Senator Grassley, in his capacity as Ranking Member of the health subcommittee, co-chaired the Committee's first hearing on the opioid epidemic in 2012. Prescription Drug Abuse: How are Medicare and Medicaid Adapting to the Challenge?, Hearing Before Subcomm. on Health of the S. Fin. Comm. 112th Cong. (2012), *https://www.finance.senate.gov/hearings/prescription-drug-abuse-how-are-medicare-and-medicaid-adapting-to-the-challenged*.

[5] The number of combined hospital inpatient stays among Medicare and Medicaid beneficiaries increased from 126,500 in 1993 to 437,800 in 2012. *See* Hospital Inpatient Utilization Related to Opioids Overuse Among Adults 1993–2012, AHRQ Table 2 (Aug. 2014), *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf*.

[6] HCUP Fast Stats—Opioid-Related Hospital Use, AHRQ, *https://www.hcup-us.ahrq.gov/faststats/OpioidUseMap* (last viewed Nov. 25, 2020).

[7] Dep't of Health and Human Servs., Off. of Inspector Gen., Opioid Use in Medicare Part D Continued to Decline in 2019, But Vigilance is Needed as COVID–19 Raises New Concerns (Aug. 13, 2020), *https://oig.hhs.gov/oei/reports/OEI-02-20-00320.asp*.

[8] *Id.*

[9] Press Release, Grassley, Wyden Press for Answers on Financial Relationships Between Opioids Manufacturers and Tax-Exempt Organizations (July 1, 2019), *https://www.grassley.senate.gov/news/news-releases/grassley-wyden-press-answers-financial-relationships-between-opioid-manufacturers*.

scholarship, and other revenue and remuneration.[10] In a separate, but related inquiry, Senator Wyden also requested information from the U.S. Pain Foundation and the American Academy of Pain Medicine.[11]

The goal of our requests was to identify these groups' largest pharmaceutical donors and to ascertain whether these payments influenced the organizations' activities in any way, especially as they pertain to opioids and opioid prescribing practices. This investigation also built on work the Committee began in 2012, when then-Chairman Max Baucus of the Senate Finance Committee and then-Ranking Member Chuck Grassley of the Senate Judiciary Committee examined Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson's financial relationship with tax-exempt medical groups, and included questions about payments made to physicians who specialize in pain management.[12] Ranking Member Wyden subsequently sent letters to Secretary Burwell,[13] Secretary Price,[14] Secretary Azar [15] and the National Academy of Medicine,[16] raising concerns about conflicts of interest of various members of Federal advisory panels who were financially linked to industry or industry-backed groups that are the subject of this investigation.[17]

2012: The Investigation Begins

The financial information collected during the Committee's 2012 inquiry showed that Purdue Pharma, L.P., (Purdue), Endo Pharmaceuticals (Endo), and Johnson & Johnson maintained strong financial ties to tax-exempt organizations and, in some cases, paid millions of dollars to them.[18] For example, Purdue reported to the Committee that it had made payments to a handful of tax-exempt organizations totaling more than $18 million. Between 1997 and 2012, these payments included approximately $3.6 million to the (now-defunct) American Pain Foundation, $3.6 million to the Center for Practical Bioethics, and $3 million to the American Pain Society, which filed for bankruptcy in 2019.[19]

These payments were part of a broad strategy Purdue took to fund tax-exempt groups. Between 2006 and 2010, an internal presentation showed that the company spent $24.5 million on education grants and donations, funding hundreds of requests annually.[20] The company also met with and closely tracked encounters with pain societies, professional associations, and professional licensing boards and "developed message points for internal and external stakeholders."[21] (The same internal presentation shows that the American Pain Foundation, American Pain Society, American Academy of Pain Medicine, the American Board of Pain Medicine, and the

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[10] *Id.*

[11] Letter from Senator Ron Wyden to Dr. Jianguo Cheng, President, American Academy of Pain Medicine (Mar. 12, 2019), *https://www.finance.senate.gov/imo/media/doc/031319%20Wyden%20letter%20to%20AAPM.pdf;* Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018), *https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20the%20U.S.%20Pain%20Foundation.pdf.*

[12] Press Release, Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups (May 8, 2012), *https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups.*

[13] Letter from Senator Ron Wyden to Sylvia Burwell, Secretary, Department of Health and Human Services (Feb. 5, 2016), *https://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS_Opioid%20Conflicts.pdf.*

[14] Press Release, Wyden Asks Price to Delay Federal Opioid Workshop Until Industry Conflicts are Examined (May 8, 2017), *https://www.finance.senate.gov/ranking-members-news/wyden-asks-price-to-delay-federal-opioid-workshop-until-industry-conflicts-are-examined.*

[15] Press Release, Wyden Reveals Opioid Industry Ties on HHS Task Force, Probes Advocacy Group's Finances (Dec. 19, 2018), *https://www.finance.senate.gov/ranking-members-news/wyden-reveals-opioid-industry-ties-on-hhs-task-force-probes-advocacy-groups-finances.*

[16] Press Release, Wyden Concerned by National Academy Ties to Opioid Manufacturers (July 5, 2016), *https://www.finance.senate.gov/ranking-members-news/wyden-concerned-by-national-academy-committee-ties-to-opioid-manufacturers.*

[17] Ranking Member Wyden's letters were based in part on information contained in CMS's Open Payments database created by the Physician Payment Sunshine Act that Chairman Grassley championed in the Senate.

[18] Letter from Theodore Hester, Counsel, King & Spalding, on Behalf of Purdue Pharma, to Senator Baucus and Senator Grassley (June 8, 2012); Letter from Raymond V. Shepherd, Counsel, Venable, on Behalf of Endo Pharmaceuticals, to Senator Baucus and Senator Grassley (June 15, 2012); Letter from Daniel Donovan, Counsel, King & Spalding, to Senator Baucus and Senator Grassley (June 8, 2012); SFC0000000l; JJ–SFC–00000001–10.

[19] SFC00000001. *See also* Appendix A and B.

[20] SFC00002172, at SFC00002193.

[21] *Id.* at SFC00002175–76, SFC00002179, SFC00002220, SFC00002186.

American Society of Pain Educators,[22] were organizations with close ties to Purdue at the time).[23]

Such deep cooperation was on display at the American Pain Foundation—a now-defunct, but once-influential non-profit. According to the American Pain Foundation's 1998 business plan, "most pain sufferers are under-medicated" and "many [physicians] are reluctant to prescribe opioids because they *mistakenly* think their patients will become addicted to the drug or because they fear investigation and sanctions by regulatory bodies."[24] The American Pain Foundation's goal at the time was to reduce the "percentage of Americans who agree that it is easy to become addicted to pain medicine."[25]

Purdue was the American Pain Foundation's largest funder during the organization's early years of existence, and the company repeatedly sent the organization checks exceeding $100,000, as well as other financial assistance such as underwriting "challenge grants." Documents also show that as the foundation solicited funds from Purdue, it provided the company's top executives frequent and detailed updates, including to its president, Richard Sackler.[26] The accomplishments memo sent to Mr. Sackler highlighted multiple initiatives, including state and Federal lobbying efforts, and a public relations efforts to fight "misconceptions about [o]pioids in the [p]ress," noting that it had sent background materials to 1,200 health journalists.[27]

Similarly, in 2007, Purdue and the American Pain Foundation worked closely to draft talking points for use during the Pain Care Forum, a coalition of drug manufacturers and other advocacy groups that met monthly to discuss opioid-related issues. According to these talking points:

> Overly restrictive regulatory policies impeded pain relief . . . [and] other barriers to effective pain care include . . . the public—including doctors and people with pain—often believe that opioid medications are addictive and produce euphoria. The fact is that when properly prescribed by a health care professional and taken as directed, these medications give relief—not a 'high.'[28]

After reviewing these draft talking points, a Purdue Pharma official wrote in track changes, "Do we want an ethical message . . . like if as a [health care provider] if you know the right thing to do and you don't do it . . . or the moral obligation to treat suffering????"[29] An employee of the American Pain Foundation wrote in a subsequent email that she "amended the talking points to reflect the Purdue Pharma official's suggestions."[30]

In addition to its close financial relationships with the American Pain Foundation, Purdue reported paying $2.1 million to the Joint Commission for Accreditation of Health Organizations (now known as the "Joint Commission"), a standard-setting body for the health care industry. The data produced in response to the Committee's 2012 investigation shows that this organization also received "support for pain management activities" from Johnson & Johnson, Ortho McNeill (now Janssen), National Pharmaceutical Council, Endo, Pfizer, and Abbott Labs.[31] This financial support occurred primarily between 2000 and 2002, when the Commission was developing a pain care guide and other materials that were distributed to providers.

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[22] The American Society of Pain Educators was founded in 2004. It operated as a tax-exempt organization from 2004 until 2012, when the IRS revoked its status. ASPE's activities included providing tests that certified providers as "pain educators," and public tax records show it was involved in a number of medical communications activities. ASPE is closely associated with Aventine Co., a medical communications firm based in New Jersey, which has done business as PainWeek, a conference and communications franchise that features presentations from many people with professional and financial ties to opioid manufacturers. PainWeek was purchased by an Irish media company in 2015 in a multi-million acquisition. Purdue was one of several pharmaceutical companies that maintained "corporate memberships" with ASPE. *See* ASPE 000029–30.

[23] SFC00002172, at SFC00002175–76, SFC00002179, SFC00002220, SFC00002186.

[24] American Pain Foundation's 1998 Business Plan, at 3–2. Emphasis added.

[25] *Id.*

[26] *See* APF65–111, APF298–99.

[27] APF65–69.

[28] SFC00011527–29.

[29] *Id.*

[30] SFC00011511.

[31] Letter from Mark Chassin, President, The Joint Commission, to Senators Baucus and Senator Grassley (June 29, 2012).

The pain care guide notes that "[s]ome clinicians have inaccurate and exaggerated concerns" about addiction, tolerance and risk of death, and that "[t]his attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[32] The Commission's data further disseminates these payments:

- In October 2001, Purdue funded the publication of a book for "Pain assessment and management: an organizational approach," totaling $58,272. The company also funded two videos in August 2000 for "Pain Management in Special Populations: Geriatric and Disease Related Pain," totaling $85,000.[33]
- In 2001, Ortho McNeill (now Janssen) provided funding for "Pain Management: An Overview for Clinicians audioconference," totaling $66,000.[34]
- The National Pharmaceutical Council paid $155,104 between 2001 and 2002 for the Joint Commission to develop "a monograph designed as a reference for clinicians, quality professionals, researchers and others involved in performance assessment, improvement, education, and policy decisions related to pain management within health care organizations."[35]

Such initiatives were lumped in with other sales and marketing investments that opioid manufacturers made to expand the market footprint of their products. For example, this approach was on display in a pair of presentations created for Opana ER, an opioid drug marketed by Endo. (The company would later stop marketing in response to an unprecedented request from the Food and Drug Administration (FDA) which determined that the "benefits of the drug may no longer outweigh its risks.")[36] Ten years earlier, Endo identified such a threat in a multi-year business plan for Opana ER stating: "increased awareness of Rx abuse may lead to tighter governmental oversight and new restrictions for opioid analgesics."[37]

Even though Endo knew of these risks, the company's business plan for marketing Opana ER included "utilize[ing] existing and newly trained pain specialist speakers in an effort to provide a platform for dialogue between pain specialists and the pain care physician community to discuss the features and benefits of Opana ER."[38] The business plan goes on to cite two physicians who served as speakers, including Bill McCarberg, a physician who Endo reported paying more than $45,000 from the company for honoraria, sales support, and pain education from 2001 to 2006.[39] McCarberg, who at one point led the American Academy of Pain Medicine,[40] has received over $700,000 from pharmaceutical manufacturers since 1998, including opioid makers Johnson & Johnson, Purdue, Pfizer, Collegium Pharmaceuticals and Janssen Pharmaceuticals.[41] Open Payments data further underscores the importance manufacturers' place on these relationships. Endo has provided more than $28 million to physicians, as well as sponsored research and development initiatives since 2013.[42] Similarly, Purdue provided $89 million to physicians and sponsored research during the same period.[43]

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[32] Thomas Catan and Evan Perez, A Pain-Drug Champion Has Second Thoughts, *Wall St. J.* (Dec. 17, 2012), *http://www.wsj.com/articles/SB10001424127887324478304578173342657044604*.

[33] Letter from Mark Chassin, President, The Joint Commission, to Senator Baucus and Senator Grassley (June 29, 2012); Attachment A.

[34] *Id.*

[35] *Id.*

[36] Press Release, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), *https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse*.

[37] SFC–00025042, at SFC–00025056.

[38] *Id.* at SFC–00025072–75.

[39] SFC00000001.

[40] SFC–00025042, at SFC–00025079.

[41] Johnson & Johnson reported to the Committee that it paid McCarberg more than $109,000 from 2003 to 2010 for promotional speaker fees, advisory board work, and honoraria. Purdue Pharma reported paying McCarberg nearly $51,000 from 1998 to 2005 for lecture programs, consulting fees, and clinical research. Open Payments data further shows that McCarberg was paid more than $504,000 from pharmaceutical manufacturers from 2013 to 2019, including tens of thousands of dollars while he was head of the American Academy of Pain Medicine. Open Payments Data, Physician Profile for Bill McCarberg, OpenPaymentsData.CMS.gov, *https://openpaymentsdata.cms.gov/physician/117086* (last viewed Dec. 2, 2020).

[42] Endo Pharmaceuticals, Inc., OpenPaymentsData.CMS.gov, *https://openpaymentsdata.cms.gov/company/100000000285* (last viewed Nov. 25, 2020).

[43] Purdue Pharma, L.P., OpenpaymentsData.CMS.gov, *https://openpaymentsdata.cms.gov/company/100000005432* (last viewed Dec. 2, 2020).

Endo also heavily invested in tax-exempt organizations focused on pain issues during this period. Endo reported that it made payments of $5.9 million to the American Pain Foundation, $4.2 million to the American Pain Society, $1.3 million to the American Academy of Pain Medicine, and $369,000 to the Federation of State Medical Boards between 1998 and 2012.[44] An internal presentation created for Endo's scientific affairs team in 2011 describes the company's interest in such investments, and the importance of developing "strategic partnerships . . . that further advance the coordination of the professional, patient, gov't and community advocacy efforts."[45] The presentation also highlighted efforts to advocate for tamper resistant opioids and the company's "strategic third party partnerships" with the American Pain Society, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, American Academy of Pain Management, Advanced Pain & Spine Institute, the Arthritis Foundation, National Council on Aging, and its membership in 17 State Pain initiatives.[46] It further notes that the company was "indisputably recognized as leader by the Pain Community and primary care for all pain therapeutic areas," citing its role in mobilizing a "rapid response" to an FDA proposal related to acetaminophen, securing an author for a white paper in the journal *Pain Medicine,* and leading in development of Risk Evaluation and Mitigation Strategies or REMS.[47]

Endo's business plan likewise noted the value of collaborating with tax-exempt organizations, their executives, and their board members. It identified conferences, and articles in their publications as components of a multi-channel marketing strategy to increase prescription volume.[48] For example, a pocket card for managing pain-and, endorsed by the American Society of Pain Educators[49]—was among a list of "valued added initiative[s]" that "Endo sales representatives perceived as adding higher value than competitive representatives."[50] During the two years leading up to the business plan presentation, Endo made contributions and grants to the American Society of Pain Educators totaling at least $45,000[51] and maintained a corporate membership with the organizations, which involved paying the organization at least $25,000.[52] That same year, the American Society of Pain Educators made over $175,000 in payments to other pain advocacy organizations, including the American Association for Pain Management and the American Pain Society.[53]

These industry-developed materials and talking points frequently downplayed or distracted from the addictive nature of prescription opioids. At the same time, companies sought to increase brand allegiance among prescribers, and adherence among patients. Meanwhile, prominent pain experts acknowledged that "much remains unknown about the number or types of chronic pain sufferer who will become addicted as a result of medical care," and an FDA spokesperson said "the risk of addiction to chronic pain patients treated with narcotic analgesics has not been well studied and is not well characterized."[54] These efforts directly influenced the medical community, causing them to widely believe that there was a low risk for addiction

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[44] Endo Pharmaceuticals, Inc. payments to organizations.

[45] SFC–00057051, at SFC–00057069.

[46] *Id.* at SFC–00057069, SFC–00057071. Data collected by the Committee in 2019 shows that Endo's relationship with the organizations continued. The company paid the American Academy of Pain Medicine $149,950 from 2013 to 2016 for corporate memberships, and various advertising at annual meetings. Endo also paid the American Academy of Physical Medicine and Rehabilitation $30,000 to maintain a seat on the organization's industry relations council from 2012 to 2014, and $8,500 to sponsor Risk Evaluation and Mitigation Strategies (REMS) at a 2012 annual assembly.

[47] *Id.* at SFC–00057069.

[48] SFC–00025042.

[49] In 2016, the National Academies of Sciences, Engineering, and Medicine removed an ASPE board member from a panel studying prescription painkillers, following conflict of interest concerns raised by Ranking Member Wyden. Andrea McDaniels, Painkiller panel drops experts linked to pharma industry, *Baltimore Sun* (July 8, 2016), *https://www.baltimoresun.com/health/bs-hs-fda-pain-panel-20160708-story.html*. *See also* Press Release, Wyden Concerned by National Academy Committee Ties to Opioid Manufacturers (July 5, 2016), *https://www.finance.senate.gov/ranking-members-news/wyden-concerned-by-national-academy-committee-ties-to-opioid-manufacturers*.

[50] SFC–00025042, at SFC–00025106.

[51] ASPE_001510. (On file with the Committee).

[52] ASPE_000025–26; ASPE_000027–28.

[53] ASPE Form 990 (2007). (On file with the Committee).

[54] Barry Meier, The Delicate Balance of Pain and Addiction, *New York Times* (Nov. 25, 2003), *https://www.nytimes.com/2003/11/25/science/the-delicate-balance-of-pain-and-addiction.html*.

among patients with chronic pain-a false narrative promoted by opioid manufacturers to increase use of their opioid products.[55]

2019: Senator Grassley and Senator Wyden Expand Their Investigations

In 2019, the Committee broadened its investigation to examine the financial relationships between a wider range of companies and non-profit organizations. We requested and received IRS Form 990s, grant contracts, and financial audits. These data were then compiled to assess each organization's financial relationship to drug manufacturers that marketed opioids and opioid-related products such as therapies to treat opioid use disorder, opioid overdoses or opioid-induced constipation. Committee staff further analyzed the data to understand the timing and purposes of these payments.[56] We also sought presentations and other internal documents, which the Committee used in combination with publicly available materials, to review and evaluate the types of activities pursued by organizations that received large sums of money from opioid manufacturers.

Based on payment data collected for this investigation, between 2012 and 2019, drug manufacturers that marketed opioids or opioid-related therapies paid almost $30 million to these organizations.[57] As the money rolled in, these organizations conducted activities similar to the ones that Purdue and Endo's internal documents previously identified as helpful to their respective businesses. Data collected by the Committee show that Teva Pharmaceuticals (Teva), Pfizer, Inc. (Pfizer), and Purdue were among the largest funders of these organizations. Teva led the way, having paid over $4.8 million, the largest beneficiaries of which included the American Chronic Pain Association, the International Association for the Study of Pain, the American Academy of Pain Medicine, the American Pain Society, and the U.S. Pain Foundation. Pfizer made payments of roughly $4.1 million, the largest share of which went towards funding programs at the International Association for the Study of Pain and the American Academy of Pain Medicine. Purdue paid $2.8 million, with the majority going to the American Association for Pain Medicine, the American Academy of Physical Medicine and Rehabilitation, and the American Chronic Pain Association. Other major funders included Daiichi Sankyo, which made payments of nearly $2 million, Endo, which made payments of almost $1.8 million, and AbbVie, which made payments of more than $1.6 million. In all, the Committee found that the tax-exempt organizations had received money from more than 40 pharmaceutical companies that market opioids or opioid-related products.

The data also shows that fees for opioid and opioid-related work is one of the biggest sources of revenue for some of these organizations. Together, Alliance for Patient Access, the American Academy of Pain Medicine, the American Chronic Pain Association, International Association for the Study of Pain, and the U.S. Pain Foundation received $23 million—millions of which came in the form of grants from drug and device manufacturers for opioid and opioid-related work. For example, the International Association for the Study of Pain received more than $4 million in funding from opioid manufacturers between 2012 and 2019. The Alliance for Patient Access came in at a close second, receiving $4.2 million.

By contrast, the American Society for Pain Management Nursing, Center for Practical Bioethics, and The Joint Commission all received less than $600,000 in payments for opioid and opioid-related work between 2012 and 2019. The Federation of State Medical Boards is the only organization that did not report receiving any funding from drug or device manufacturers between 2012 and 2019, opting instead to adopt a policy which precludes its acceptance of any grants or funding from pharmaceutical companies.[58] The Federation of State Medical Boards appears to have changed its policy shortly after the Committee's 2012 inquiry which showed that,

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[55] Peter Whoriskey, Rising painkiller addiction shows damage from drugmakers' role in shaping medical opinion, *Washington Post* (Dec. 30 2012), *http://www.washingtonpost.com/business/economy/2012/12/30/014205a6-4bc3-11e2-b709-667035ff9029_story.html*.

[56] These data were categorized for each type of donor (*i.e.,* pharmaceutical company, biotech company, device company, government, hospital, foundation, etc.), and the product developed by that donor (*i.e.,* opioids, opioid-related drugs, non-opioid pain drugs, other drugs, or devices). Categories were also created to systematically label each program type across all organizations. For example, donations were labeled as: "program," "conference," "membership fees," "grant," "advocacy," "advertising" and "education/lecture." When possible, all payments were cross-referenced with 990 forms and other financial statements to eliminate duplicate observations [hereinafter "payment data"].

[57] *See* Form 990s and accompanying Schedule Bs. (On file with the Committee).

[58] Letter from Humayun Chaudhry, President and CEO, Federation of State Medical Boards, to Senator Grassley and Senator Wyden (July 29, 2019).

between 2007 and 2012, the organization received approximately $1.3 million from Purdue, Johnson & Johnson, and Endo.[59] The American Pain Society filed for bankruptcy the day it received our June 28th letter due to legal costs related to opioid litigation.[60]

The American Chronic Pain Association

The American Chronic Pain Association (ACPA) provides a clear example of how a tax-exempt organization benefited from opioid manufacturers funding its activities. The organization received funding from opioid makers, medical device manufacturers, and companies that market therapies for opioid-related conditions. These payments funded materials that appear to help sell products sold by opioid manufacturers, discussed opioid therapy while sidestepping the addictive nature of the drugs, and attributed responsibility for overdoses to people who misuse opioids.

For example, in recent years, the ACPA has received funding for videos that promote "abuse-deterrent formulation" opioids. Daiichi Sankyo, which sells an opioid with an abuse-deterrent label called MorphaBond (morphine sulfate),[61] paid the ACPA $75,000 to support the organization's abuse deterrent activities in 2018. The payment appears to be connected to a survey and video the company funded 1 month earlier.[62] The video that was subsequently posted on the ACPA's website opens with the host saying "pharmaceutical companies that make opioid medications now offer versions of these drugs that are more difficult to misuse," before moving to a series of questions and answers with a pain doctor who, for the most part, hews closely to warnings on the drug's FDA label.[63] (It's important to note that abuse-deterrent formulations have not been proven to be any less addictive than other types of opioids).[64] The doctor (Ajay Wasan, now president of the American Academy of Pain Medicine) has received $26,000 in payments from opioid manufacturers.[65] At one point in the video, Dr. Wasan appears to downplay the risk of addiction for patients using abuse-deterrent opioids:

> It is possible to get addicted to abuse-deterrent formulations. It's *unusual,* but one way is if someone takes an opioid and immediately feels a high. That is one possibility that can lead to addiction. The other possibility is if someone misuses their medications and takes extra medications over and over again. That can also lead to addiction.[66] (Emphasis added).

In the February letter to Daiichi Sankyo, Penny Cowan, President of the ACPA, notes that the manufacturer's money would support an anonymous survey done on people with pain in order to "investigate general population knowledge, attitudes, beliefs and behaviors as it relates to opioids and [abuse-deterrent formulation]."[67] She goes on to explain that the survey will inform the video content by "address[ing] the misconceptions and help them understand what they need to know about [abuse-deterrent formulations], so they are used, stored and dispose[d] of properly."[68] She further states "this video will communicate all aspects of [abuse-deter-

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[59] Letter from Raymond V. Shepherd, Counsel, Venable, to Senator Baucus and Senator Grassley (June 15, 2012); SFCO000O00 1; JJ–SFC 00000001.

[60] Alia Paavola, Ameriwn Pain Society files for bankruptcy as legal costs mount, *Becker Hospital Review* (July 1, 2019), *https://www.beckershospitalreview.com/pharmacy/american-pain-society-files-for-bankruptcy-as-legal-costs-mount.html*.

[61] Press Release, Daiichi Sankyo, Daiichi Sankyo, Inc. and Inspirion Delivery Sciences LLC Announce U.S. Licensing Agreement for MorphaBond™ Formulated with SentryBond™ Abuse-Deterrent Technology (Oct. 26, 2016), *https://www.daiichisankyo.com/media/press_release/detail/index_3394.html*.

[62] SFC_ACPA_0006. (On file with the Committee). *See also* SFC_ACPA_0221–39.

[63] Abuse Deterrent Formulation, American Chronic Pain Association at 0:27 to 0:34, *https://www.acpanow.com/apps/search?q=Abuse+Deterrent+Formulation#/* (lasted viewed Nov. 27, 2020).

[64] Abuse-Deterrent Opioids Analgesics, Food & Drug Administration, *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics* (last updated June 11, 2019). (Here the FDA acknowledges that ADFs are not addiction proof, and highlights that it is requiring manufacturers with ADF labeling claims to conduct post-market studies to determine the real world impact of their products). *Id.*

[65] Open Payments Data, Physician Profile for Steven Feinberg, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/1272772/general-payments* (last viewed Nov. 27, 2020).

[66] Abuse Deterrent Formulation, American Chronic Pain Association at 2:21, *https://www.acpanow.com/apps/search?q=Abuse+Deterrent+Formulation#/* (lasted viewed Nov. 27, 2020).

[67] SFC_ACPA_0221–39.

[68] *Id.* at SFC_ACPA_0221.

rent formulations] and the importance of their use," and would be posted to ACPA's website as well as turned into a DVD for distribution to health care professionals, at medical conventions, for patient education, and would be incorporated into all of ACPA's presentations.[69] The ACPA estimated that around 50,000 people will view the video.[70]

While much of the ACPA's funding came from opioid manufacturers, companies that have a financial stake in opioid-based pain treatment also contributed heavily to the organization. In turn, the organization produced programming and materials that hewed closely to the company's business interests, including at least one instance in which products were referred to in the material.[71] AstraZeneca, which markets Movantik (naloxegol),[72] a drug used to treat opioid-induced constipation, heavily funded the ACPA's opioid-induced constipation programming. In 2014, the same year that Movantik received FDA approval,[73] AstraZeneca was one of ACPA's corporate members that paid the organization tens of thousands of dollars annually to maintain its status. In addition, the company paid ACPA $215,000 in a 2-year span to fund programming related to opioid-induced constipation.[74] (During the same time period, ACPA's expenses related to opioid-induced constipation was $207,000, according to a financial audit).[75] One video produced by ACPA, titled "Opioid Induced Constipation,"[76] singles out AstraZeneca' s product, even though at least one study published five months prior found that a competing product, subcutaneous methyl naltrexone, "was found to perform better than other interventions for managing opioid-induced constipation."[77]

Other educational videos posted on the ACPA's website specifically target conditions and treatments for pain. For instance, several videos are dedicated to explaining implantable medical devices like medication pumps and neurostimulators for treating pain. These videos are funded by Medtronic, a device manufacturer of pain medication pumps and nerve stimulators,[78] which donated $100,000 for the production of a DVD and web segment on implantable devices.[79] Other videos walk the viewer through how the devices work, as well as benefits, risks, goals for treatment, what is involved in implantation procedures, what living with a pump is like, and maintenance of the pump.[80] One physician featured in the video is an anesthesiologist who received 235 payments, for a total of $113,830, from Medtronic between 2013 and 2018.[81]

Alliance for Patient Access

Some tax-exempt organizations also proved to be helpful vehicles for opioid manufacturers to lobby the Federal Government. One example is the Alliance for Patient Access (AfPA), an organization that describes itself as "a national network of physi-

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[69] *Id.* at SFC_ACP_A_0229.

[70] *Id.* at SFC_ACPA_0233.

[71] *See* Opioid Induced Constipation, American Chronic Pain Association, at 4:22. *https://www.theacpa.org/pain-management-tools/surveys/oic/* (last viewed Nov. 27, 2020). In this video, the narrator states that, if over-the-counter medication and increasing hydration is not enough, patients should consider methylnaltrexone or naloxegol, as these are "easier to take" than other treatment options. Id. It's important to note that naloxegol is manufactured under the trade name MOVANTIK™ by AstraZeneca. *See* Press release, AstraZeneca, FDA approves MOVANTIK™ (naloxegol) tablets C–11 for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain (Sept. 16, 2014), *https://www.astrazeneca.com/media-centre/press-releases/2014/fda-approved-movatnik-opioid-induced-constipation-chronic-non-cancer-pain-patients-16092014.html#*.

[72] Press release, AstraZeneca, FDA approves MOVTAIK™ (naloxegol) tablets C–11 for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain (Sept. 16, 2014), *https://www.astrazeneca.com/media-centre/press-releases/2014/fda-approved-movatnik-opioid-induced-constipation-chronic-non-cancer-pain-patients-16092014.html#*.

[73] *Id.*

[74] SFC_ACPA_0127–41.

[75] SFC_ACPA_0067, at SFC_APCA_0069, 0077, 0089, 00102.

[76] *See also* Opioid Induced Constipation, American Chronic Pain Association, *https://www.theacpa.org/pain-management-tools/surveys/oic/*.

[77] *See* Kannan Sridharan, Gowri Sivaramakrishnan, Drugs for Treating Opioid-Induced Constipation: A Mixed Treatment Comparison Network Meta-analysis of Randomized Controlled Clinical Trials, *J. of Pain and Symptom Management* 55(22): 468–479(2018), *https://pubmed.ncbi.nlm.nih.gov/28919541/*.

[78] Drug Infusion Systems, MEDTRONIC, *https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/drug-infusion-systems.html* (last visited Nov. 27, 2020).

[79] SFC_ACPA_572, at SFC_ACPA_573–75, 593.

[80] Intrathecal Medication Pumps, American Chronic Pain Association, *https://www.theacpa.org/pain-management-tools/videos/conditionstreatments/* (last viewed Nov. 27, 2020).

[81] Open Payments Data, Physician Profile for David Provenzano, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/172676* (last viewed Nov. 27, 2020).

cians and other health care providers dedicated to ensuring patient access to approved therapies and appreciate clinical care."[82] In 2017, all of the AfPA's approximately $2 million in revenue was generated from contributions and grants, of which 90% were from pharmaceutical manufacturers.[83] Of these payments, three opioid makers accounted for 17% of contributions to the AfPA that year—Teva ($225,000), Mallinckrodt ($75,000), and Pfizer ($40,000). Opioid manufacturers have consistently made large contributions to the AfPA. Since 2012, the AfPA has received at least $2.1 million in payments from opioid manufacturers including AbbVie, Endo, Grunenthal, Mallinckrodt, Pfizer, Purdue and Teva.

Open Payments data further shows that opioid manufacturers' influence at the AfPA does not stop at direct payments to the organization. Doctors who sat on the organization's board of directors have received more than $5 million in payments from pharmaceutical manufacturers and device manufacturers, of which more than $1.9 million came from opioid makers.[84]

Since 2013, Director Srinivas "Sri" Nalamachu, alone, received nearly $1.7 million in payments from pharmaceutical companies, of which $792,000 came from opioid makers—Purdue ($231,000), Collegium Pharmaceutical ($148,000), Endo ($113,000), Insys ($103,000), Assertio ($81,000), Pernix Therapeutics ($63,000) and Teva ($53,000).[85] Similarly, Director Robin Dore received more than $2.1 million from pharmaceutical manufacturers since 2013, including $538,000 from opioid makers Pfizer ($286,000), AbbVie ($145,000), and UCB ($107,000).[86] Opioid makers also paid Director Jack Schim $271,000 and Howard Hoflberg $180,000.[87] As the AfPA and its board received millions of dollars from opioid makers, the organization lobbied executive branch agencies and Congress on legislation related to opioids.[88] The AfPA also joined other organizations funded by opioid manufacturers that sought to limit restrictions on opioid prescribing while promoting expanded use of so-called "abuse-deterrent formulations."

For example, in October 2014, Brian Kennedy, Executive Director of the AfPA, wrote to the National Institutes of Health (NIH) decrying the agency's focus on "the deleterious effects of treating pain with opioids" and urged the agency to explore "how untreated or under-treated pain affects patients and communities."[89] Mr. Kennedy also suggested examples of studies the NIH might consider, including how reducing access to opioid medications may lead to "consequences of restricting access for patients with legitimate medical need" and "higher rates of depression, increased risks of suicide, loss of productivity and restricted mobility that requires additional care for patients."[90] The letter pointed to the work of AfPA's "Pain Therapy Access Physicians Working Group,"[91] arguing that "undertreated pain may result in impaired concentration, which may in turn increase the risk of falls, fractures or motor vehicle injuries."[92] What went unsaid is that Pfizer paid the AfPA $125,000 to fund the working group from 2014 to 2018, and another$25,000 in 2012 to the Prescription Drug Abuse and Diversion Education Initiative, part of more than $300,000 the company had paid the AfPA.[93] The working group included Dr. Nalamachu and Bob Twillman, who held leadership positions at the American Academy of Pain Management (another group with strong ties to opioid manufacturers).

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[82] Letter from Sam Dewey, Counsel, McDermott Will & Emery, on behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019).

[83] AfPA Form 990 (2017). (On file with the Committee).

[84] The majority of these payments overlapped with directors' time on AfPA's board. In some instances, it was not clear when some directors joined or left the board.

[85] Open Payments Data, Physician Profile for Srinivas Nalamachu, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/158026/general-payments* (last viewed Dec. 3, 2020).

[86] Open Payments Data, Physician Profile for Robin Kathleen Doore, *OpenPayments Data.CMS.gov, https://openpaymentsdata.cms.gov/physician/209026/general-payments* (last viewed Dec. 3, 2020).

[87] Open Payments Data, Physician Profile for Howard Hoffberg, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/185850/general-payments* (lasted viewed Dec. 3, 2020); Open Payments Data, Physician Profile for Jack D. Schim, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/151945* (last viewed Dec. 3, 2020).

[88] AfPA_SFC_000193–241.

[89] *Id.* at AfPA_SFC_000233–34.

[90] *Id.*

[91] *See* Pain Management Working Group, AfPA, *https://allianceforpatientaccess.org/pain* (last viewed Dec. 2, 2012).

[92] AfPA_SFC_000193, at AfPA_SFC_000233–34.

[93] Pfizer-Medical, Scientific & Patient-Education Grant Transparency, Pfizer, *https://www.pfizer.com/purpose/transparency/transparency-in-grants* (last viewed Nov. 28, 2020).

In another example, on August 27, 2015, Dr. Nalamachu wrote to the FDA "on behalf of AfPA . . . in support of the oxycodone extended-release capsules for oral use submitted by Collegium Pharmaceuticals."[94] Dr. Nalamachu wrote that he had been an investigator for the Collegium drug and explained that the "efficacy of oxycodone is well established," and "further, those of us in pain medicine know how important extended-release formulations are for patients who require around-the-clock pain management."[95] The following year, Collegium Pharmaceuticals began making payments directly to Dr. Nalamachu, who would receive more than $148,000 from the company.[96]

Again, on March 5, 2018, AfPA co-signed a letter with several opioid manufacturers, including Purdue, Grunenthal GmbH, and Collegium Pharmaceuticals, and other tax-exempt organizations funded by opioid manufacturers, raising concerns about a CMS proposal to require prior authorization and dosage limits for abuse-deterrent opioids in Medicare Part D.[97] The letter highlighted diversion (the practice of transferring legally prescribed opioids to another person for illicit use) as a driver of the opioid epidemic, while sidestepping the fact that the U.S. has significantly higher rates of opioid prescribing when compared to other countries.[98] The coalition also told CMS that "increasing the availability of [abuse-deterrent] opioids represents a critical component of drug abuse prevention efforts," and repeatedly touted their benefits to patients even while acknowledging that "[o]pioids with abuse-deterrent properties are not abuse-proof and do not prevent or reduce the risk of addiction."[99] The coalition went on to urge CMS to "review plan formularies to ensure adequate access to [abuse-deterrent] opioids."[100] It was one of three letters AfPA sent with the coalition.[101] (Funders of the organization, including Pfizer, Teva, and Purdue, marketed opioids with abuse-deterrent label).

Finally, the AfPA manages a coalition called the Alliance for Balanced Pain Management, which it acquired from Mallinckrodt in 2016.[102] At the time of the acquisition, Mallinckrodt paid AfPA $200,000 to support the coalition and pay for an annual summit the coalition hosts.[103] The coalition, which was previously managed by Green Room Communications,[104] describes its mission as advocating "for balanced pain management by supporting organizations and individuals who share a common goal to reduce pain, reduce medicine abuse and improve care."[105] Its members include patient groups such as American Chronic Pain Foundation and the U.S. Pain Foundation, which have strong financial links to opioid manufacturers, and is led by a steering committee that includes several individuals who have received roughly $480,000 from opioid manufacturers, according to CMS's Open Payments data.[106] The AfPA also told the Committee that the coalition includes industry members, but did not identify them, and further noted that "Mallinckrodt's representative joined periodic membership calls and had an opportunity to review the Alliance for Balanced Pain Management's educational materials in response to a group invitation for feedback."[107] However, the AfPA stated that it maintains sole discretion to de-

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[94] AfPA_SFC_000193, at AfPA_SFC_000232.

[95] *Id.*

[96] Open Payments Data, Physician Profile for Srinivas Nalamachu, *OpenPaymentsData.CMS.gov, https://openpaymentsdata.cms.gov/physician/158026/general-payments* (last viewed Dec. 3, 2020).

[97] AfPA_SFC_000193–97.

[98] *See* Karim Ladha, et al., Opioid Prescribing After Surgery in the United States, Canada, and Sweden, JAMA Network (Sept. 4, 2019), *https://jamanetwork.com/joumals/jamanetworkopen/fullarticle/*. (An original investigation published in the JAMA Network, which concludes that the United States has the highest average dose of opioid prescriptions for most surgical procedures when compared to Canada and Sweden.)

[99] AfPA_SFC_000193–97.

[100] *Id.*

[101] AfPA_SFC_000193–205.

[102] Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019). AfPA_SFC_000001–05.

[103] Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020).

[104] *Greenroompr.com, https://www.greenroompr.com/* (last viewed Dec. 7, 2020).

[105] Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020). About AfBPM, Alliance for Balanced Pain Management, *https://alliancebpm.org/events/* (last viewed Nov. 28, 2020).

[106] Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020).

[107] Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019).

termine the coalition's "advocacy efforts, annual summit events, and educational materials."[108] According to the AfPA, these efforts have explored "issues such as the value of multimodal analgesia—an opioid-sparing approach to surgical pain, technology-based solutions for treating pain in patients who've battled opioid addiction, and the value of non-pharmacologic interventions like physical therapy, chiropractic care, and yoga."[109]

International Association for the Study of Pain

Between 2012 and 2018, fifteen opioid makers paid the International Association for the Study of Pain (IASP) more than $4 million. These funds were used to support conferences the organization hosted, such as the World Congress on Pain, the International Symposium on Pediatric Pain, the International Congress on Neuropathic Pain, special interest group meetings, and various grants for activities such as the development of a tool to connect "healthcare professionals with access to independently created online education."[110] During this time period, Pfizer was the largest of these contributors, making payments of more than $1.3 million to IASP, the majority of which were made in the form of grants in 2018. Other opioid manufacturers that made major payments included subsidiaries and affiliates of Mundipharma, (making more than $1 million in payments combined),[111] Teva ($627,000, of which $300,000 was made in 2018)[112] and Allergan ($161,000). Two Grunenthal entities, and a third party connected to the company, also paid IASP $601,000 during this time period.

Pfizer, which as noted above manufactures two extended-release prescription opioids that the FDA designated as "abuse-deterrent,"[113] made payments of nearly $4 million to various pain-related tax-exempt organizations, according to payments reviewed by the Committee.[114] The largest share of these funds went to IASP. For example, Pfizer provided a $527,000 education grant to the Japan chapter of the IASP in 2018.[115] (This was the single largest payment to IASP from any company during the 2012–2018 time period). The grant was intended to fund nursing student pain education programs, publish medical school textbooks on pain, and develop a recurrent educational program for physical and occupational therapists.[116] That grant was part of $918,000 the organization received from Pfizer that year.

IASP's activities also suggest that opioid manufacturers are engaging in the same pattern of behavior in Asia and Europe. One such initiative is the World Congress on Pain. Opioid manufacturers have made more than $2 million in payments to IASP in connection with the last four conferences, which in recent years have been held in Boston, Massachusetts (2018), Yokohama, Japan (2016), Buenos Aires, Argentina (2014), and Milan, Italy (2012).[117] The meeting is advertised as the preeminent global meeting devoted to sharing new developments in pain research, treatment, and education, and attendees are predominantly clinicians, researchers,

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[108] *Id.*

[109] *Id.*

[110] IASP Submission Question 2 Attachment—Accounting Report. (On file with the Committee).

[111] IASP reported receiving payments during the 2012–2018 period from Mundipharma International (UK), Mundipharma International Ltd., Mundipharma Pte, Mundipharma Pte Limited, MundiPharma PTY (Australia), and Mundipharma Research GmbH.

[112] The organization reported to the Committee that it received $147,550 in payments from Teva in 2018. However, it reported receiving $300,230 from Teva that year on its IRS Form 990. (On file with the Committee).

[113] Press Release, Pfizer, FDA Approves Abuse Deterrent Labeling For Emeda ® (Morphine Sulfate and Natlrexone Hydrochloride) Extended-Release (ER) Capsules CII, (Oct. 17, 2014), *https://www.pfizer.com/news/press-release/press-release-detail/;* Press Release, Pfizer, FDA Approves Troxyca ® (Oxycodone Hydrochloride and Naltrexone Hydrochloride) Extended-Release Capsules CII with Abuse-Deterrent Properties for the Management of Pain, Pfizer (Aug. 19, 2016), *https://www.pfizer.com/news/press-release/*.

[114] Based on IASP's Form 990s collected during this investigation. (On file with the Committee).

[115] IASP Submission Question 2 Attachment—Accounting Report. *See also* Pfizer Independent Grants for Learning & Change (IGLC), International Association for the Study of Pain, *https://www.iasp-pain.org/Education/GrantDetail.aspx?ItemNumber=7756* (last viewed Nov. 28, 2020).

[116] According to IASP, "Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly." *See* Pfizer Independent Grants for Learning & Change (IGLC), IASP, *https://www.iasp-pain.org/Education/GrantDetail.aspx?ItemNumber=7756* (last viewed Dec. 8, 2020).

[117] Past Congresses, IASP, *https://www.iasp-pain.org/Meetings/WorldCongressList.aspx* (last viewed Nov. 28, 2020).

students, and educators.[118] Each year, opioid manufacturers have made payments to fund the World Congress events, accounting for up to 16% of the conferences' total expenses.[119]

In addition to its global conferences, IASP has also developed region-specific programs to advance the availability and accessibility of opioids. In 2018, Pfizer made a payment of approximately $190,000 to a program titled, "Develop, Equip, and Pilot: Guide for Multidisciplinary Pain Clinics in South East Asia Project."[120] Other programs like "IASP Pain Management Camp" are intensive courses that are designed to provide "information targeted to the educational and organizational aspects of health-care services for pain management" for health care professionals who want to start pain services or are already working with patients with chronic pain.[121] IASP's Latin America Pain Camp received $25,000 from Grunenthal in 2014 and, three years later, received a payment of $87,000 from Teva to support the "independent development and execution" of the event.[122] In a similar vein, IASP also offers "pain schools" which are held in North America and Europe, which sezye as longer version of the camp program. Sponsors to the North American Pain School include Grunenthal, Eli Lilly, the Mayday Fund, and the American Pain Society.[123]

Documents provided to the Committee also show that from 2012 to 2019, the IASP received a total of $1 million from Mundipharma, a global affiliate of Purdue owned by the Sackler family.[124] This funding has gone towards World Congress on Pain events and special interest group meetings held all over the world.[125] Mundipharma has reportedly been distributing marketing materials for OxyContin in places like China, Australia, and Italy, and is using the same pitch that Purdue admitted was false in the U.S. more than a decade ago.[126] For instance, Mundipharma allegedly provided physicians with documents that claimed the risks of opioid addiction were "virtually non-existent and that OxyContin's slow-release formulation made it even safer."[127] Mundipharma is also allegedly targeting China with aggressive sales teams who provide gift cards, complementary dinners, all-expense paid trips to meetings, and compensated speaking events to push opioid prescriptions.[128]

Conclusion

While we continue to evaluate the information produced to the Committee, our initial review has revealed troubling instances in which patient advocacy groups, provider groups, and other tax-exempt organizations, their officers, and their board members have engaged in initiatives that appear to echo and amplify messages to increase use of opioid manufacturers' drugs, including abuse-deterrent opioids that have not been proven to be any less addictive than other types opioids.[129]

Consumers, health care providers, and policymakers seeking unbiased information may not immediately recognize the significant industry ties these groups possess,

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[118] About the IASP World Congress on Pain, IASP, *https://www.iaspworldcongress.org/attend* (last viewed Dec. 8, 2020).

[119] IASP Form 990 (2012–2018). (On file with the Committee.).

[120] IASP Submission Question 2 Attachment—Accounting Report. (On file with the Committee).

[121] Latin American Pain Management Camp Leaves Students Smiling, International Association for the Study of Pain (Nov. 2014), *https://www.iasp-pain.org/PublicationsNews/JASPNewsletterArticle.aspx?ItemNumber=4009*.

[122] IASP Submission Question 2 Attachment—Accounting Report. (On file with the Committee).

[123] Sponsors, Organizers and Supporters, North American Pain School, *https://northamericanpainschool.com/* (last viewed Nov. 28, 2020).

[124] IASP Submission Question 2 Attachment—Accounting Report. (On file with the Committee).

[125] *Id.*

[126] Erika Kinetz, Fake Doctors, pilfered medical records drive Oxy China Sales, ABC News (Nov. 20, 2019), *https://abcnews.go.com/Business/wireStory/fake-doctors-misleading-claims-drive-oxycontin-china-sales-67154163*.

[127] *Id.*

[128] *Id.*

[129] Abuse-Deterrent Opioids Analgesics, Food & Drug Administration, *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics* (last updated June 11, 2019). (Here the FDA acknowledges that ADFs are not addiction proof, and highlights that it is requiring manufacturers with ADF labeling claims to conduct post-market studies to determine the real world impact of their products). *Id.*

especially when they are cited as resources on Federal health websites,[130] testify before Congress,[131] and have officers that sit on Federal advisory boards.[132] This is why the Committee is releasing the financial information collected during the 2012 investigation, in addition to data collected over the past two years, because we remain concerned that the opioid epidemic was driven, in part, by misinformation and dubious marketing practices used by pharmaceutical companies and the tax-exempt groups they fund.

Congress must continue to shed light on pharmaceutical and medical device manufacturers' financial dealings with tax-exempt organizations. While such financial entanglements are of particular concern in regards to opioids, given their danger and addictive potential, such funding and influence is not limited to this therapeutic class.[133] This investigation clearly shows that such payments are viewed as key marketing and policy influencing tools, which, in the case of opioids, contributed to addiction, sickness, and death for millions of Americans. Therefore, Congress must continue to advocate for stronger safeguards within tax-exempt organizations and within the Federal Government. Steps we recommend taking:

1. Expand CMS's Open Payments database to require pharmaceutical manufacturers and device manufacturers to report payments made to tax-exempt organizations.
2. Require the Secretary of HHS to develop guidelines and procedures to increase transparency among members of Federal task forces, as well as research groups and panels convened or contracted by HHS.

In the next Congress, we plan to continue our work on these important issues and we encourage my colleagues to do the same.

Charles Grassley
Chairman
Senate Finance Committee

Ron Wyden
Ranking Member
Senate Finance Committee

Appendix A

This appendix contains payment data provided to the Finance Committee by pharmaceutical companies in response to letters sent by Senator Baucus and Senator Grassley in 2012. The data from Endo Pharmaceuticals, Johnson & Johnson, and Purdue Pharma, L.P., show payments made by the companies to tax-exempt organizations from 1997 through early 2012. In total, the companies reported paying the listed organizations more than $36 million.

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[130] *See* Resources/References, NIIH Pain Consortium—COEPEs, NIH *https://coepes.nih.gov/module/joan-pain-policy-analysis-and-advocacy/resourcesreferences* (lasted viewed Nov. 28, 2020).

[131] Managing Pain During the Opioid Crisis, Hearing Before the S. Comm. Health, Education, Labor & Pensions, 116th Cong. (Feb. 2019), *https://www.help.senate.gov/hearings/managing-pain-during-the-opioid-crisis*.

[132] *E.g.,* the FDA's advisory committee on analgesics, which evaluate the safety of opioids includes Kevin Zacharoff who sat on the ASPE board, and Lonnie Zeltzer who was the APS and APF boards. *See* Anesthetic and Analgesic Drug Products Advisory Committee Roster, FDA, *https://www.fda.gov/advisory-committees/anesthetic-and-analgesic-drug-products-advisory-committee/anesthetic-and-analgesic-drug-products-advisory-committee-roster* (last viewed Dec. 10, 2020).

[133] *See* Drug Pricing in America: A Prescription for Change, Part II: Hearing Before S. Comm. Fin. 116th Cong. at 70, 147, 477, 529, 716 (2019), *https://www.finance.senate.gov/imo/media/doc/37143.pdf*. *See also* Alex Ruoff, AbbVie, Bristol-Myers Among Patient Advocacy Groups' Big Backers, Bloomberg, *https://about.bgov.com/news/abbvie-bristol-myers-among-patient-advocacy-groups-big-backers/*.

Endo/Johnson & Johnson/Purdue Payments (1997–2004)

Company/Organization	1997	1998	1999	2000	2001	2002	2003	2004
Endo Pharmaceuticals		**$35,000**	**$215,055**	**$237,960**	**$272,853**	**$283,662**	**$361,850**	**$627,765**
American Academy of Pain Medicine			$20,090	$26,500	$22,000	$48,150	$46,200	$115,000
American Alliance of Cancer Pain			$13,500					
American Geriatrics Society				$6,500				$750
American Pain Foundation			$20,000	$25,000	$20,000	$25,000	$15,000	$40,000
American Pain Society		$20,000	$48,665	$55,935	$132,400	$152,162	$75,650	$393,015
Beth Israel Medical Center		$15,000	$75,000	$50,000	$5,000	$5,000	$182,000	
Federation of State Medical Boards				$4,025				
Joint Commission				$37,500	$37,500			
University of Wisconsin			$37,800	$32,500	$55,953	$53,350	$43,000	$79,000
Johnson & Johnson	**$189,715**	**$495,305**	**$206,735**	**$518,586**	**$239,683**	**$155,100**	**$108,285**	**$465,950**
American Academy of Pain Medicine	$43,500	$14,400	$135,140	$74,050	$66,764	$43,975	$33,000	$35,620
American Geriatrics Society								$259,080
American Pain Foundation								$5,000
American Pain Society	$146,215	$480,905	$71,595	$444,536	$158,000	$111,125	$75,285	$166,250
Center for Practical Bioethics								
Joint Commission					$14,919			
Purdue Pharma	**$172,286**	**$200,441**	**$764,617**	**$1,003,016**	**$2,261,102**	**$1,795,737**	**$2,161,197**	**$1,930,897**

American Academy of Pain Medicine	$36,800	$25,000	$32,300	$37,600	$80,272	$198,824	$382,295	$572,463
American Geriatrics Society	$11,985	$24,481	$38,248	$78,446	$127,850	$68,750		$1,950
American Pain Foundation			$250,000		$606,500	$15,000	$461,056	$250,087
American Pain Society	$48,501	$75,960	$391,520	$108,065	$211,211	$383,530	$606,332	$311,603
Beth Israel Medical Center			$40,000	$118,542	$25,000	$185,615	$96,334	$62,679
Center for Practical Bioethics				$25,000	$17,500	$270,000	$250,000	$250,000
Federation of State Medical Boards			$12,549	$75,363	$36,410	$6,345	$85,180	$199,895
Joint Commission				$560,000	$981,359	$582,649		
University of Wisconsin	$75,000	$75,000			$175,000	$85,024	$280,000	$282,220
Annual Total	**$362,001**	**$730,746**	**$1,186,407**	**$1,759,562**	**$2,773,638**	**$2,234,499**	**$2,631,332**	**$3,024,612**

Endo/Johnson & Johnson/Purdue Payments (2005–2012)

Company/Organization	2005	2006	2007	2008	2009	2010	2011	2012 (Partial Year)	Grand Total 1997–2012
Endo Pharmaceuticals	**$657,211**	**$792,948**	**$1,097,939**	**$760,628**	**$1,620,021**	**$2,545,277**	**$2,771,140**	**$1,286,405**	**$13,565,716**
American Academy of Pain Medicine	$137,000	$237,000	$125,000	$155,000	$80,000	$80,000	$85,000	$135,000	$1,311,940
American Alliance of Cancer Pain									$13,500
American Geriatrics Society	$95,000	$40,000	$112,585		$44,850	$17,100	$25,000		$341,785
American Pain Foundation	$5,000	$20,000	$138,000	$51,000	$671,012	$2,116,315	$2,080,171	$715,173	$5,941,671

Endo/Johnson & Johnson/Purdue Payments (2005–2012)—Continued

Company/Organization	2005	2006	2007	2008	2009	2010	2011	2012 (Partial Year)	Grand Total 1997–2012
American Pain Society	$319,961	$338,650	$523,038	$369,628	$748,178	$75,000	$528,969	$430,232	$4,211,484
Beth Israel Medical Center	$57,250	$52,298	$24,316	$60,000	$35,981	$32,500	$40,000		$634,345
Federation of State Medical Boards		$40,000	$100,000	$100,000		$125,000			$369,025
Joint Commission									$75,000
University of Wisconsin	$43,000	$65,000	$75,000	$25,000	$40,000	$99,362	$12,000	$6,000	$666,965
Johnson & Johnson	**$172,193**	**$51,255**	**$65,250**	**$101,580**	**$58,775**	**$424,509**	**$785,329**	**$40,500**	**$4,078,750**
American Academy of Pain Medicine	$21,300	$13,375	$42,050	$20,000	$5,000	$5,000	$9,500		$562,674
American Geriatrics Society	$126,383	$1,950				$158,209	$20,004		$565,626
American Pain Foundation	$5,000		$5,000	$75,000	$45,000	$235,300	$238,000	$25,000	$633,300
American Pain Society	$19,510	$35,930	$18,200	$6,580	$8,775	$21,000	$17,500	$12,500	$1,793,906
Center for Practical Bioethics						$5,000		$3,000	$8,000
Joint Commission							$500,325		$515,244
Purdue Pharma	**$1,682,095**	**$697,895**	**$823,630**	**$1,165,106**	**$1,185,040**	**$1,000,430**	**$1,785,575**	**$71,626**	**$18,700,690**

American Academy of Pain Medicine	$17,000	$14,000	$159,100	$78,500	$45,000	$88,695	$171,170	$96,500	$2,035,519
American Geriatrics Society			$6,000		$44,850		$40,988		$443,548
American Pain Foundation	$251,210	$177,037	$231,150	$375,000	$275,000	$456,500	$368,962	−$75,000	$3,642,502
American Pain Society	$154,050	$102,858	$80,690	$121,430	$149,015	$137,190	$149,310	$60,000	$3,091,265
Beth Israel Medical Center	$447		$4,190	$5,000	$70,000	$15,000	$120,375		$743,182
Center for Practical Bioethics	$250,000	$201,500	$100,000	$510,176	$525,000	$302,800	$934,770	$25,000	$3,661,746
Federation of State Medical Boards	$339,000	$50,000	$100,000						$904,742
Joint Commission									$2,124,008
University of Wisconsin	$670,388	$152,500	$142,500	$75,000	$76,175	$245		−$34,874	$2,054,178
Annual Total	**$2,511,499**	**$1,542,098**	**$1,986,819**	**$2,027,314**	**$2,863,836**	**$3,970,216**	**$5,342,044**	**$1,398,531**	**$36,345,156**

Appendix B

This appendix contains payment data collected by Chairman Grassley and Ranking Member Wyden from 2019 to 2020, when the Finance Committee broadened its investigation to examine the financial relationships between a wider range of pharmaceutical manufacturers, device manufacturers, and the tax-exempt organizations they fund. In total, the Committee identified $29.7 million in payments made to these organizations by pharmaceutical companies that market or manufacture opioids or opioid-related therapies.

The Committee requested and received IRS Form 990s, grant contracts, and financial audits from the tax-exempt organizations. These data were then compiled to assess each organization's financial relationship to manufacturers of opioids and opioid-related products (such as companies that market devices to deliver opioid medication, or market therapies to treat opioid use disorder, opioid overdoses, or opioid-induced constipation). Committee staff further analyzed the data to understand the timing and purposes of these payments.

These data were categorized for each type of donor (*i.e.,* pharmaceutical company, biotech company, government, hospital, foundation, etc.) and the type of product developed by that donor (*i.e.,* opioids, opioid-related drugs, non-opioid pain drugs, other drugs, or devices). Categories were also created to systematically label each program type across all organizations. For example, donations were labeled as: "program," "conference," "membership fees," "grant," "advocacy," "advertising," and "education/lecture."

When possible, all payments were cross-referenced with IRS Form 990s and other financial statements to eliminate duplicate observations. In cases when an organization reported payments from multiple entities or affiliates of the same parent company, the payments were attributed to the parent company.

The appendix contains payments made by pharmaceutical manufacturers that market opioids and opioid-related products. It excludes the American Society of Pain Educators, and the Joint Commission, both of which reported receiving less than $100,000 from opioid manufacturers prior to 2016. The Federation of State Medical Boards also is excluded as it reported receiving no payments from pharmaceutical manufacturers since 2012.

Alliance for Patient Access

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Abbvie			$175,000	$125,000	$405,000			**$705,000**
AstraZeneca	$30,000	$30,000	$30,000	$50,000		$100,000		**$240,000**
Endo Pharmaceuticals	$10,000	$10,000		$5,000	$10,000			**$35,000**
GlaxoSmithKline				$50,000	$50,000			**$100,000**
Grunenthal					$15,000			**$15,000**
Mallinckrodt Pharmaceuticals			$25,000	$25,000	$450,000	$75,000	$40,000	**$615,000**
Pfizer	$25,000	$35,000	$90,000	$25,500	$115,000	$40,000	$100,000	**$430,500**
Purdue Pharma	$15,000	$25,000	$25,000	$75,000	$25,000			**$165,000**
Sanofi Aventis					$50,000	$250,000		**$300,000**
Teva Pharmaceuticals		$50,000	$125,000	$50,000	$10,000	$265,000		**$500,000**
UCB, Inc.					$25,000			**$25,000**
Annual Total	**$80,000**	**$150,000**	**$470,000**	**$405,500**	**$1,155,000**	**$730,000**	**$140,000**	**$3,130,500**

American Academy of Physical Medicine and Rehabilitation

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Actavis, Inc.	$8,150								**$8,150**
AstraZeneca						$10,000	$12,500	$12,500	**$35,000**
Collegium Pharmaceutical					$3,000				**$3,000**

American Academy of Physical Medicine and Rehabilitation—Continued

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Daiichi Sankyo					$104,500	$275,400	$224,450	$12,500	**$616,850**
Depomed [1]		$18,450	$5,000	$34,650	$15,000	$2,700			**$75,800**
Egalet [2]					$88,450	$250			**$88,700**
Endo Pharmaceuticals	$18,500	$10,000	$10,000						**$38,500**
Forest Pharmaceuticals [3]	$2,200	$500							**$2,700**
Janssen Pharmaceuticals	$500								**$500**
The Medicines Company				$3,300					**$3,300**
Pernix Therapeutics				$2,850	$5,700	$2,700	$3,100		**$14,350**
Pfizer	$132,300	$25,000	$20,000	$25,000	$15,000	$15,000	$101,700		**$334,000**
Purdue Pharma	$121,860	$107,450	$65,000	$145,850	$12,000				**$452,160**
Teva Pharmaceuticals				$75,000					**$75,000**
U.S. WorldMeds Solstice	$250	$5,300	$100	$4,050	$7,400	$250	$10,500	$9,300	**$37,150**
Zogenix			$3,700						**$3,700**
Annual Total	**$283,760**	**$166,700**	**$103,800**	**$290,700**	**$251,050**	**$306,300**	**$352,250**	**$34,300**	**$1,788,860**

[1] Changed name to Assertio Therapeutics in August 2018.
[2] Changed name to Zyla Life Sciences in June 2019.
[3] Acquired by Actavis in July 2014.

American Academy of Pain Medicine [1]

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
AbbVie		$7,500	$6,000						**$13,500**
Allergan [2]	$2,750	$17,900	$3,000						**$23,650**
AstraZeneca			$78,750	$84,167	$50,000	$25,000			**$237,917**
Cara Therapeutics				$67,000	$60,000	$73,625			**$200,626**
Cephalon [3]			$120,000						**$120,000**
Collegium Pharmaceutical					$11,000	$28,500	$15,000	$17,700	**$72,200**
Daiichi Sankyo					$52,225	$329,510	$161,250	$147,000	**$689,985**
Depomed	$20,925	$57,000	$57,825	$46,000	$60,500	$53,500	$11,000	$7,500	**$314,250**
Endo Pharmaceuticals	$75,000	$10,000	$10,000	$6,400	$96,920	$26,630			**$224,950**
Insys Therapeutics		$18,000	$19,200	$9,725		$5,800			**$52,725**
Janssen Pharmaceuticals	$83,475								**$83,475**
Johnson & Johnson		$7,500							**$7,500**
KaJeo				$87,000	$75,000	$77,500			**$239,500**
Mallinckrodt Pharmaceuticals		$17,900	$37,021	$8,350					**$63,271**
Nektar Therapeutics		$92,400	$97,050	$24,000	$15,000	$15,000	$15,000		**$258,450**
Novartis Pharmaceuticals		$3,000	$3,000					$143,365	**$149,365**
Pernix Therapeutics				$15,000	$82,000	$91,000	$76,500		**$264,500**
Pfizer	$110,000	$127,125	$88,333	$75,000	$75,000	$83,333	$110,000		**$668,791**

American Academy of Pain Medicine[1]—Continued

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Purdue Pharma	$185,000	$164,250	$171,000	$117,000	$83,500	$42,500			**$763,250**
Salix Pharmaceuticals	$5,500	$21,474	$0	$0	$7,000	$38,500	$10,000	$19,500	**$101,974**
Shionogi				$5,000	$15,000	$50,000			**$70,000**
Teva Pharmaceuticals	$30,000	$129,900	$138,540	$323,185	$281,050	$95,500		$19,710	**$1,017,885**
Zogenix		$95,800	$174,000	$84,800					**$354,600**
Annual Total	**$512,650**	**$769,749**	**$1,003,719**	**$952,627**	**$964,195**	**$1,035,898**	**$398,750**	**$354,775**	**$5,992,363**

[1] During the final stages of the Committee's investigation, the American Academy of Pain Medicine (AAPM) provided additional data showing millions of dollars in additional payments from opioid manufacturers to AAPM and an affiliated 501(c)(3) entity, the American Academy of Pain Medicine Foundation (the Foundation). In addition to nearly $6 million AAPM received directly from opioid manufacturers, the organization reported $1.1 million in revenue from the Foundation from 2013 to 2017. The additional data provided by AAPM shows that the Foundation, in turn, received $1 million in payments from opioid manufacturers from 2013 to 2019.
[2] Acquired by Actavis in November 2014.
[3] Acquired by Teva in May 2011.

American Academy of Pain Medicine Foundation

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Collegium Pharmaceutical						$10,000		$10,000	**$20,000**
Daiichi Sankyo						$167,275		$47,425	**$214,700**
Depomed	$5,000		$100,000	$50,000	$148,265				**$303,265**
Egalet						$5,000			**$5,000**
Mallinckrodt Pharmaceuticals			$191,000				$9,600	$58,400	**$259,000**
Nektar Therapeutics		$15,000				$25,000			**$40,000**
Pfizer				$20,000					**$20,000**

Purdue Pharma		$75,000							**$75,000**
Salix Pharmaceuticals				$45,000					**$45,000**
Teva Pharmaceuticals							$50,000		**$50,000**
Annual Total	**$5,000**	**$90,000**	**$291,000**	**$115,000**	**$148,265**	**$207,275**	**$59,600**	**$115,825**	**$1,031,965**

American Chronic Pain Association

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Abbvie		$5,000	$5,000	$5,000				**$15,000**
AstraZeneca		$20,000	$65,000	$215,000	$40,000			**$840,000**
Cephalon	$10,000							**$10,000**
Collegium Pharmaceutical				$15,000	$10,000	$15,000	$45,000	**$85,000**
Daiichi Sankyo						$10,000	$125,000	**$135,000**
Depomed			$35,000	$5,000	$15,000	$12,500		**$67,500**
Egalet				$5,000	$27,000	$10,000		**$42,000**
Endo Pharmaceuticals	$235,250	$49,000	$90,000					**$874,250**
Endo Labs	$25,000							**$25,000**
Forest Laboratories [1]	$10,000	$10,000	$5,000	$5,000				**$80,000**
Janssen Pharmaceuticals	$25,000							**$25,000**
Johnson & Johnson	$30,000	$35,000	$25,000	$10,000	$10,000	$10,000		**$120,000**
Kaleo				$5,000	$18,000	$65,000	$10,000	**$98,000**
Mallinckrodt Pharmaceuticals		$25,000	$5,000	$25,775				**$55,775**

American Chronic Pain Association—Continued

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Pernix Therapeutics					$10,000	$10,000	$5,000	**$25,000**
Pfizer	$125,000	$34,875	$5,000	$20,000	$10,000	$20,000		**$214,875**
Purdue Pharma	$206,500	$99,970	$35,000	$25,000	$20,000			**$886,470**
Sanofi Aventis					$5,000	$5,000	$10,000	**$20,000**
Shionogi				$10,000	$15,000			**$25,000**
Teva Pharmaceuticals	$65,000	$78,800	$401,000	$194,997	$200,578	$50,600	$15,000	**$1,005,975**
Tonix Pharma		$5,000		$5,000				**$10,000**
Zogenix	$5,000		$60,000	$18,950				**$83,950**
Annual Total	**$736,750**	**$362,645**	**$731,000**	**$564,722**	**$380,578**	**$208,100**	**$210,000**	**$3,193,795**

[1] Acquired by Actavis in July 2014.

American Pain Society

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
AstraZeneca				$35,000				**$35,000**
Daiichi Sankyo					$80,000	$44,711	$20,000	**$144,711**
Depomed		$10,000	$10,000	$82,500	$61,500	$15,000		**$179,000**
Endo Pharmaceuticals	$429,307	$417,274	$150,000					**$996,581**
Janssen Pharmaceuticals	$60,000							**$60,000**
Kaleo				$5,000				**$5,000**

Mallinckrodt Pharmaceuticals			$25,000	$25,000				**$50,000**
Mylan				$9,375				**$9,375**
Nektar Therapeutics	$60,000							**$60,000**
Pfizer		$37,000	$25,000	$35,000	$346,000	$217,500	$45,000	**$705,500**
Purdue Pharma	$108,465	$93,480	$85,000	$20,000		$20,000		**$326,945**
Salix Pharmaceuticals[1]		$5,000	$5,000					**$10,000**
Teva Pharmaceuticals	$90,000	$90,000	$100,000	$179,500	$229,500	$60,000	$15,000	**$764,000**
Zogenix		$5,000	$25,000					**$30,000**
Annual Total	**$747,772**	**$657,754**	**$425,000**	**$391,375**	**$717,000**	**$357,211**	**$80,000**	**$3,376,112**

[1] Salix was acquired by Valeant Pharmaceuticals in April 2015.

American Society for Pain Management Nursing

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
AccreditEd/Salix Pharmaceuticals	$37,000							**$37,000**
AstraZeneca				$65,000				**$65,000**
Collegium Pharmaceutical						$1,500	$7,500	**$9,000**
Depomed	$7,500	$10,700						**$18,200**
Endo Pharmaceuticals						$10,000		**$10,000**
Mallinckrodt Pharmaceuticals				$10,000				**$10,000**
Pernix Therapeutics					$6,500	$19,500		**$26,000**
Pfizer	$10,000		$15,000	$15,000	$1,000	$20,000		**$61,000**

American Society for Pain Management Nursing—Continued

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Purdue Pharma	$23,700	$92,200	$11,000	$35,200	$37,500			**$199,600**
Teva Pharmaceuticals			$3,500	$10,000				**$13,500**
Annual Total	**$78,200**	**$102,900**	**$29,500**	**$135,200**	**$45,000**	**$61,000**	**$7,500**	**$469,300**

Center for Practical Bioethics [1]

Company	2012	2013	2014	2015	2016	Grand Total
Endo Pharmaceuticals			$1,000			**$1,000**
Janssen Pharmaceuticals	$3,000		$10,000			**$13,000**
Johnson & Johnson			$5,000			$5,000
Mallinckrodt Pharmaceuticals				$30,000		$30,000
Pfizer	$1,000	$25,000				**$26,000**
Purdue Pharma	$25,000	$100,000	$15,000	$3,500	$500	**$144,000**
Teva Pharmaceuticals	$7,000		$105,000			$112,000
Zogenix				$500		**$500**
Annual Total	**$36,000**	**$225,000**	**$136,000**	**$34,000**	**$500**	**$331,500**

[1] None of the payments reported by the Center for Practical Bioethics for 2017 or 2018 were made by opioid manufacturers or other pharmaceutical manufacturers.

International Association for the Study of Pain

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Acel Rx		$62,500	$18,750					**$81,250**
AstraZeneca		$63,105	$31,105		$45,000	$110,000		**$249,210**
Charleston Laboratories, Inc.						$20,000		**$20,000**
Collegium Pharmaceutical							$10,700	**$10,700**
Daiichi Sankyo					$70,300			**$70,300**
Eli Lilly	$28,418	$51,034						**$79,452**
Excerpta Medical (Agency for Grunenthal)	$40,308							**$40,308**
Glenmark Pharmaceuticals				$600				**$600**
Grunenthal	$65,943	$215,000	$92,000		$10,000	$20,000	$120,000	**$522,943**
Janssen Pharmaceuticals						$52,903		**$52,903**
Johnson & Johnson Ltd/Janssen Mumbai						$52,903		**$52,903**
Mallinckrodt Pharmaceuticals				$2,500				**$2,500**
Mundipharma	$86,546	$228,130	$143,360	$251,580	$196,999	$22,401	$76,667	**$1,005,683**
Pfizer	$29,100		$105,000	$141,000	$45,000	$114,865	$918,045	**$1,353,010**
Purdue Pharma	$9,448				$20,000		$5,400	**$34,848**
QRx Pharma Ltd.	$13,847							**$13,847**
Sanofi Aventis				$47,000				**$47,000**
Teva Pharmaceuticals		$71,460	$44,497	$30,000	$93,800	$87,680	$300,230	**$627,667**

International Association for the Study of Pain—Continued

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Zibrant Ltd (agency for Pfizer)	$2,001							**$2,001**
Annual Total	**$275,610**	**$691,229**	**$434,712**	**$472,680**	**$481,099**	**$427,850**	**$1,431,042**	**$4,214,222**

U.S. Pain Foundation

Company	2012	2014	2015	2016	2017	2018	Grand Total
Abbvie		$9,500		$310,000	$300,000	$300,000	**$919,500**
AstraZeneca		$38,800		$145,000			**$183,800**
Collegium Pharmaceutical			$9,500				**$9,500**
Daiichi Sankyo			$14,500	$35,000		$50,000	**$99,500**
Egalet				$32,500			**$32,500**
Endo Pharmaceuticals		$25,000		$55,000	$50,000		**$130,000**
GlaxoSmithKline		$9,500	$9,500				**$19,000**
Insys Therapeutics [1]					$2,900,000	$350,000	**$3,250,000**
Janssen Pharmaceuticals		$7,500					**$7,500**
Johnson & Johnson	$7,500	$9,500	$55,000	$40,000	$80,000		**$192,000**
Mallinckrodt Pharmaceuticals		$9,989					**$9,989**
Pfizer	$50,000	$80,000	$40,000		$55,000	$60,000	**$285,000**
Purdue Pharma	$25,000	$104,600	$120,000				**$249,600**
Shionogi			$12,500				**$12,500**

Teva Pharmaceuticals	$43,000	$266,000	$250,000	$110,000		$120,000	$789,000
UCB, Inc.		$25,000	$25,000	$45,000	$25,000		**$120,000**
Zogenix		$21,368					**$21,368**
Annual Total	**$125,500**	**$606,757**	**$536,000**	**$772,500**	**$3,410,000**	**$880,000**	**$6,330,757**

[1] Payments from Insys were in relation to a patient assistance program (PAP) operated by the U.S. Pain Foundation. Ranking Member Wyden is continuing to investigate the U.S. Pain Foundation and the PAP. *See* Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018).

Appendix C

Drug Companies

Endo Pharmaceuticals

1. Letter from Raymond V. Shepherd, Counsel. Venable, on Behalf of Endo Pharmaceuticals, to Senator Baucus and Senator Grassley (June 15, 2012), *https://www.finance.senate.gov/download/baucus_-grassley-letter-read.*
2. Summary of payments made by Endo Pharmaceuticals between 1997–2012, *https://www.finance.senate.gov/download/endo-payments-to-organizations.*
3. 2008–2012 Opana ER Business Plan, November 29, 2007 (SFC–00025042), *https://www.finance.senate.gov/download/sfc-00025042.*
4. Scientific Affairs Overview Business Plan 2011 (SFC–00057051), *https://www.finance.senate.gov/download/sfc-00057051.*

Johnson & Johnson

5. Letter from Daniel Donovan, Counsel, King & Spalding, to Senator Baucus and Senator Grassley (June 8, 2012), *https://www.finance.senate.gov/download/060812_jandj_letter.*
6. Summary of payments made by Johnson & Johnson between 1997–2012 (SFC00000001), *https://www.finance.senate.gov/download/jj-summary-of-payments_6-7-2012.*

Purdue Pharma, L.P.

7. Letter from Theodore Hester, Counsel, King & Spalding, on Behalf of Purdue Pharma, to Senator Baucus and Senator Grassley (June 8, 2012), *https://www.finance.senate.gov/download/letter-purdue.*
8. Summary of payments made by Purdue Pharma, L.P., between 1997–2012 (SFC00000001), *https://www.finance.senate.gov/download/sfc00000001.*
9. Purdue payment details 1997-2012 (SFC000000002), *https://www.finance.senate.gov/download/sfc00000002.*
10. Health Policy Presentation by J. David Haddox, September, 9, 2010 (SFC00002172), *https://www.finance.senate.gov/download/sfc00002172.*
11. Email from Pamela Bennett, Vice President, Purdue, re: Pain Care Forum, March 2, 2007 (SFCO00l 1511), *https://www.finance.senate.gov/download/sfc00011511.*
12. Email from Pamela Bennett, Vice President, Purdue, re: Pain Care Forum, February 27, 2007 (SFC00011527), *https://www.finance.senate.gov/download/sfc00011527.*
13. Attachment re: Pain Care Forum (SFC00011528), *https://www.finance.senate.gov/download/sfc00011528.*

Tax-Exempt Organizations

American Chronic Pain Association

14. ACPA Financial Statements & Independent Auditor's Report 2012–2018, *https://www.finance.senate.gov/download/acpa-67-102-financial-statements.*
15. ACPA-AstraZeneca Correspondence (SFC_ACPA_127), *https://www.finance.senate.gov/download/acpa-127-141-astrazeneca-documents.*
16. ACPA-Daiichi Sankyo Correspondence (SFC_ACPA_221), *https://www.finance.senate.gov/download/acpa-221-239-daiichi-sankyo.*
17. ACPA-Medtronic Correspondence (SFC_ACPA_572), *https://www.finance.senate.gov/download/acpa-572-612-medtronic-docs.*

Alliance for Patient Access

18. AfPA-Mallinckrodt Agreement, January, 2016 (AfPA_SFC_000001), *https://www.finance.senate.gov/download/afpa_sfc_000001-05.*
19. AfPA Letters to Federal Government, 2014–2018 (AfPA_SFC_000193-AfPA_SFC_000241), *https://www.finance.senate.gov/download/afpa_sfc_000193-241.*
20. Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020), *https://www.finance.senate.gov/download/01302020113346.*
21. Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden (Oct. 10, 2019), *https://www.finance.senate.gov/download/afpa-second-production-to-sfc-10-october-2019.*

22. Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019), *https://www.finance.senate.gov/download/afpa-sfc-29-july-2019.*

American Pain Foundation (Defunct)

23. American Pain Foundation Business Plan, 1998, *https://www.finance.senate.gov/download/apf-1998-business-plan.*
24. APF-Purdue Correspondence 2001–2005 (APF65), *https://www.finance.senate.gov/download/apf-purdue-correpondence-2001-2005-apf65-111.*
25. APF-Purdue Correspondence and Checks (2001–2004) (APF106), *https://www.finance.senate.gov/download/apf106_-apf-purdue-correspondence-and-checks-2001-2004.*
26. Report to Purdue on 2002 Accomplishments (APF254), *https://www.finance.senate.gov/download/apf254_-report-to-purdue-on-2002-accomplishments-to-purdue.*
27. APF email re: briefing with Purdue officials (APF298), *https://www.finance.senate.gov/download/email-regarding-briefing-with-senior-purdue-officials-apf298-299.*
28. APF Operating Plan and Budget for 2001 (APF394), *https://www.finance.senate.gov/download/apf_-operating-plan-and-budget-for-2001-apf-394-404.*

American Society for Pain Educators

29. Letter from Noam Fischman, Counsel, Polsinelli, on Behalf of American Society of Pain Educators, to Senator Grassley and Senator Wyden (Nov. 11, 2020), *https://www.finance.senate.gov/download/1111-letter-from-aspe-to-senate-finance-committee.*
30. Letter from Noam Fischman, Counsel, Polsinelli, on Behalf of American Society of Pain Educators, to Senator Grassley and Senator Wyden (Sept. 30, 2020), *https://www.finance.senate.gov/download/aspe-ltr-to-senate-finance-committee-930.*
31. Endo Corporate Membership, December 2007 (ASPE_000027), *https://www.finance.senate.gov/download/aspe_000027-28_-endo-pharmaceuticals-corporate-membership-dec-2007.*
32. Endo Corporate Membership, October 2009 (ASPE_000025), *https://www.finance.senate.gov/download/aspe_000025-26_-endo-corporate-membership-29-oct-2009.*
33. Purdue Corporate Membership. February 2008 (ASPE 000029), *https://www.finance.senate.gov/download/aspe_000029-30_-purdue-corporate-membership-13-feb-2008.*

Federation of State Medical Boards

34. Letter from Humayun Chaudhry, President and CEO, Federation of State Medical Boards, to Senator Grassley and Senator Wyden (July 29, 2019), *https://www.finance.senate.gov/download/fsmb-response-to-senate-finance-committee-07292019.*

International Association for the study of Pain

35. Letter from Lars Arendt-Nielsen, President, International Association for the Study of Pain, to Senator Grassley and Senator Wyden (Aug. 28, 2019), *https://www.finance.senate.gov/download/iasp-official-response-to-senate-finance-committee_-ii.*
36. Letter from Lars Arendt-Nielsen, President, International Association for the Study of Pain, to Senator Grassley and Senator Wyden (July 29, 2019), *https://www.finance.senate.gov/download/iasp-response-to-the-senate-finance-committee.*

Joint Commission

37. Letter from Mark Chassin, President and CEO, The Joint Commission, to Senator Grassley and Senator Wyden (July 29, 2019), *https://www.finance.senate.gov/download/7292019-senate-finance-letter.*
38. Letter from Mark Chassin. President and CEO, The Joint Commission, to Senator Baucus and Senator Grassley (June 29, 2012), *https://www.finance.senate.gov/download/joint-commission-letter-to-sens-baucus-and-grassley-_june292012.*

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The US Is Failing Substance-Exposed Infants

Sarah Font et al.

June 4, 2024

The stark human and societal cost of the drug epidemic is undeniable, directly taking over 100,000 lives each year since 2021.[1] Due to infrequent and inconsistent testing,[2] there is no reliable count of how many children are exposed to substances in utero, but, even before the current drug epidemic began, researchers estimated that 400,000–480,000 children born each year were prenatally exposed to drugs or alcohol.[3] Because the estimated number of adults meeting criteria for substance use disorder increased from 22 million in 2010[4] to 46 million in 2021,[5] prenatal exposure has likely increased as well. Recent data on drug and alcohol use among preg-

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[1] National Institute on Drug Abuse, "Drug Overdose Death Rates," June 30, 2023, *https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates;* and Centers for Disease Control and Prevention, "Provisional Drug Overdose Death Counts," March 13, 2024, *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm*.

[2] Rates of toxicology testing are typically below 5 percent. Discretion in testing by medical professionals results in disproportionate testing of low-income and racial minority mothers. See Samuel Cohen et al., "Disparities in Maternal-Infant Drug Testing, Social Work Assessment and Custody at 5 Hospitals," *Academic Pediatrics* 23, no. 6 (August 2023): 1268–75, *https://pubmed.ncbi.nlm.nih.gov/36754165;* and Sebastian Schoneich et al., "Incidence of Newborn Drug Testing and Variations by Birthing Parent Race and Ethnicity Before and After Recreational Cannabis Legalization," *JAMA Network Open* 6, no. 3 (2023): e232058, *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802124*.

[3] Rachel N. Lipari and Struther L. Van Horn, "Children Living with Parents Who Have a Substance Use Disorder," US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavior Health Statistics and Quality, August 24, 2017, *https://www.samhsa.gov/data/sites/default/files/report_3223/ShortReport-3223.html*.

[4] US Department of Health and Human Services, Substance Abuse and Mental Health Administration, Center for Behavior Health Statistics and Quality, "Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings," September 2011, *https://www.samhsa.gov/data/sites/default/files/NSDUHNationalFindingsResults2010-web/2k10ResultsRev/NSDUHresultsRev2010.htm*.

[5] US Department of Health and Human Services, "SAMHSA Announces National Survey on Drug Use and Health (NSDUH) Results Detailing Mental Illness and Substance Use Levels in 2021," press release, January 4, 2023, *https://www.hhs.gov/about/news/2023/01/04/samhsa-announces-national-survey-drug-use-health-results-detailing-mental-illness-substance-use-levels-2021.html*.

nant women,[6] pediatric poisonings,[7] Narcan administrations to infants,[8] and child fatalities[9] all signal an unmitigated crisis. To date, however, the US response has centered on parents and other adults experiencing addiction with inadequate attention to the needs of the infants and young children in their care.

Advocates have been highly successful in advancing nonpunitive harm-reduction approaches to substance use and addiction. These approaches, by definition, reject the involvement of the criminal justice system and the use of strategies that coerce individuals to seek or accept treatment.[10] Although reducing the use of incarceration as a response to addiction has broad public support,[11] a majority of the public also wants the child protection system (CPS) to respond to the needs of infants whose parents abuse drugs or alcohol.[12]

Yet many states, with the encouragement of the federal government and major foundations, seek to limit CPS responsibility for substance-exposed infants.[13] Several states are considering laws to prevent doctors from conducting a toxicology test on a newborn child without parental consent, even when there is reasonable suspicion that the child was prenatally exposed.[14] Without formal identification of substance exposure, there is often an insufficient basis for a CPS report.[15] Even when substance exposure is detected, doctors may be encouraged not to report, or their reports may be screened out.[16] The threshold for mandatory reporting of child mal-

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[6] US Department of Health and Human Services, Substance Abuse and Mental Health Administration, *2020 National Survey on Drug Use and Health: Women,* July 2022, *https://www.samhsa.gov/data/sites/default/files/reports/slides-2020-nsduh/2020NSDUHWomenSlides072522.pdf;* and Lucinda J. England et al., "Alcohol Use and Co-Use of Other Substances Among Pregnant Females Aged 12–44 Years—United States, 2015–2018," *Morbidity and Mortality Weekly Report* 69, no. 31 (August 7, 2020): 1009–14, *https://www.cdc.gov/mmwr/volumes/69/wr/mm6931a1.htm*.

[7] Julie R. Gaither, Veronika Shabanova, and John M. Leventhal, "US National Trends in Pediatric Deaths from Prescription and Illicit Opioids, 1999–2016," *JAMA Network Open* 1, no. 8 (2018): e186558, *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719580.*

[8] John Cardinale, "Bernalillo County Court Records Show Babies Are Overdosing," KOAT Action News, June 15, 2023, *https://www.koat.com/article/bernalillo-county-court-records-show-babies-are-overdosing/44214139*.

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[14] Sen. B. S320B, 2023–2024 Reg. Sess. (N.Y. 2023), *https://www.nysenate.gov/legislation/bills/2023/S320/amendment/B;* and LLS 24–0344.02, 74th Gen. Assemb., 2d Reg. Sess. (Colo. 2023), *https://leg.colorado.gov/sites/default/files/images/bill_3_24-0344.02.pdf*.

[15] Lex Talamo, "Majority of Louisiana Babies Born to Addicted Mothers Are Sent Home—by Law," *Shreveport Times,* February 15, 2018, *https://www.shreveporttimes.com/story/news/2018/02/15/majority-louisiana-babies-born-addicted-mothers-sent-home-law/314127002/#:~:text=Substance%2Dexposed%20newborns,extenuating%20circumstances%20also%20are%20present*.

[16] Requirements to notify CPS and develop a plan of safe care pertain to cases in which the child was identified as "being affected by substance abuse or withdrawal symptoms resulting from prenatal drug exposure." The federal government allows states to define "affected by," and they may exclude substance-exposed infants who do not exhibit immediate signs of harm upon their birth. US Department of Health and Human Services, Administration for Children and Families, "Guidance on Amendments Made to the Child Abuse Prevention and Treatment Act (CAPTA) by Public Law 114–198, the Comprehensive Addiction and Recovery Act of 2016," January 17, 2017, 3, *https://www.acf.hhs.gov/cb/policy-guidance/pi-17-02*. See also, from Pennsylvania guidelines: "[Question:] What if a delivering woman admits to substance use but the baby does not exhibit any symptoms at birth? Must I make a notification? [Answer:] No; under Act 54 and CAPTA, a health care provider is required to make a notification when an effect on the infant is detected." Pennsylvania Department of Human Services, "Plans of Safe Care Frequently Asked Questions," 4, *https://www.dhs.pa.gov/KeepKidsSafe/Resources/Documents/POSC_FAQ.pdf;* from New York City guidelines: "A positive toxicology result for a parent or a newborn, by itself, does not constitute reasonable suspicion of child abuse or maltreatment, and thus does not necessitate a report to the Statewide Central Registrar of Child Abuse and Mal-

treatment typically includes "imminent risk" to the child—but policies in several states are clear that a person with an untreated substance use disorder being the sole caregiver of a newborn is not, in itself, sufficient to make a CPS report.[17] A small number of states, like Connecticut, have gone even further, enacting policies to prevent CPS from even knowing the identity of substance-exposed infants.[18] Efforts are underway to make deidentified notifications national policy.[19]

The current alternative to CPS for substance-exposed infants is a "Plan of Safe Care" (POSC), also known as "Family Care" or "Family Recovery Plan"—positioned as a family-friendly approach to addressing the needs of substance-exposed infants and their families without the stigma and coerciveness of CPS.[20] POSCs are often described as a "public health" or "harm-reduction" approach. The basic idea is appealing—if addiction is a disease, then it should be treated with the same type of compassionate, voluntary, and nonpunitive care provided for diseases like cancer or diabetes.

Proponents of this approach to substance use make four general arguments: (1) Stigma and fear of CPS may deter people from seeking help,[21] (2) a drug test is "not a parenting test,"[22] (3) CPS is ineffective or harmful in addressing the needs of children and families affected by substance use, and (4) unwarranted variation in rates of toxicology testing contributes to disproportionality in CPS involvement. These arguments warrant serious consideration in policy evaluation and reform, but POSCs do not directly address these concerns. Moreover, it is not clear what other entity can respond when parental substance use is likely to inhibit minimally adequate caregiving and that parent rejects or does not benefit from a voluntary offer of services.

The term "plan" implies a set of objectives or steps that will be implemented, but a POSC can be nothing more than a form[23] that documents services the mother or

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treatment (SCR)." New York City Administration for Children's Services and Department of Health and Mental Hygiene, "Reporting and Planning Requirements for Newborns Prenatally Exposed to Substances and Their Caregivers," November 12, 2020, *https://www.nyc.gov/assets/acs/pdf/child_welfare/2020/PositiveToxicology.pdf;* and Stephanie Anne Deutsch et al., "Factors Associated with Child-Welfare Involvement Among Prenatally Substance-Exposed Infants," *Journal of Pediatrics* 222 (July 2020): 35–44, *https://pubmed.ncbi.nlm.nih.gov/32418814/*.

[17] See, for example, New York City Administration for Children's Services and Department of Health and Mental Hygiene, "Reporting and Planning Requirements for Newborns Prenatally Exposed to Substances and Their Caregivers."; Elise Takahama, "WA Hospitals No Longer Required to Report All Substance-Exposed Infants," *Seattle Times,* June 28, 2023, *https://www.seattletimes.com/seattle-news/health/wa-hospitals-no-longer-required-to-report-all-substance-exposed-infants;* and Brittany Costello, "4 Investigates: Is CARA Helping or Hurting Families Struggling with Substance Abuse?," KOB, January 18, 2024, *https://www.kob.com/new-mexico/4-investigates-is-cara-helping-or-hurting-families-struggling-with-substance-abuse*.

[18] National Center on Substance Abuse and Child Welfare, "How States Serve Infants and Their Families Affected by Prenatal Substance Exposure," *https://ncsacw.acf.hhs.gov/files/prenatal-substance-exposure-brief1.pdf;* and Margaret Lloyd Sieger et al., "Novel Implementation of State Reporting Policy for Substance-Exposed Infants," Hospital Pediatrics 12, no. 10 (October 2022): 841–48. *https://pubmed.ncbi.nlm.nih.gov/36093638/*.

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[20] Sen B. SB3136, 103rd Gen. Assemb., 2023–2024 Reg. Sess. (Ill. 2024), *https://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=112&GA=103&DocTypeId=SB&DocNum=3136&GAID=17&LegID=152361&SpecSess=&Session=*.

[21] Joy D. Scheidell et al., "Parenting and Childcare Responsibilities, Harm Reduction Service Engagement, and Opioid Overdose Among Women and Men Who Use Illicit Opioids in New York City," Drug and Alcohol Dependence Reports 3 (June 2022): 100054, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9224239/;* and Elizabeth Peacock-Chambers et al., "Engagement in Early Intervention Services Among Mothers in Recovery from Opioid Use Disorders," *Pediatrics* 145, no. 2 (February 2020), *https://publications.aap.org/pediatrics/article/145/2/e20191957/68257/Engagement-in-Early-Intervention-Services-Among*.

[22] Joyce McMillen quoted in Eran Chan Ding, "Number of Children Separated from Their Families Due to Parental Substance Use Has More Than Doubled," *Youth Today,* November 18, 2022, *https://youthtoday.org/2022/11/number-of-children-separated-from-their-families-due-to-parental-substance-use-has-more-than-doubled*.

[23] See Nebraska Department of Health and Human Services, "Comprehensive Addiction and Recovery Act (CARA)," *https://dhhs.ne.gov/Pages/Comprehensive-Addiction-and-Recovery-Act.aspx;* Connecticut Clearinghouse, "Template Plan of Safe Care," *https://www.ctclearinghouse.org/Customer-Content/www/topics/CAPTA_POSC_template.pdf;* and Pennsylvania Department of Human Services, "Plan of Safe Care Template (Example)," *https://www.dhs.pa.gov/KeepKidsSafe/Resources/Documents/POSC%20Template_PDF.pdf*.

infant already received or were referred to.[24] The voluntary nature of POSCs may mean that the vast majority of parents eligible for a POSC receive no substance use treatment, as studies in New Mexico[25] and Delaware found.[26] In addition, state and federal laws inhibit CPS or other agencies from assessing or monitoring the uptake or efficacy of substance abuse treatment.[27]

Individuals with substance use disorders may take many years to be "ready" for treatment, but there is no pause button on infants' development. Beyond the effects of prenatal substance exposure itself,[28] the effects of untreated substance use disorders on parenting are undeniable: Young children face increased risks of fatality, poisonings, injuries, physical and sexual abuse, and severe neglect, in addition to poor physical, cognitive, and emotional development.[29]

As states and the federal government myopically prioritize the avoidance of CPS as an end unto itself, POSCs have been applauded without any evidence—or even requirements to collect evidence—as to their actual efficacy in keeping children safe and ensuring that their basic developmental needs are met. This is not compassion but instead an abdication of responsibility. As an ideologically and experientially diverse group of researchers, foundation leaders, and child welfare professionals, we put forth four principles for better responding to the needs of substance-exposed infants and their parents.

1. **Children must be at the center of policymaking.** Children are entitled to receive minimally adequate care and to be protected from foreseeable harms. Parental addiction is a foreseeable risk to infant health and safety that the state has an obligation to mitigate.
2. **A compassionate response to parents experiencing addiction or engaged in problematic substance use can include CPS and court-ordered treatment.** CPS involvement and the desire to maintain or regain custody can be a powerful motivator for parents to engage in treatment[30]

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[24] Child Welfare Information Gateway reports that 13 states require child welfare agencies to monitor compliance with the plan of safe care. Yet, it is not clear how that requirement is met when deidentified notifications are used or the child welfare system does not conduct an assessment. See Child Welfare Information Gateway and Children's Bureau, "Plans of Safe Care for Infants with Prenatal Substance Exposure and Their Families," August 2019, *https://cwig-prod-prod-drupal-s3fs-us-east-1.s3.amazonaws.com/public/documents/safecare.pdf?VersionId=SsISyDYxLAtZdECsRRp5fX8QRj66iaFx*.

[25] New Mexico Legislative Finance Committee, Program Evaluation: Implementation and Outcomes of the Comprehensive Addiction and Recovery Act, October 27, 2023, *https://nmlegis.gov/Entity/LFC/Documents/Program_Evaluation_Reports/Program%20Evaluation_Implementation%20and%20Outcomes%20of%20CARA%20FINAL%20(1).pdf*.

[26] Stephanie Anne Deutsch et al., "Impact of Plans of Safe Care on Prenatally Substance Exposed Infants," *Journal of Pediatrics* 241 (February 2022): 54–61, *https://www.jpeds.com/article/S0022-3476(21)01025-8/abstract*.

[27] US Government Accountability Office, Substance-Affected Infants: Additional Guidance Would Help States Better Implement Protections for Children, January 19, 2018, *https://www.gao.gov/products/gao-18-196*.

[28] Effects of prenatal exposure include elevated risk of SIDS. See Louise Makarious, Arthur Teng, and Ju Lee Oei, "SIDS Is Associated with Prenatal Drug Use: A Meta-Analysis and Systematic Review of 4 238 685 Infants," *Archives of Disease in Childhood—Fetal and Neonatal Edition* 107, no. 6 (2022), 617–23, *https://fn.bmj.com/content/107/6/617*.

[29] Vincent C. Smith et al., "Families Affected by Parental Substance Use," *Pediatrics* 138, no. 2 (August 2016), *https://publications.aap.org/pediatrics/article/138/2/e20161575/52464/Families-Affected-by-Parental-Substance-Use;* Anthony N. Maluccio and Frank Ainsworth, "Drug Use by Parents: A Challenge for Family Reunification Practice," *Children and Youth Services Review* 25, no. 7 (July 2003): 511–33, *https://www.researchgate.net/publication/4823858_Drug_Use_by_Parents_A_Challenge_for_Family_Reunification_Practice;* Venla Berg et al., "Parental Alcohol and Drug Abuse and Offspring Mortality by Age 10: A Population-Based Register Study," *European Journal of Public Health* 32, no.6 (December 2022): 933–38, *https://academic.oup.com/eurpub/article/32/6/933/6726391;* Denise Hatzis et al., "Quality of Caregiving in Mothers with Illicit Substance Use: A Systematic Review and Meta-Analysis," *Substance Abuse: Research and Treatment,* March 14, 2024, *https://journals.sagepub.com/doi/full/10.1177/11782218176940 38;* Nicole Landi et al., "Maternal Neural Responses to Infant Cries and Faces: Relationships with Substance Use," *Frontiers in Psychiatry* 2 (2011): 32, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118477;* Amanda F. Lowell et al., "Substance Use and Mothers' Neural Responses to Infant Cues," *Infant Mental Health Journal* 41, no. 2 (March 2020): 264–77, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7160016;* Rebecca Rebbe et al., "Child Protection System Interactions for Children with Positive Urine Screens for Illicit Drugs," *JAMA Network Open* 7, no. 3 (2024): e243133, *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2816598;* and Stephanie Anne Deutsch et al., "Impact of Plans of Safe Care on Prenatally Substance Exposed Infants."

[30] Kristen D. Seay et al., "Substance Abuse Treatment Engagement Among Mothers: Perceptions of the Parenting Role and Agency-Related Motivators and Inhibitors," *Journal of Family*

and is a critical safeguard for children when parents are unable to provide minimally adequate care.[31] Policies or practices that generically discourage the involvement of CPS, rather than incentivizing the right tool for the situation, are misguided.

3. **Timely and comprehensive treatment access is essential.** At the first sign of problematic substance use, pregnant women and parents should be provided with immediate and comprehensive substance use treatment and aftercare to maximize the odds that they can safely and permanently care for their child or children. The treatment array should include coresidential treatment slots for parents and children, as well as robust outpatient treatment and recovery supports.
4. **Data collection and evaluation are necessary to inform and revise existing policy.** Massive policy and practice changes have been made without any systematic data collection or evaluation to understand the relative harms and benefits to children and families. Current evidence is insufficient to determine whether, and under what circumstances, POSCs are an effective or safe alternative to CPS. Practices such as deidentified notifications preclude rigorous impact evaluations of POSCs, thus inhibiting reforms or improvements.

Sincerely,

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Social Work 20, no. 3 (2017): 196–212, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6519925;* Lisa Hines, "The Treatment Views and Recommendations of Substance Abusing Women: A Meta-Synthesis," *Qualitative Social Work* 12, no. 4 (July 2013): 473–89, *https://journals.sagepub.com/doi/10.1177/1473325011432776;* Sugy Choi et al., "Differential Gateways, Facilitators, and Barriers to Substance Use Disorder Treatment for Pregnant Women and Mothers: A Scoping Systematic Review," *Journal of Addiction Medicine* 16, no. 3 (May 2022): 185–96, *https://journals.lww.com/journaladdictionmedicine/abstract/2022/05000/differential_gateways,_facilitators,_and_barriers.28.aspx;* Linda S. Kahn et al., "Treatment Experiences Among People Who Use Opioids: A Social Ecological Approach," *Qualitative Health Research* 32, no. 8–9 (2022): 1386–98, *https://journals.sagepub.com/doi/10.1177/10497323221104315;* and Dean Rivera, Donna Dueker, and Hortensia Amaro, "Examination of Referral Source and Retention Among Women in Residential Substance Use Disorder Treatment: A Prospective Follow-Up Study," *Substance Abuse Treatment, Prevention, and Policy* 16, no. 1 (2021): 2, *https://substanceabusepolicy.biomedcentral.com/articles/10.1186/s13011-021-00357-y*.

[31] Janet U. Schneiderman, John Prindle, and Emily Putnam-Hornstein, "Infant Deaths from Medical Causes After a Maltreatment Report," *Pediatrics* 148, no. 3 (2021): e2020048389, *https://publications.aap.org/pediatrics/article/148/3/e2020048389/181076/Infant-Deaths-From-Medical-Causes-After-a;* Alice Heath, "Government Reactions to Tragedy: How Maltreatment Deaths Impact Child Protection," January 1, 2024, *https://aliceheath.github.io/jmp;* and Max Gross and E. Jason Baron, "Temporary Stays and Persistent Gains: The Causal Effects of Foster Care," *American Economic Journal: Applied Economics* 14, no. 2 (April 2022): 170–99, *https://www.aeaweb.org/articles?id=10.1257/app.20200204*.

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Re: Hearing on Front Lines of the Fentanyl Crisis: Supporting Communities and Combating Addiction through Prevention and Treatment.

Dear Chairman Wyden and Ranking Member Crapo:

Thank you for holding this important hearing on the fentanyl crisis. The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies. Many of our members play a critical role in treating and preventing addiction in rural and underserved areas.

Fentanyl misuse has had a devastating impact on communities throughout the country. According to recent Centers for Disease Control (CDC) data, there were an estimated 81,083 deaths from synthetic opioids in 2023.[1] While slightly down from 2022 numbers, fentanyl is 50 to 100 times more potent than morphine, and therefore the risk of overdose is higher than with other opioids, particularly when the

[1] *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.htm*.

person consuming the fentanyl is not aware of its presence or has not developed a tolerance to it.

Pharmacists' Role in Treating Addiction: Pharmacists play a critical role with other providers in treating addiction. Since Congress eliminated the X-waiver in January 2023, several states have empowered pharmacists to prescribe medications for opioid use disorder (MOUD), greatly increasing the overall access to care. Thirteen states currently permit pharmacists to prescribe MOUD either independently or via collaborative practice agreements.[2] In the last year alone, Nevada, Oregon, and Colorado have authorized pharmacists statewide to prescribe MOUD. Finding additional opportunities for pharmacists to provide addiction treatment, including for misuse of fentanyl, will help reduce overdoses. Buprenorphine in combination with naloxone is a highly effective form of medication treatment for MOUD. Access to MOUD is associated with improved overall survival, fewer relapses, and increased rates of employment among patients with a history of OUD.[3] Buprenorphine-containing MOUD has particular advantages in that it has a superior overdose safety profile when compared with methadone and can be obtained from community pharmacies.[4]

Despite a wealth of evidence supporting the efficacy and benefits of MOUD, and the dire magnitude of opioid misuse in the United States, lack of access to treatment overwhelmingly remains the primary barrier to achieving remission for most patients. A 2022 analysis estimated nearly 90 percent of U.S. individuals with OUD did not receive evidence-based treatment in the prior year.[5] We recommend Congress direct the Department of Health and Human Services to use their authority under the Public Readiness and Emergency Preparedness (PREP) Act to authorize pharmacists, as part of a physician-led care team, to initiate MOUDs, such as buprenorphine.

Support for Fentanyl Test Strips Legislation: Detection of fentanyl adulteration is critical to avoiding overdoses. ASHP is a strong supporter of providing access to fentanyl and xylazine test strips (FTS) and has endorsed two pieces of legislation that would expand access to these important countermeasure. Senator John Cornyn (R–TX) introduced Fentanyl Safe Testing and Overdose Prevention Act (S. 2569), that would clarify in the Controlled Substances Act that the possession, sale, purchase, importation, exportation, or transportation of FTS is not unlawful, making this countermeasure more available. Senator Cory Booker (D–NJ) also introduced the Expanding Nationwide Access to Test Strips Act (S. 2483), that would also decriminalize FTS. We recommend swift passage of S. 2569 and S. 2483.

ASHP thanks you for holding this important hearing and considering our recommendations. We look forward to continuing to work with you to ensure Americans have access to the life-saving pharmacy services in rural and underserved areas. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus

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[2] WA, OR, CA, ID, MT, NV, UT, CO, NM, OH, NC, MA, and TN.

[3] Callister C, Lockhart S, Holtrop JS, Hoover K, Calcaterra SL. Experiences with an addiction consultation service on care provided to hospitalized patients with opioid use disorder: A qualitative study of hospitalists, nurses, pharmacists, and social workers. Subst Abus. 2022; 43(1):615–622; and Substance Abuse and Mental Health Services Administration. Medication-Assisted Treatment (MAT), 2018, *https://www.samhsa.gov/medication-assisted-treatment*.

[4] Schesinger EB, Geminn W, Hohmeier KC, Burley HL Jr. Development and Implementation of Tennessee Nonresidential Buprenorphine Treatment Guidelines. Innov Pharm. 2018;9(3):1–4. Published 2018 Oct 19. *https://doi.org/10.24926/iip.v9i3.1317.*

[5] *https://patientengagementhit.com/news/nearly-90-of-patients-with-opioid-use-disorder-lack-medication-access.*

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Statement of Libby Jones, Program Director, Overdose Prevention Initiative

Thank you for the opportunity to provide this statement for the record.

At the Overdose Prevention Initiative, we recognize that to reduce the overdose death rate in our country, we must address the federal policies at the root of the crisis. It is our mission to ensure that all Americans—regardless of race, class, or geography—have access to lifesaving, evidence-based treatment and harm reduction services.

Our nation's overdose crisis has continued to escalate in recent years. The increased availability of illicitly manufactured fentanyl, coupled with the mental health effects of the COVID–19 pandemic contributed to a surge of overdose deaths. In 2022 alone, more than 109,000 lives were lost to overdose. Despite the effectiveness of methadone and buprenorphine, two FDA-approved medications for opioid use disorder (MOUD) that are proven to prevent overdose, this treatment remains out of reach for a majority of the estimated 2.5 million Americans who suffer from opioid use disorder. A recent study found that 88% of individuals who would benefit from OUD treatment did not receive it.[1]

As the largest payer of substance use disorder (SUD) treatment in the United States, Medicaid is perhaps the most influential federal program affecting health outcomes for Americans with SUD. Medicaid policy plays an outsized role in determining the availability and access to life-saving treatments for millions of Americans. We urge this committee to take up important legislation regarding MOUD that could make a significant impact on overdose prevention.

The prevalence of illicitly manufactured fentanyl proves our drug supply to be dynamic and demands more proactive solutions. The interventions that previously slowed overdose death rates are losing effectiveness as our supply changes. According to the DEA, fentanyl is 100 times more potent than morphine and 50 times more potent than heroin.[2] Every fentanyl-related death is a tragedy, but also preventable. Congress has been successful in expanding access to naloxone, the medication used to reverse drug overdoses, including fentanyl. And it has proven worthwhile. Not only is naloxone effective in reversing more than 93% of overdoses,[3] every $1 spent on community-based naloxone programs saves nearly $2,742 by preventing overdose deaths.[4] Additionally, the Mainstreaming Addiction Treatment Act passed in December 2022 paved the way for making treatment more accessible by removing the waiver needed to prescribe the MOUD buprenorphine.

Congress must act quickly to continue passing legislation to prevent overdose deaths. The following interventions in increased methadone accessibility, removing treatment barriers like prior authorization, and expanding treatment access for incarcerated populations are the fastest way for Congress to reduce fentanyl-related deaths, as well as reduce the costs associated with these tragedies.

Expanding Access to FDA-Approved Medications

Methadone Access

The U.S. Food and Drug Administration (FDA) has approved two medications for opioid use disorder that have been found to prevent overdose fatality—methadone and buprenorphine. Methadone remains largely inaccessible when used to treat an opioid use disorder, despite being effective and our greatest line of defense against illicitly manufactured fentanyl.

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[1] Krawczyk et al. (2022). Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019. *International Journal of Drug Policy*. doi.org/10.1016/j.drugpo.2022.103786.

[2] United States Drug Enforcement Administration. Fentanyl. *https://www.dea.gov/factsheets/fentanyl.*

[3] Weiner, S.G., MD, MPH, Baker, O., PhD, Bernson, D., MPH, & Schuur, J.D., MD, MS (2022). One year mortality of patients treated with naloxone for opioid overdose by emergency medical services. *Substance abuse,* 43(1), 99–103. *https://doi.org/10.1080/08897077.2020.1748163.*

[4] Naumann, R.B., Durrance, C.P., Ranapurwala, S.I., Austin, A.E., Proescholdbell, S., Childs, R., Marshall, S.W., Kansagra, S., & Shanahan, M.E. (2019). Impact of a community-based naloxone distribution program on opioid overdose death rates. *Drug and alcohol dependence,* 204, 107536. *https://doi.org/10.1016/j.drugalcdep.2019.06.038.*

FDA first approved methadone for the treatment of pain in 1947.[5] Methadone first emerged as a maintenance treatment model for substance use disorder in the mid-1960s, prompted by an increase in heroin use.[6] With methadone now primarily being used for addiction treatment, the federal government took interest in preventing its diversion and illicit use. In 1972, the FDA in conjunction with the Drug Enforcement Administration (DEA) implemented strict federal regulations specific to methadone to treat an opiate addiction.[7] These additional regulations do not apply to methadone used for the treatment of pain.

In the regulations, methadone used to treat substance use disorders may only be prescribed by and dispensed from an Opioid Treatment Program (OTP). OTPs require patients to receive their daily dose of methadone in person. While the objective was to prevent diversion and illicit use, the formation of OTPs was also born out of necessity, as the medical community generally isolated and refused to treat substance use disorders.[8] As a result, requiring individuals to travel to a physical location every day to receive methadone has created significant barriers for people wanting to treat their substance use disorder.

Opioid use disorder is recognized as a chronic brain disease,[9] and our approach to the current overdose crisis must prioritize access to treatment. Existing treatment gaps in the United States are well documented, and with the increase in illicit fentanyl and fentanyl-related overdose, methadone is our best line of defense.

Despite the known effectiveness of methadone, concerns regarding the potential diversion of methadone have served as a barrier to improving access to this treatment. These concerns are misguided, the rate of diversion for methadone is lower than that of oxycodone or hydrocodone.[10] In fact, methadone used for substance use treatment is most likely to be diverted when it is made harder to access this treatment. The National Institute on Drug Abuse (NIDA) has reported [11] that methadone diversion is primarily associated with methadone prescribed for the treatment of pain and is largely driven by lack of access to medication. Among those using illicit methadone, the most common reason was a missed medication pick-up from an OTP, which can be contributed to the requirement that the medication be picked up in person each day.

Additionally, the Centers for Disease Control and Prevention (CDC) published a research study in 2022 that analyzed the impact of take-home methadone on overdose during the COVID–19 Public Health Emergency (PHE).[12] At the start of the PHE, regulations were altered to allow OTP patients to pick up a supply of take-home doses to comply with social distancing practices. Findings from this period show that the percentage of overdose deaths involving methadone declined, with 4.5% of over-

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[5] Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig, R.A., & Yarmolinsky, A., editors. Federal Regulation of Methadone Treatment. Washington (DC): National Academies Press (US); 1995. Executive Summary. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK232111/*.

[6] National Academies of Sciences, Engineering, and Medicine; Action Collaborative on Countering the U.S. Opioid Epidemic; Health and Medicine Division; Board on Health Care Services; Board on Health Sciences Policy; Stroud, C., Posey Norris, S.M., & Bain, L., editors. Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2022 Jul 15. 3, The History of Methadone and Barriers to Access for Different Populations. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK585210/*.

[7] Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig, R.A., & Yarmolinsky, A., editors. Federal Regulation of Methadone Treatment. Washington (DC): National Academies Press (US); 1995. Executive Summary. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK232111/*.

[8] National Academies of Sciences, Engineering, and Medicine; Action Collaborative on Countering the U.S. Opioid Epidemic; Health and Medicine Division; Board on Health Care Services; Board on Health Sciences Policy; Stroud, C., Posey Norris, S.M., & Bain, L., editors. Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2022 Jul 15. 3, The History of Methadone and Barriers to Access for Different Populations. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK585210/*.

[9] *https://www.yalemedicine.org/conditions/opioid-use-disorder.*

[10] *https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder#footnote-42-p7531.*

[11] *https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-treatment-need-versus-diversion-risk-opioid-use-disorder-treatment.*

[12] Jones, C.M., Compton, W.M., Han, B., Baldwin, G., & Volkow, N.D. 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. doi:10.1001/jamapsychiatry.2022.1776.

dose deaths involving methadone in January 2019 declining to 3.2% by August 2021—indicating that relaxed regulations on methadone dispensing did not lead to an increase in overdose deaths involving methadone. Additional positive outcomes associated with take-home methadone flexibilities include the finding that patients with more take-home doses were more likely to remain on treatment and less likely to use illicit opioids.[13]

The recently enacted FY 2024 Consolidated Appropriations Act ensures permanent Medicaid coverage of FDA-approved medications for opioid use disorder, including methadone. However, **to better ensure evidence-based treatment is accessible to the individuals and communities that need it, the Overdose Prevention Initiative supports the Modernizing Opioid Treatment Act (MOTAA).** MOTAA expands access to methadone nationwide by allowing board-certified addiction specialists and addiction psychiatrists to prescribe and allow pharmacies to dispense methadone, in addition to the OTPs.

Prior Authorizations

Historically for MOUD, insurers have required prior authorization, which is reported as a key barrier to MOUD prescribing.[14] Prior authorization describes the requirement by some health plans to review a service, medication, or procedure before it is performed or received to determine if they will cover it.[15] The process varies by insurer but generally requires administrative and clinical information from the provider, and sometimes the patient.[16]

Flagging MOUD for prior authorization reinforces an already harmful stigma and creates barriers that prevent providers from offering life-saving medication—not because it is not effective treatment, but because prescribing it is unnecessarily burdensome. Restrictive policies like prior authorization have negative impacts on treatment accessibility, with research indicating that Medicare Part D plans that removed prior authorization had an associated increase in the use of buprenorphine, whereas plans that added prior authorization had an associated decrease in buprenorphine use.[17] While some states have passed legislation to eliminate the prior authorization for MOUD, federal action must be taken to create uniformity across all federally supported programs, including Medicaid, to reduce this barrier to treatment.

Providing Treatment in Jails and Prisons

Nearly 65% of the U.S. prison population has a substance use disorder, far greater than the general population.[18] Not only are Americans with substance use disorder overrepresented in the prison population, but recently incarcerated individuals are at significantly increased risk of fatal overdose. Recent studies found that individuals reentering the community from incarceration are 40 times more likely to die of a drug overdose during the two weeks following their release than the general population.[19] Providing MOUD during incarceration, specifically buprenorphine and methadone, is associated with an 80% reduction in overdose mortality risk for the first month post-release.[20] Furthermore, if an individual initiates treatment while

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[13] Hoffman, K.A., Foot, C., Levander, X.A., Cook, R., Terashima, J.P., McIlveen, J.W., Korthuis, P.T., & McCarty, D. (2022). Treatment retention, return to use, and recovery support following COVID–19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. *Journal of substance abuse treatment,* 141, 108801. *https://doi.org/10.1016/j.jsat.2022.108801.*

[14] Andraka-Christou, B., Golan, O., Totaram, R., Ohama, M., Saloner, B., Gordon, A.J., & Stein, B.D. Prior authorization restrictions on medications for opioid use disorder: trends in state laws from 2005 to 2019. *Ann Med.* 2023 Dec;55(1):514–520. doi: 10.1080/07853890.2023.2171107. PMID: 36724766; PMCID: PMC9897778.

[15] *https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/.*

[16] *https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/.*

[17] Mark, T.L., Parish, W.J., & Zarkin, G.A. (2020). Association of Formulary Prior Authorization Policies With Buprenorphine-Naloxone Prescriptions and Hospital and Emergency Department Use Among Medicare Beneficiaries. *JAMA network open,* 3(4), e203132. *https://doi.org/10.1001/jamanetworkopen.2020.3132.*

[18] *https://nida.nih.gov/publications/drugfacts/criminal-justice#ref.*

[19] *https://ajph.aphapublications.org/doi/10.2105/AJPH.2018.304514.*

[20] Lim, S., Cherian, T., Katyal, M., Goldfeld, K.S., McDonald, R., Wiewel, E., Khan, M., Krawczyk, N., Braunstein, S., Murphy, S.M., Jalali, A., Jeng, P.J., MacDonald, R., & Lee, J.D. (2022). Association between jail-based methadone or buprenorphine treatment for opioid use disorder and overdose mortality after release from New York City jails 2011–2017. *Addiction* (Abingdon, England), 10.1111/add.16071. Advance online publication. *https://doi.org/10.1111/add.16071.*

in a correctional setting, they have a greater chance of continuing care upon reentry, which contributes to a 32% reduction in recidivism rates.[21]

The Supreme Court has affirmed that a failure to provide medical care to inmates is a violation of an individual's constitutional rights (see *Estelle v. Gamble,* 429 U.S. 97 (1976)), yet only an estimated 32% of jails offer any form of MOUD,[22] the established standard of care for the treatment of opioid use disorder. For many jails and prisons, a lack of funding and skilled workforce makes providing these basic health care services impossible. With limited exception, states may not spend federal Medicaid dollars on health care for individuals who are incarcerated. The "Medicaid inmate exclusion policy" (MIEP) prohibits the use of federal funds and services for medical care for "inmates of a public institution" and prevents Medicaid-eligible incarcerated individuals, regardless of whether they have been convicted, from receiving services funded by Medicaid.

In recent years, Congress has passed two provisions that chipped away at the MIEP. The SUPPORT Act prohibited the termination of Medicaid eligibility for incarcerated individuals under the age of 21 (age 26 for individuals involved with the foster care system). The law also required CMS to issue guidance on how states can use Section 1115 demonstration waivers to improve health care transitions for individuals being released from jail. Given the magnitude of the current crisis, Congress must now take those measures further.

To deliver effective treatment to incarcerated individuals, during and after incarceration, the Overdose Prevention Initiative supports the Due Process Continuity of Care Act led by Senator Cassidy. This legislation would permit incarcerated individuals to remain eligible for Medicaid benefits prior to conviction and is based on the constitutional principle that all individuals are innocent until proven guilty. Having Medicaid enrollment terminated after intake into a correctional facility leads to disruption in care and it can take individuals a significant amount of time to re-enroll after release. Many states have already chosen to suspend Medicaid enrollment, however, a mandate requiring this for all states would create a more uniform system.

Additionally, the Overdose Prevention Initiative supports the Reentry Act to ensure individuals re-enter the community having initiated or maintained treatment for substance use disorder at a critical intervention point. In complement with the Due Process Continuity of Care Act, the Reentry Act would allow Medicaid-eligible individuals to resume receiving Medicaid benefits thirty days prior to their release. Allowing individuals to resume benefits prior to release increases access to treatment, preventing risk of future overdose and reducing the likelihood of recidivism. This policy allows for Medicaid benefits to be reinstated at a critical time, ensuring that an individual is stabilized on MOUD and connected to treatment providers in the community.[23]

Thank you again for this opportunity to provide a statement for the record.

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[21] Evans, E.A., Wilson, D., & Friedmann, P.D. (2022). Recidivism and mortality after in-jail buprenorphine treatment for opioid use disorder. *Drug and alcohol dependence,* 231, 109254. *https://doi.org/10.1016/j.drugalcdep.2021.109254.*

[22] Sufrin, C., Kramer, C., Terplan, M., Fiscella, K., Olson, S., Voegtline, K., & Latkin, C. (2022). Availability of Medications for Opioid Use Disorder in U.S. Jails. *Journal of general internal medicine,* 10.1007/s11606-022-07812-x. Advance online publication. *https://doi.org/10.1007/s11606-022-07812-x?.*

[23] Wennerstrom, A., Sugarman, O.K., Reilly, B., Armstrong, A., Whittington, A., & Bachhuber, M.A. (2023). Health services use among formerly incarcerated Louisiana Medicaid members within one year of release. PloS one, 18(5), e0285582. *https://doi.org/10.1371/journal.pone.0285582.*

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The Honorable Ron Wyden
Chairman
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Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
United States Senate
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Dear Chairman Wyden and Ranking Member Crapo:

Sparian Biosciences is grateful for the opportunity to submit a statement for the record for the May 23, 2024 hearing titled, "Front Lines of the Fentanyl Crisis: Supporting Communities and Combating Addiction through Prevention and Treatment." We commend your leadership and commitment to ending the fentanyl crisis, which is part of the nation's ongoing substance use disorder (SUD) epidemic.

By the way of background, Sparian Biosciences is a clinical stage biopharmaceutical company that is at the forefront of developing novel therapeutics to combat fentanyl. One of Sparian's highest priority drug programs is a novel therapeutic, dubbed SBS–371, that has the potential to improve how fentanyl overdoses are reversed. In addition, SBS–371 could serve as a prophylactic agent or a bio-shield to protect first responders and law enforcement from bioterror attacks deploying highly potent synthetic opioids like fentanyl.

As Chairman Wyden noted in his opening statement, "more needs to be done to head off opioid use in the first place and encourage more non-opioid pain management to be used in American health care."[1] Sparian could not agree more; Sparian is working tirelessly to develop a non-opioid pain treatment (SBS–1000 and SBS–147) for patients requiring long-term pain management. This therapeutic is a first-in-class AEAr agonist that is currently in Phase 1 clinical trials. Sparian is proud to be working closely with the National Institutes of Health (NIH) and National Institute of Drug Abuse (NIDA) to advance this much-needed alternative to opioids.

The collaboration between Sparian and NIH/NIDA is supported by the Helping to End Addiction Long-term (HEAL) Initiative, which currently supports 1,800 prevention, treatment and recovery projects focused on fentanyl and other SUDs. HEAL Initiative funding is distributed across all 50 States.[2] **Sparian is grateful for the Committee's longstanding bipartisan support for HEAL and would encourage the Committee to continue this support as it represents one of the federal government's largest commitments to addressing fentanyl.**

Sparian is also greatly appreciative of the leadership of Chairman Wyden and Ranking Member Crapo to enact bipartisan legislation that will expand access to medication-assisted treatment (MAT).[3,4] As Chairman Wyden said in his opening statement, MAT "is the gold standard treatment for opioid use disorder."[5] Sparian concurs with this is sentiment and is expeditiously advancing, SBS–226, which would provide clinicians with a new pharmacological treatment alongside buprenorphine and methadone to use in MAT.

As Ranking Member Crapo said in his opening remarks, the country needs "targeted policies that can make a difference and address the root causes of the fentanyl crisis."[6] Sparian strongly support this position and would add that these targeted policies should involve interdisciplinary approaches. To ensure appropriate use of federal resources on targeted policies, **Sparian would encourage the Committee to support a whole-of-government initiative to tackle fentanyl that is modeled after best practices from the bipartisan Operation Warp Speed initiative.** This collaborative approach would elevate the urgency of the fentanyl crisis, pool

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[1] *https://www.finance.senate.gov/imo/media/doc/0523_wyden_statement.pdf.*
[2] NIH Heal Initiative 2024 Annual Report: Research in Action, *https://heal.nih.gov/files/2024-02/nih-heal-initiative-annual-report-2024.pdf.*
[3] *https://www.finance.senate.gov/imo/media/doc/0523_crapo_statement.pdf.*
[4] *https://www.finance.senate.gov/imo/media/doc/0523_crapo_statement.pdf.*
[5] *https://www.finance.senate.gov/imo/media/doc/0523_wyden_statement.pdf.*
[6] *https://www.finance.senate.gov/imo/media/doc/0523_crapo_statement.pdf.*

public and private expertise as well as avoid duplication of federal programs and resources.

Sparian would also urge the Committee to consider making targeted investments in bolstering the nation's SUD workforce. As the Committee knows well from the work of its Bipartisan Medicare GME Working Group, the U.S. has looming shortages of crucial healthcare roles.[7] The nation's SUD workforce, however, is already experiencing such shortages, which will only get worse. The American Society of Addiction Medicine, for instance, recently found the U.S. has about 4,400 physicians certified in addiction medicine, but this falls short of 6,000 currently needed.[8] These shortages disproportionately affect medically underserved and rural communities. To alleviate these SUD workforce challenges, Sparian would encourage the Committee to direct Medicare to set-aside additional residency slots for addiction medicine, expand the National Health Service Corp's SUD loan repayment program, among other initiatives.

Thank you for the opportunity to share Sparian's perspective. Sparian Biosciences shares your mission of ending the fentanyl crisis that has claimed far too many lives and hurt millions of American families from every walk of life. If Sparian can serve as a resource on these matters, please do not hesitate to reach out to Sahil Chaudhary at sahil@sparianbiosciences.com.

Sincerely,

Jeffrey Reich, MD
CEO

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May 29, 2024

The Hon. Ron Wyden
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United States Senate
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The Hon. Mike Crapo
Ranking Member
Committee on Finance
United States Senate
239 Dirksen Senate Office Building
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Dear Chairman Wyden and Ranking Member Crapo:

In light of the Committee's May 23, 2024, hearing, Front Lines of the Fentanyl Crisis: Supporting Communities and Combating Addiction through Prevention and Treatment, attached please find Western Governors' Association (WGA) Policy Resolution 2024–04, Combating the Opioid Crisis.

In the resolution, Western Governors highlight unique challenges posed by opioids, including fentanyl. The Governors discuss the importance of addressing the causes and long-term prevention of substance use disorder more fully and considering flexible programs and innovative strategies that reflect the multiplicity of recovery approaches at the federal level.

I request that you include this document in the permanent record of the hearing, as it articulates Western Governors' collective and bipartisan policy positions and recommendations on this important issue.

Thank you for your consideration of this request. Please contact me if you have any questions or require further information.

Sincerely,

Jack Waldorf
Executive Director

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[7] *https://www.finance.senate.gov/imo/media/doc/052424_bipart_gme_policy_outline_for_feedback.pdf.*

[8] *https://www.asam.org/docs/default-source/advocacy/asam-training-demo-one-pagerb1ff289472bc604ca5b7ff000030b21a.pdf?sfvrsn=264348c2_2.*

Western Governors' Association

Policy Resolution 2024–04

Combating the Opioid Crisis

A. BACKGROUND

The opioid epidemic, initiated by the precipitous rise of potent prescription opioids classified as painkillers in the 1990s, has become one of the nation's most devastating and lethal public health and safety crises. While federal investment to address this crisis has increased drastically in recent years, so have rates of substance use disorders (SUDs), overdoses, and deaths. Currently, the leading driver of opioid-related overdose deaths is illicit fentanyl, a drug that is 30 to 50 times more powerful than heroin. Combating the opioid crisis requires a comprehensive approach that reflects the complexity of the problem—from the potency and availability of these drugs to the social and economic damage that they impose—across all levels of government and the continuum of care.

B. GOVERNORS' POLICY STATEMENT

1. Reducing the impact of the opioid crisis involves stemming the supply of illegally produced opioids and limiting inappropriate and nonmedical uses of prescription opioids. Western Governors urge the federal government to provide financial support and reimbursement to states for interdiction activities—including through the High Intensity Drug Trafficking Areas Program—and work closely with Governors to combat over-prescribing of opioids for inappropriate uses and durations, illicit drug trafficking, and the manufacturing and distribution of counterfeit medications.

2. Western Governors recognize that social and economic factors are key drivers of substance use disorder (SUD). While SUD funding focused on these upstream drivers has expanded, it has not kept pace with the need. We advocate for increased federal support for population-level public health strategies at the Centers for Disease Control and Prevention (CDC) to address the causes and long-term prevention of SUD more fully. Western Governors are especially interested in support for Overdose Data to Action in States and Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities (LOCAL) Grants, supportive housing, and prevention and treatment for other diseases or health issues that may arise from SUDs, such as hepatitis and sexually transmitted infections.

3. The State Opioid Response (SOR) Program and the Tribal Opioid Response (TOR) Program provide critical resources to states and tribes to support the continuum of prevention, harm reduction, treatment, and recovery services for opioid use disorder and other concurrent SUDs. In addition, despite suffering disproportionately from high overdose rates, some tribes offer free treatment services not only to their members but to surrounding non-tribal communities as well. Western Governors request that Congress continue to appropriate needed funding to the SOR and TOR Programs and include ongoing support for polysubstance programming and initiatives.

4. Emerging threats, such as the combination of fentanyl with xylazine, have changed the nature of the opioid crisis over the years. States and the federal government must stay apprised of these threats to develop effective policy and programs to mitigate the crisis. Western Governors urge the Administration and federal agencies to coordinate more effectively with states and Fusion Centers and improve the dissemination of information about emerging threats across all levels of government.

5. Western Governors encourage the Drug Enforcement Administration (DEA) or Congress to prohibit the distribution and use of xylazine for human purposes while protecting its important applications in the veterinary and livestock sectors. We recommend that the federal government consider the perspectives of veterinary and livestock stakeholders in the development and implementation of such legislation or regulation.

6. Western Governors advise the Administration and Congress to utilize available tools, including sanctions, against individuals and groups involved in the illicit production and distribution of fentanyl and other drugs.

7. Western Governors urge the Department of Health and Human Services to expand state Medicaid waivers for opioid use disorder, especially waivers that would increase access to new models to address prevention, harm reduction, treatment, and recovery for incarcerated people and other populations.
8. Education and awareness campaigns are necessary tools to foster public dialogue and mobilize action across communities. Western Governors encourage the federal government, in partnership with states, to further develop a comprehensive, evidence-based, and culturally competent national education and awareness campaign about the opioid crisis, highlighting issues such as fentanyl and counterfeit medication, and incorporating best practices from state campaigns. Agencies should continue to target susceptible populations, including youth. Western Governors also urge Congress to dedicate resources directly to states to develop and disseminate targeted and culturally specific opioid awareness and education campaigns that meet the unique needs of our populaces, as such efforts are complementary to those at the national level.
9. Teen overdoses involving fentanyl are a tragic problem that continues to grow at an alarming rate. Western Governors request that the federal government focus on strategies, funding, and other resources to increase the use of naloxone among youth and relay accurate information to teens who are experimenting with substances about the dangers of fentanyl and the importance of only taking pills prescribed to them and dispensed by a licensed pharmacy. More efforts are also needed to increase the use of medications for opioid use disorder (OUD) for teens with OUD, including messaging focused on teens, parents, educators, and prescribers. In addition, federal efforts should incorporate expanded upstream approaches for young kids, such as social supports and coaching for parents, particularly for those with at-risk kids, and prosocial activities in schools, communities, and tribes.
10. The federal government should allocate more resources and release updated guidance for treatment medications that reflect the challenges raised by fentanyl. Western Governors support increasing access to the full slate of treatment options that address patient needs and ensure that they are not subject to outdated limits.
11. Western Governors acknowledge that recovery from SUD is a process—one impacted by a number of conditions and context, including economic status, geographical location, access to treatment, and suitable support systems. We recognize the importance of all stages of the recovery process, including harm reduction, outpatient and inpatient treatment, and more. Effective treatment is not a one-size-fits-all approach, and needs a diversity of voices, experiences, and ideas to address the changing landscape of both the epidemic that we are facing and the recovery options. We believe that the federal government should design flexible programs and grant opportunities and consider innovative strategies that reflect the multiplicity of recovery approaches and increase public understanding about recovery.
12. Western Governors recommend creating and adequately investing in federal programs and policies that enhance access to harm reduction strategies at low costs, including opioid antagonists such as naloxone, and provide training on the administration and use of these strategies.
13. The federal government should also ensure that permanent regulations enacted by the DEA to govern the use of telemedicine for medication-assisted treatment prescribing and monitoring—now that the extension of COVID–19 flexibilities has expired—continue to permit the use of telemedicine for both buprenorphine inductions and ongoing medication management.
14. Western Governors emphasize the importance of treating and preventing behavioral health conditions and increasing access to services to reduce dependence on opioids. We have highlighted substantive policy recommendations on behavioral health, including SUD, in WGA's health care resolution.

C. GOVERNORS' MANAGEMENT DIRECTIVE

1. The Governors direct WGA staff to work with Congressional committees of jurisdiction, the Executive Branch, and other entities, where appropriate, to achieve the objectives of this resolution.
2. Furthermore, the Governors direct WGA staff to consult with the Staff Advisory Council regarding its efforts to realize the objectives of this resolution and to keep the Governors apprised of its progress in this regard.

This resolution will expire in December 2026. Western Governors enact new policy resolutions and amend existing resolutions on a semiannual basis. Please consult http://www.westgov.org/resolutions for the most current copy of a resolution and a list of all current WGA policy resolutions.

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